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

26 April 2023

2nd Call for Submissions – Proposal P1028

Infant Formula

FSANZ has assessed a proposal to review regulation of infant formula products in the Australian New Zealand Food Standards Code, and has prepared a draft food regulatory measure extending across four Standards and five Schedules. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. You can email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 7 July 2023

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Executive summary

Proposal P1028 Infant Formula reviews the regulatory requirements for infant formula products in the Australia New Zealand Food Standards Code (the Code). We have sought to clarify and revise standards relating to the regulatory framework, composition, labelling, category definitions and representation of infant formula products. Primarily these are covered under Standard 2.9.1 *Infant formula* and Schedule 29 *Special purpose foods,* but other standards have been considered where relevant. Through P1028, FSANZ has aimed to ensure the regulation of infant formula products is clear, reflects the latest scientific evidence and, where possible, aligns with international regulations.

This proposal is being assessed under FSANZ's major procedure, which requires two rounds of statutory public consultation. FSANZ completed a first round of statutory public consultation in June 2022. Each submission received in response to that consultation was considered as part of our assessment and informed our decision to prepare proposed draft variations to the Code. FSANZ prepared two draft variations: the Food Standards (Proposal P1028 – Infant Formula) Variation (referred to in this report as the 'primary draft variation') and the Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation (referred to in this report as the 'consequential draft variation'). A copy of each variation is at Attachment A. The primary draft variation would amend Standard 2.9.1 *Infant formula products.* The consequential draft variation would make consequential amendments to Standard 1.1.2 *Definitions used throughout the Code*, Standard 1.3.1 *Food additives*, Standard 1.5.1 *Novel Foods*, 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* and Schedule 29 *Special purpose foods.*

Each proposed amendment or requirement has been considered and reviewed through scientific risk assessment, analysis of international regulations and public consultation. Key conclusions and FSANZ reasons for preparing the proposed draft variations to the Code are summarised in this report.

FSANZ now seeks submissions to inform its decision whether its proposed regulatory approach and the related proposed draft variations should be approved, amended or rejected.

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Supporting documents

The following attached documents informed the assessment of this Proposal:

Supporting Document 1	Food technology (SD1)
Supporting Document 2	Nutrient composition (SD2)
Supporting Document 3	Labelling (SD3)
Supporting Document 4	Costs and benefits (SD4)

1 Introduction

1.1 The Proposal

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

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

Proposal P1028 – Infant Formula aims to revise and clarify standards relating to infant formula products in the Code. In addition to the assessment criteria prescribed by the FSANZ Act, the following regulatory objectives are considered in the assessment of this Proposal:

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

1.2 Reasons for preparing the Proposal

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

Revision and clarification of the relevant standards in the Code works to ensure that infant formula products remain safe and suitable, account for market developments and reflect changes in the international regulatory context.

The outcome of this Proposal, if approved, will be a set of revised standards covering composition, labelling and representation of infant formula products that:

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

1.3 Procedure for the Proposal

This Proposal is being assessed under the Major Procedure requirements of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) which requires two rounds of

statutory Calls for Submissions (CFS). This paper is the 2nd CFS and seeks submissions on, among other things, proposed draft variations to the Code prepared by FSANZ. Submissions received in response to the 2nd Call for Submissions will inform FSANZ's decision whether to approve, amend or reject the proposed draft variations. If approved by FSANZ, the draft variations must then be referred to the Food Ministers' Meeting for ministerial consideration.

1.4 Scope

This paper summarises FSANZ's assessment for the Proposal in accordance with the FSANZ Act. FSANZ assessed the Proposal to revise and clarify standards for the composition, labelling, category definitions and representation of infant formula products. The assessment and consideration includes all aspects of Standard 2.9.1 and Schedule 29, and other requirements relating to infant formula products included in Standards 1.1.2, 1.3.1 and 1.5.1 and Schedules 8, 15, 19, and 25.

FSANZ has undertaken iterative and rigorous assessment on all issues. Reports for the assessments were published with previous consultation papers in 2016, 2017 and 2021. Conclusions from risk assessments are considered and cited in this CFS and Supporting Documents (SD) where applicable. The risk assessments that have been completed are:

- Nutrition assessment (FSANZ 2016a)
- Safety & Food Technology - Risk profile of contaminants in infant formula (FSANZ 2016b)
- Food additives safety assessment (FSANZ 2021d)
- Microbiology risk assessment: L(+) lactic acid producing microorganisms (FSANZ 2021e)
- Microbiological safety of powdered infant formula: Effect of storage temperature on risk (FSANZ 2021f)
- Nutrition assessment (FSANZ 2021g).

In addition, the following consumer research reviews were completed:

- Consumer research in relation to safe preparation and use of infant formula (FSANZ 2021h)
- NZ MPI research (NZFS 2020)
- Microbiological safety of powdered infant formula: Effect of water temperature on risk (FSANZ 2022c)
- Consumer research on infant formula labelling (FSANZ 2022f).

Additional risk assessment and consumer research reports were also completed and taken in account for this CFS. The following have been considered in the SDs:

- Rapid Systematic Evidence Summary on Infant Formula Stage Labelling and Proxy Advertising (Attachment 1 to SD3)
- Analysis of Current Stage Labelling and Proxy Advertising Practices of Infant Formula Products in Australia and New Zealand (Attachment 2 to SD3).

As the Proposal has been under review since 2013, there have been multiple iterations to the scope of the work and which aspects of the regulation are and are not considered within scope. Initially Proposal P1028 was intended to include only infant formula and not infant formula products for special dietary use (IFPSDU) or follow-on formula (FSANZ 2016). This decision was taken to limit the size of the proposal and to allow the review of the Codex Proposed Draft Revised Standard for Follow-up Formula for Older Infants (6 - 12 months) (Codex Draft Standard for FuFOI) to progress. In our non-statutory consultations in 2016, 2017 and 2021, FSANZ sought views on aspects of Standard 2.9.1 and Schedule 29 and other standards relevant to infant formula requirements only. Many stakeholders supported inclusion of follow-on formula and specialised infant formulas. It was considered that overlap

in compositional and labelling requirements for these subcategories of infant formula products would overly complicate the standard if the categories were not included in this Proposal.

Additionally, the review of the Codex Standard for Follow-up Formula (CODEX CXS 156-1987) has significantly progressed. This standard covers follow-up formula for ages 6 - 36 months. The proposed revised Codex Draft Standard has separated follow-up formula for older infants aged 6 - 12 months from products for young children aged 12 - 36 months. This separation aligns with the Code's age range for follow-on formula (6 - 12 months) and the European Union (EU) regulation for follow-on formula (EU 2016/127). FSANZ notes that at the time of publishing this CFS, the draft text is in Section A (Follow-up Formula for Older Infants) and is at Step 5 and Step 5/8 (Codex 2023).

Proposal P1028 does not include:

- Products marketed as toddler milks, which are designed for children aged one to three years. In the Code, these products are regulated as 'formulated supplementary foods for young children' under Standard 2.9.3 *Formulated Meal Replacements and Formulated Supplementary Foods*.
- Permissions for new optional ingredients (nutritive substances or novel foods).
- Review of nutrient definitions that are used throughout the Code (such as trans-fatty acids, carbohydrates).
- Products marketed as infant food, which are currently regulated by Standard 2.9.2 - *Foods for infants*.
- Regulation of specialised medical food and products for infants that are not infant formula products. This includes modulatory products such as human milk fortifiers, feed thickeners and special medical purpose infant foods.

The scope of Proposal P1028 covers all infant formula products including infant formula, follow-on formula and specialised medical infant formulas. The latter are currently referred to in the Code as IFPSDU, but will be called Special Medical Purpose Products for infants (SMPPi) if the proposed draft variations are approved.

1.5 Regulatory Environment

1.5.1 Australian and New Zealand standards

Provisions across the Code regulate infant formula products, with requirements contained in four Standards and five Schedules. These regulatory requirements include permissions for definitions, food additives, contaminants and natural toxins, novel foods, nutrient composition and labelling that relate to infant formula products. Proposal P1028 aims to revise regulatory requirements related to infant formula products.

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

- Division 1 deals with preliminary matters.
- Division 2 sets out general compositional requirements for infant formula products.
- Division 3 sets out compositional requirements for infant formula and follow-on formula.
- Division 4 sets out compositional requirements for infant formula products for special dietary use.
- Division 5 sets out labelling and packaging requirements for infant formula products.

- Division 6 sets out guidelines for infant formula products. The guidelines are not legally binding.

1.5.2 International standards

Internationally, requirements for infant formula products vary. However, most standards are developed with reference to the international Codex standards. Codex and overseas regulations from the European Union, the United States of America and Asian countries are particularly relevant for the trade of products to and from Australia and New Zealand. To assist trade, it is preferable for regulations to be harmonised as much as possible between countries and consistent with the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) of the World Trade Organization (WTO). Support for this is provided in both the FSANZ Act and the Ministerial Policy Guideline.

Specific comparison between international standards and the Code have been considered throughout the assessment for this Proposal and are noted in this CFS and accompanying SDs.

1.6 Consultation

1.6.1 Prior to 1st CFS

Given the size and complexity of this Proposal, extensive public consultation[1] and targeted consultation was conducted. As part of the assessment for this Proposal, FSANZ sought stakeholder views through several consultation papers (CP) on a range of topics and requested stakeholder views. These consultations were not required under the FSANZ Act but were used to explore potential regulatory options and gather views on these options. Submissions provided by stakeholders have been used to inform the assessment of the Proposal. FSANZ responses to these previous rounds of consultation were presented in the 1st CFS.

Details of previous papers and consultations for P1028 are listed in Table 1.6.1. As applicable, reference to these papers are cited throughout this CFS including within SDs. The CPs and submissions are available on the FSANZ website.[2]

Table 1.6.1 - Consultation papers that informed the assessment of P1028

Title	Released	Products and Topics covered
Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code (FSANZ 2012)	September 2012	Preliminary review
Infant formula (FSANZ 2016)	February 2016	Infant formula for infants 0 to <12 months: background for P1028, category definitions, essential composition, microbiological criteria, safe preparation, use and storage, warning, advisory and other statements, nutritive substances and novel foods, contaminants, food additives and processing aids, provision of information to inform consumers/caregivers, and representation of products.
Regulation of Infant formula – Infant formula	August 2017	Infant formula for special dietary use: regulatory framework, organisation of products subcategories, definitions, product

[1] Previous consultation papers and stakeholder submissions are available on the FSANZ website: P1028 – Infant Formula (foodstandards.gov.au)
[2] https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

products for special dietary use (FSANZ 2017)		categories and prescribed name, approach to composition, food additives, safety (contaminants, renal solute load, safe preparation and use), labelling, and distribution and access.
Safety and Food Technology (FSANZ 2021a)	May 2021	Infant formula for infants 0 to <12 months: consideration of stakeholder comments; proposed approaches for food additives, contaminants, L(+) lactic acid producing microorganisms (LAM), and labelling for safe preparation and use.
Nutrient Composition (FSANZ 2021b)	July 2021	Infant formula for infants 0 to <12 months: consideration of stakeholder comments; proposed approaches for nutrient composition.
Regulatory framework and definitions (FSANZ 2021c)	September 2021	Infant formula products: consideration of stakeholder comments; proposed approaches for pre-market assessment framework for infant formula products, definitions for infant formula products, regulatory framework and detailed approach to regulation of IFPSDU, labelling considerations for IFPSDU.
1st CFS (FSANZ 2022a)	April 2022	As a Major proposal, 2 statutory calls for submissions are required under FSANZ Act. The purpose of the 1st CFS was to summarise the entire assessment.

1.6.2 Stakeholder comments to 1st CFS

Pursuant to section 72 of the FSANZ Act, FSANZ called for submissions to assist further consideration of the Proposal and to inform the decision on whether to prepare draft variations to the Code or abandon Proposal P1028. The 1st CFS presented the summary of FSANZ's assessment for the Proposal and the preferred options which included amending Standard 2.9.1, Schedule 29 and related standards and schedules.

The 1st CFS was released for public comment between 4 April and 17 June 2022. During the consultation period, FSANZ held a series of workshops with stakeholders to provide information and discuss key issues on regulatory options proposed in the 1st CFS.

FSANZ received a total of 33 submissions - seven from jurisdictions, 24 from industry, one from a public health group and one from an academic. The submissions reflected diverse comments and suggestions, some of which had been considered by FSANZ in previous consultations for P1028. The submissions and a report summarising key results was published on the FSANZ website on 6 September 2022 (FSANZ 2022).

FSANZ has carefully analysed the comments in each submission and responded to issues raised in this 2nd CFS. Table 1.6.2 (below) provides a summary where particular topics have been addressed in the CFS package. For detailed submission responses, please see the appropriate document noted below.

Table 1.6.2 – Location of submission responses

Topic	Document
Food additives	SD1
Contaminants	
Processing aids	
Nutrient composition – Infant formula	SD2
Nutrient composition – Follow-on formula	
Nutrient composition – SMPPi	
Labelling for safety related provisions	SD3
Labelling for provision of information	

Labelling for SMPPi	
Costs and benefits for consumers	SD4
Costs and benefits for industry	
Transitional arrangements	
Regulatory framework	CFS (Appendix 1)
Definitions	
Novel foods and nutritive substances	
LAM[3]	

FSANZ notes that Table 1.6.2.1 includes all submitters to the 1st CFS.

Table 1.6.2.1 - Submitters to the 1st CFS

Submitter	**Abbreviation**
A2 Milk	A2M
Additive Solutions	AS
Allergy & Anaphylaxis Australia	AAA
Australian Food & Grocery Council	AFGC
Blue River Dairy	BRD
BODCO Dairy	BODCO
Care A2 Plus	CareA2
Chr. Hansen	ChrH
Complementary Medicines Australia	CMA
Dairy Goat Cooperative	DGC
Danone Nutricia	DAN
Dansico/IFF	DIFF
Dietitians Australia	DA
Fonterra Co-operative Group Limited	FCG
Infant Nutrition Council	INC
Australian Breastfeeding Association and World Breastfeeding Trends Initiative Australia	ABA and WBTi
Lonza	LON
Maui Milk	MM
Ministry of Health New Zealand	NZMoH
Morinaga Milk Industry	MMI
National Allergy Strategy	NAS
Nestlé	NES
New Zealand Food & Grocery Council	NZFGC
New Zealand Food Safety	NZFS
NSW Food Authority	NSWFA
Produco	PRO
Queensland Health	QLDH
Sanulac	SAN
South Australia Health	SAH
Spring Sheep Milk Company	SSM
Victoria Department of Health	VICDoH
WA Department of Health	WADoH

[3] L(+) lactic acid producing microorganisms (LAM), also referred to as L(+) lactic acid producing bacteria.

Sprout Organic	SO

2 Regulatory Framework

2.1 Background

At 1st CFS, the preferred option was to amend the Code to change the regulatory framework for infant formula products. This included separating infant formula products from specialised products for regulatory purposes by creating two new categories:

Category 1 - Infant formula products were proposed to include the following:

1. Nutritionally complete infant formula products with a standard nutrient formulation which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.

2. Nutritionally complete infant formula products with a modified formulation relating only to partially hydrolysed protein and/or low lactose/lactose free which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.

Category 2 - Special medical purpose products for infants (SMPPi) were proposed to be:

1. Nutritionally complete with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, when used under medical supervision in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the infants for whom it is intended.

2. Nutritionally incomplete with a nutrient-adapted formulation specific for a disease, disorder or medical condition that is supplementary and is not suitable to be used as the sole source of nourishment.

The creation of the new category of SMPPi meant that the current category of Infant Formula Products for Special Dietary Use (IFPSDU) and its associated subcategories would be removed. The SMPPi category was proposed to also capture modulatory products such as human milk fortifiers and pre-term supplementary products and enable these products to be clearly regulated under Standard 2.9.1.

In the 1st CFS, FSANZ also proposed to include formulas that deviate from the baseline infant formula or follow-on formula composition by only having modified protein and/or lactose free/low lactose content. These products would be categorised as infant formula products and intended to address transient gastrointestinal conditions linked to poor digestion of protein or lactose. FSANZ did not intend to set a definition for the proposed subcategory for modified infant formula products, but proposed that the characteristics of these products would include:

- only modified protein and/or lactose content for the dietary management of infants with a transient gastrointestinal condition based on appropriate scientific evidence
- modified protein meaning partial hydrolysis of one or more of the proteins on which infant formula is normally based (i.e. current definition in Standard 2.9.1), not including extensively hydrolysed protein
- intended to be used following advice from a health professional
- safe if consumed by healthy infants.

Because the 'modified' products would be required to meet the baseline infant formula products composition, products that are formulated on extensively hydrolysed protein or

include substances such as thickeners would cause these products to fall into the SMPPi category.

2.2 Stakeholder comments

As with previous consultations on the regulatory framework there were diverse views on FSANZ's proposed approach, broadly summarised as follows:

- Industry submitters generally agreed that all infant formulas for a special medical purpose must be used under medical supervision but did not agree that a 'low risk' formula should be restricted from sale at grocery stores. They also considered that a low risk formula (which would be categorised as infant formula products and not SMPPi) should state the conditions it is used for to provide adequate information for healthcare professionals and caregivers.
- Jurisdictional submitters did not agree with composition and labelling flexibility that would be applied to SMPPi, considering this a means for industry to create a pseudo self-substantiation pathway.
- Public health professionals considered specific medical conditions, disorders and diseases should be defined in the standards.
- Submitters across all stakeholder groups opposed the proposed modified infant formula products citing various issues including disagreement on whether such products (i.e. for transient gastrointestinal conditions) should exist, compositional characteristics (i.e. defining 'partial hydrolysis'), and concerns that greater clarity on the regulations for infant formulas designed for transient gastrointestinal conditions were needed.

Responses to specific submitter comments are provided in Appendix 1, Table 1.

2.3 Discussion

The current Division 4 in Standard 2.9.1 covers a range of specialised formulas which were summarised in the 2017 CP, as reproduced below. The 2017 CP also noted that some of these products would not be safe for use by healthy infants while others could be consumed by healthy infants with little risk of harm. It was noted that there were some areas of regulatory uncertainty related to the broad nature of the current subcategories, the range of products in each category and related definitions. Thus, despite a current regulatory framework that basically continues to protect infant health and safety and supports availability of specialised formulas for the infants that need them, FSANZ undertook through Proposal P1028 to revise the regulatory framework with objectives to more clearly differentiate the various types of products and address specific labelling and composition issues, as discussed below.

Table 2.3 - Current regulation of IFPSDU in Standard 2.9.1 and examples of how current products on the market are positioned

IFPSDU subcategory	Defined term in the Code?	Which section of Standard 2.9.1?	Examples of current positioning of formula on the market
Products for specific dietary use based on a protein substitute	Yes – protein substitute is defined in Standard 1.1.2	2.9.1—15	Partially hydrolysed protein
			Extensively hydrolysed protein
			L-amino acid-based formula or elemental formulas
Products for metabolic, immunological, renal, hepatic and malabsorptive conditions	No	2.9.1—14(3) to 2.9.1—14(6) 2.9.1—14(1) to 2.9.1—14(2)	Lactose free and low lactose Inborn errors of metabolism For transient gastro conditions and feeding problems: - gastro-oesophageal reflux - colic - constipation
Products formulated for premature or low birthweight infants	Yes, for pre-term formula	2.9.1—13	In-hospital premature formula Low birthweight formula Post discharge premature formula

2.3.1 Low and high risk formulas

Since the start of Proposal P1028, FSANZ has proposed four options to stakeholders for a regulatory framework that would best regulate the 'specialised' infant formulas. Through consultation, the main issue identified has been how to categorise special medical purpose formulas so that they would still be captured under Standard 2.9.1, while also enable definition, composition and labelling requirements for the various products available to be appropriately regulated. The standard needs to provide flexibility for manufacturers to formulate products consistent with a stated medical purpose to ensure products intended for very sick infants are available, and at the same time be appropriately restrictive for products designed for less serious conditions but which can still potentially be misused through inappropriate labelling or messaging to consumers.

Each stage of consultation drew mixed support from stakeholders. Overall, the comments indicated a fundamental difference of opinion amongst stakeholders leading to our view that there is no perfect solution to this flexibility issue.

Within the 1st CFS FSANZ discussed and proposed regulatory options relating to compositional modifications for infant formula products including products based partially hydrolysed protein and low lactose/lactose free formulas. FSANZ did not propose to define a subcategory for modified infant formula products. A number of submitters to the 1st CFS opposed the 'modified' category. FSANZ clarifies that the intent of the preferred option from the 1st CFS was that products based partial hydrolysis of one or more of the proteins on which infant formula is normally based (i.e. current definition in Standard 2.9.1), and/or low lactose/lactose free content would continue to be permitted as general infant formula products (not SMPPi) as long as they met all other compositional requirements for infant formula or follow on formula.

Therefore, consistent with the 1st CFS, FSANZ considers a two-tiered framework provides the clearest differentiation of products for healthy infants versus products for infants with special medical needs, as follows:

(1) Infant formula and follow-on formula (as subcategories of infant formula products). These products are intended only for healthy infants. Differentiating characteristics of infant formula and follow-on formula include:
    - Mandatory composition requirements. Any change to composition such as addition of a new substance is subject to pre-market assessment.
    - Prescribed names for infant formula and follow-on formula: the prescribed name must be used in the labelling of products and must be stated on the front of the package. Products that are represented as infant formula and follow-on formula must not be represented as another food, such as a FSFYC.
    - Required warning statements on preparation and use, and age statements indicating for whom the product is intended.
    - A statement of nutrition information that is mandatory for infant formula and follow-on formula and with prescribed formatting.
    - Prohibited representations including words describing the nutritional content other than that which is expressly permitted in the Standard.

(2) SMPPi (as a subcategory of infant formula products). Includes any infant formula specifically formulated for the dietary management of a medically diagnosed disease, disorder or condition. Differentiating characteristics of SMPPI include:
    - Restriction of sale for SMPPi: must not be sold to a consumer other than from or by a medical practitioner or dietitian; a medical practice, pharmacy or responsible institution; or a majority seller of SMPPi. This requirement will have the effect of limiting the proliferation for formulas for transient gastrointestinal conditions.
    - Compositional requirements that are compliant with the baseline composition for infant formula, unless deviation is required for a particular medical purpose or would otherwise prevent sale of the food.
    - Prohibited nutrition content and health claims as specified in the Standard.
    - Mandatory labelling information including: a name or description to indicate the true nature of the food; a statement that the food must be used under medical supervision; a statement indicating the medical purpose of the food; and a statement indicating the properties or characteristic of the food that make it appropriate for the medical purpose, as well as other statements that delineate that the product is intended for a medical purpose and not for use by a healthy infant.

The restriction of sale and labelling requirements would have the effect of making it clear that the SMPPi is not intended for a healthy infant and limits the likelihood that a caregiver inadvertently selects one of these products for their healthy infant (discussed further below). It should be noted that highly specialised, high risk products for very ill infants are unsafe for a healthy infant and would continue to be available through current practice which is under prescription.

2.3.2 Human milk fortifiers and supplementary products

The 1st CFS proposed the SMPPi category to sit separately but parallel to infant formula products i.e. not as a subcategory of infant formula products. The objective of that proposed structure was to enable products intended for infants as a partial source of nourishment i.e. human milk fortifiers and supplementary products, to be captured under Standard 2.9.1, however, not to be categorised as infant formula products which, by definition, are intended as the sole or principal liquid source of nourishment for infants. Based on submitter

comments to the 1st CFS (see Table 1, Appendix 1), FSANZ is now aware that many supplementary products are multipurpose, and their use goes beyond those intended as a principle liquid source of nourishment. To include these supplementary and modular products within the review of infant formula regulations is significantly expanding the scope of Proposal P1028. Therefore, human milk fortifiers and supplementary products will not be covered under Standard 2.9.1 requirements or in this review. This is reflected in the definitions as discussed in Section 3 below.

2.3.3 Composition: partially versus extensively hydrolysed protein

Infant formula and follow-on formula can contain partially hydrolysed protein from a compositional perspective. However, labelling requirements for representations about partially hydrolysed infant formula only are separate and addressed below in section 2.3.5. Extensively hydrolysed protein is not permitted in either infant formula or follow-on formula. This exclusion is controlled by the prescribed protein sources and differences in food additive permissions for infant formula, follow-on formula and SMPPi. Based on both permissions, extensively hydrolysed protein can only be added to SMPPi where required to address the medical condition, disease or disorder.

2.3.4 Composition: low lactose or lactose free

Low lactose and lactose free formulas are regulated through compositional requirements, which include no more than 0.3 g lactose/100 mL if it is a low lactose formula, or no detectable lactose if it is a lactose free formula. Formulas represented as being ‘low lactose’ or ‘lactose free’ must have these words included in the statement of the name of the food (the prescribed name).

Low lactose and lactose free formulas are intended for infants with cow milk protein intolerance (lactose intolerance), reported in 2 - 5% of infants within the first 1 to 3 months of life. Cow milk protein intolerance also typically resolves by the age of one year (AAP 2000, Host 1995). Formulas represented for allergies are categorised as SMPPi and are not considered within this category.

Cow milk protein intolerance typically occurs earlier in an infant’s life, is not seen as a late onset intolerance and resolves by the age of one. Because of this, formula currently on the market represented as being suitable for lactose intolerance are positioned as infant formulas suitable for infants aged 0 – 12 months. These formulas do not differentiate between 0 – 6 months or 6 – 12 months. FSANZ considers this appropriate given it reflects the nature of the intolerance and has been incorporated within the primary draft variation. Formulas represented as low lactose or lactose free will be regulated as infant formula, to ensure the composition for infant formula is applied instead of the compositional deviates prescribed for follow-on formula.

2.3.5 Provision of information

Infant formulas (marketed as suitable for infants aged from birth up to 12 months) that are represented as ‘partially hydrolysed’, ‘lactose free’ or ‘low lactose’ are low-risk products and would be subject to:

- general labelling requirements for infant formula and follow-on formula
- additional, specific requirements to label as ‘partially hydrolysed’, ‘lactose free’ or ‘low lactose’, where relevant.

Under the proposed regulatory framework categorisation, infant formula will not be permitted to reference conditions such as ‘anti-reflux’, ‘colic’ or ‘lactose intolerance’ because they

would constitute a prohibited health claim. ‘Lactose free’, ‘low lactose’ and ‘partially hydrolysed’ representations made about a follow-on formula will be prohibited.

FSANZ stated previously that the Code is clear that nutrition content and health claims must not be made about an infant formula product and that this prohibition is consistent with Ministerial policy guidance (see Section 3 of SD3; FSANZ 2016a).

Similarly, it is proposed that nutrition content and health claims must not be made about a SMPPi. This approach would reflect the status quo in the Code, which in turn reflects Ministerial policy guidance. However, SMPPi would be required to include a statement describing the properties or characteristics which make the food appropriate for the medical purpose on the label. These labelling provisions are included in the primary draft variation at subsection 2.9.1—37 and 2.9.1—38.

2.3.6 Restriction of sale

After careful consideration of submissions received in response to the 1st CFS, FSANZ’s position has remained unchanged. The primary draft variation prepared by FSANZ would restrict the sale of all SMPPi. Sale would be limited to sale by a medical practitioner or dietitian, medical practice, pharmacy or responsible institution or a majority seller of that SMPPi. This proposed restriction is aligned with the sale requirements of *Standard 2.9.5 – Foods For Special Medical Purpose (FSMP)*. As SMPPi are a medical purpose product for a very vulnerable population, FSANZ considers a restriction of sale an important and appropriate risk mitigation strategy.

If a sale restriction was not applied, SMPPi would be the only medical purpose product in the Code not subject to a restriction of sale. Such a regulatory outcome would not reflect the level of risk associated with the consumption of medical purpose products by healthy infants. Due to the compositional variance between SMPPi and infant formula, the consumption of these medical products by healthy infants could lead to serious issues related to impaired growth and development, and have further unknown lifelong consequences.

The proposed sale restriction will only effect specialised formulas currently sold in the grocery retail channel, which are typically formulas for transient gastrointestinal conditions such as diarrhoea, constipation, colic and regurgitation. FSANZ is not aware of other specialised formulas currently sold in the grocery retail channel and is cognisant that the majority of products that will be regulated as SMPPi are prescription based and/or are on the Pharmaceutical Benefits Scheme.

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

Stakeholders have also noted that a restriction on sale is not consistent with international

requirements. While FSANZ appreciates this in principle, retail channels operate substantially differently overseas, where pharmacies can be located inside of supermarkets and grocery stores. FSANZ also notes the restriction of sale posed by the primary draft variation would not affect the import or export market of these products.

Submissions to the 1st CFS claim that a restriction of sale for SMPPi may cause issues related to access and availability of products, specifically in rural areas. This is attributed to pharmacies or responsible institutions having less stock and stock keeping unit (SKU) lines available than grocery retailers, which may potentially lead to consumers being unable to purchase the formula they need. Within the rural setting, pharmacies and responsible institutions may not be as accessible with barriers such as travel and location being apparent. While FSANZ understands the significance of limiting access and availability to infants and caregivers, SMPPi are required to be used under medical supervision. This provides an additional safeguard in ensuring that infants have continued access to the formula they require as the sole or principal source of nutrition. Any issues relating to access and availability can be handled by the treating medical professional through direct contact with the majority seller or pharmacy. FSANZ also notes that supply and demand issues can be addressed during the proposed five year transition period.

Table 1 to Attachment 1 provides a summary of FSANZ's response to submitter comments on this issue. The sale restriction in also included in the primary draft variation at subsection 2.9.1—31.

2.4 Conclusion

For the reasons outlined above, the proposed primary draft variation prepared by FSANZ would change the structure of Standard 2.9.1 to that set out in Figure 2.4.

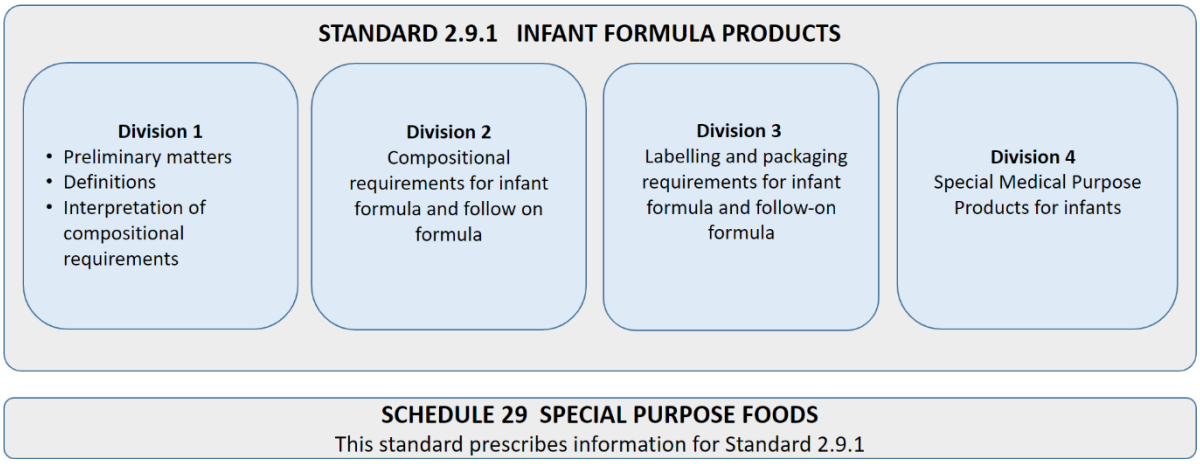

Figure 2.4 - The proposed structure of Standard 2.9.1 for regulation of infant formula products

The difference from the regulatory approach proposed in the 1st CFS is that infant formula products would now comprise three subcategories: infant formula, follow-on formula and SMPPi, with definitions revised accordingly (see Section 3).

The proposed primary draft variation would remove the current Division 6 Guidelines. Requirements that were listed in this division would now be covered by Guidance Upper Limits (GULs) described in Schedule 29 and Standard 2.9.1, with accompanying Notes explaining that GULs are not mandatory or binding, and that 'Guidance Upper Levels are recommended upper levels for nutrients which pose no significant risks on the basis of

current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons'. GULs are discussed in further detail in Section 3.2 of SD2.

The reasons justifying this proposed regulatory framework are that it would:

- support infant health and safety by more clearly delineating products that are intended for a medical purpose (SMPPi) but still retain these products under Standard 2.9.1
- set requirements for composition and labelling to enable SMPPi to be available for infants that need them
- impose a restriction of sale and labelling requirements on SMPPi to minimise the likelihood that caregivers will access formulas that are inappropriate for their infant
- prescribe specific labelling information for infant formula and follow-on formula to enable specified characteristics of products based on hydrolysed protein and low lactose/lactose free to inform caregivers
- simplify structure and format which assists in enforcement, compliance and readability of the regulation. The formatting of the Divisions within the proposed variation would also assist in simplifying any future revision of the Standard.

3 Definitions

3.1 Definitions for infant formula products and related terms

3.1.1 Background

Definitions are set in sections 1.1.2—2 and 1.1.2—3 of the Code. The preferred options for "infant formula product", "infant formula" and "follow-on formula" in the 1st CFS were to retain existing definitions. These are:

> **Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.
>
> **Infant formula** means an infant formula product that:
>
> a. is represented as a breast milk substitute for infants; and
> b. satisfies by itself the nutritional requirements of infants under the age of 6 months.
>
> **Infant** means a person under the age of 12 months.
>
> **Follow-on formula** means an infant formula product that:
>
> a. is represented as either a breast milk substitute or replacement for infant formula; and
> b. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

These definitions were set according to the proposed regulatory framework in the 1st CFS which separated infant formula products from SMPPi. This framework is no longer considered appropriate (see Section 2). The proposed definition for SMPPi is discussed in the Section 3.2.

3.1.2 Stakeholder comments

There were comments provided from 13 submitters on definitions with conflicting views in six submissions that stem from: (1) the need for a simplified set of definitions, (2) the need to

capture all products as partial source of nourishment i.e. fortifiers, (3) the need to include ingredients that are safe to use for infant feeding, (4) the need for better alignment with Codex, and (5) specific inclusion of edible food constituents of plant origin. There was some agreement from three submitters that existing definitions are working well and do not need to be changed.

FSANZ responses to specific comments are listed in Table 4, 5, 6 and 7 of Appendix 1.

3.1.3 Discussion

As a general rule, statutory definitions should not impose an obligation or state a requirement. Similarly, compositional standards should only establish compositional requirements and not attempt to define foods or food products. Definitions should include only the identifying characteristics of the food, with compositional requirements stated separately. In 2014, as part of P1025 – Code Revision, Australian and New Zealand Food Ministers approved this approach and agreed to the removal of substantive requirements from food definitions and restating compositional requirements independently of those definitions (FSANZ 2014). At that time the definitions for infant formula products, infant formula and follow-on formula were not revised as they were still under consideration in P1028.

The purpose of definitions for 'infant formula product' and related terms are to unambiguously capture the products intended to be regulated under Standard 2.9.1. The purpose of the definition is not to set compositional requirements (these are set in Standard 2.9.1 and Schedule 29), set parameters for the assessment of new substances (these are defined in the Application Handbook), ensure the Ministerial Policy Guideline is supported (this is a FSANZ Act requirement), or to promote breastfeeding (this is a policy area which is addressed through initiatives such as the MAIF Agreement). FSANZ therefore considers that incorporating these concepts in definitions for infant formula products and related terms is not warranted.

3.1.4 Conclusion

FSANZ's conclusion is to modify the current definitions for "infant formula product", "infant formula" and "follow-on formula" as indicated below. These changes have the effect of ensuring the products that represent themselves or are represented to consumers as an infant formula product, infant formula, or follow-on formula are captured and regulated under Standard 2.9.1.

> **Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is represented to be nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.
>
> **Infant formula** means an infant formula product that is represented:
>
> a. as a breast milk substitute for infants; and
> b. satisfying by itself the nutritional requirements of infants under the age of 6 months.
>
> **Follow-on formula** means an infant formula product that is represented:
>
> a. as either a breast milk substitute or replacement for infant formula; and
> b. as being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

There is no change to the definition of "infant".

3.2 Definition for SMPPi

3.2.1 Background

The preferred option at 1st CFS was a new definition for SMPPi, as follows:

A **special medical purpose product for infants** means a food that is:

a. specially formulated for the dietary management of infants

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and

(ii) whose dietary management cannot be completely achieved without the use of the food; and

b. intended to be used under medical supervision; and

c. represented as being

(i) a food for special medical purposes intended for infants; or

(ii) for the dietary management of a disease, disorder or medical condition in infants.

The definition was intended to mimic the FSMP definition but enable SMPPi to be appropriately positioned as a medical purpose product for infants. The definition was also based on the proposed regulatory framework at that time; and which separated infant formula products from SMPPi to enable supplementary products, such as human milk fortifiers, to be captured under the definition for SMPPi.

3.1.2 Stakeholder comments

Submitters to the 1st CFS provided various suggestions regarding the definition for SMPPi including adding words to emphasise the medical need for use of such products, the scope of products to be captured by the definition, setting a prescribed name, specifying the diseases, disorders or conditions relevant to SMPPi products, and additional wording that in general sits outside the general purpose of a definition.

Specific submitter comments and FSANZ's responses are listed in Table 6 of Appendix 1.

3.1.3 Discussion

As discussed in Section 2, FSANZ no longer proposes to define SMPPi separately from infant formula products. SMPPi are intended to be positioned in Standard 2.9.1 as a subcategory of infant formula products and no longer includes supplementary products not intended as breast milk substitutes, such as human milk fortifiers.

As noted above, as a general rule, Code definitions should not impose an obligation or state a requirement. However, an exception to that rule is considered warranted in this case. The proposed definition for SMPPi must set specific requirements that delineate SMPPi from other FSMP and infant formula and follow-on formula. Therefore, specific descriptive elements proposed for the definition at 1st CFS are proposed to be retained in the new proposed definition.

3.1.4 Conclusion

For the reasons summarised above, the proposed draft variations prepared by FSANZ would add the following definition for SMPPi to the Code:

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.

This definition is modified slightly from that proposed in 1st CFS. The revised definition, among other things, removes the reference to 'partial feeding' which is relevant to supplementary products no longer intended to be covered in this category.

3.3 Definition for protein substitute

3.3.1 Background

In line with the proposed regulatory framework, the 1st CFS proposed the removal of the definition for "protein substitute". Instead, those products intended for the dietary management of a medically diagnosed disease, disorder or condition (such as allergy) would be categorised as SMPPi to allow their formulation to deviate from the base infant or follow-on formula composition specific to their medical purpose. These products include elemental formulas and those based on extensively hydrolysed protein or L-amino acids.

3.3.2 Stakeholder comments

Most submitters agreed with FSANZ's approach in the 1st CFS. Those who disagreed considered that further distinction between partially hydrolysed protein versus extensively hydrolysed protein was needed for enforcement purposes. This aspect is discussed in Section 2.3.3.

Specific comments and FSANZ responses are listed in Table 2 in Appendix 1.

3.3.3 Discussion and conclusion

FSANZ view remains that the definition for "protein substitute" should be removed for reasons explained in the 1st CFS and in Section 2.3.3 of this CFS. The proposed draft variations prepared by FSANZ would therefore make this change.

3.4 Other definitions

3.4.1 Background

At 1st CFS, FSANZ proposed to remove the definitions for:

- "soy-based formula"
- "pre-term"
- "medium chain triglycerides".

These terms were considered to be self-explanatory. For "pre-term", it was considered that it is best defined through guidance about infant feeding of pre-term and underweight infants from medical professionals.

3.4.2 Stakeholder comments

Specific comments and FSANZ responses are listed in Table 8 in Appendix 1.

3.4.3 Discussion and conclusion

FSANZ retains its view from the 1st CFS to remove definitions for “soy-based formula”, “pre-term” and “medium chain triglycerides” for reasons explained in this and the 1st CFS. No additional definitions are proposed to be added to the Code.

4 Novel Foods and Nutritive Substances

4.1 Pre-market assessment requirements

4.1.2 Background

The preferred option in the 1st CFS was to consider any new requirements for novel foods and nutritive substances in infant formula products as part of the broader review of these substances for all food categories under the Proposal P1024. FSANZ proposed no change to the status quo, which is a general prohibition on the addition of novel foods or nutritive substances to infant formula products unless these are expressly permitted through an application or proposal. The 1st CFS also noted there is no exemption for food additives and processing aids used for infant formula products. All novel foods and nutritive substances as defined in the Code that are added to infant formula products require pre-market assessment. Any food additives and processing aids that are used require the same pre-market approval process as for general foods.

4.1.2 Stakeholder comments

Regarding a broader review of requirements for the assessment of novel foods and nutritive substances in infant formula products, jurisdictions maintained their opposition to FSANZ’s preferred option on the basis that it did not ensure the regulatory certainty needed for all substances added to infant formula products. They also cited regulatory gaps in the Code that they considered enable novel foods used in infant formula products to be managed under Standard 1.5.1 and Schedule 25 instead of Standard 2.9.1 and Schedule 29. Other submitters supported FSANZ’s preferred option in the 1st CFS.

Responses to specific submitter comments are provided in Appendix 1, Table 9.

4.1.3 Discussion

The 2016 CP (FSANZ 2016b) reviewed the issues related to the regulation of nutritive substances and novel foods in infant formula products. In that paper, FSANZ wrote:

> *FSANZ is currently undertaking work on the regulation of nutritive substances and novels foods under Proposal P1024 – Nutritive Substances and Novel Foods. Proposal P1028 will consider the regulation of nutritive substances and novel foods in infant formula, as infant formula products are excluded from the scope of P1024. FSANZ will consider the basis for requiring pre-market assessment of new substances for use in infant formula, and subsequently the procedure and information required to determine the safety and the nutritive or health benefit of these substances.*
>
> *Background information is provided on the intent of the Code, problems with the current definitions of nutritive substance and novel food, the differing interpretations of the provision for nutritive substances naturally present in an ingredient, stakeholder views, ministerial policy guidance, and international and overseas approaches.*
>
> *The review of the regulatory approach for the addition of new substances to infant formula will progressively develop over the course of P1028. At this stage, we are seeking input on the principles for the overarching regulatory approach.*

In the 2021 CP3, we proposed that the review of the regulatory approach for the addition of

new substances to infant formula would be best placed as part of the broader review of the Code's provisions for novel foods and nutritive substances applicable to all foods. The arguments for removing a review of pre-market assessment requirements from the scope of P1028 were:

- amendments made under P1025 – *Code Revision* added clarity around the definition of a nutritive substance and thus more certainty around substances that require pre-market assessment
- deferment of P1024 – *Revision of the Regulation of Nutritive Substances and Novel Foods* pending outcomes of the FSANZ Act review and the need for parallel assessment of the two proposals to ensure that inconsistencies and regulatory ambiguity are not introduced into the Code
- the relatively small number of substances with uncertain regulatory status, based on a label survey of infant formula products on the market in 2021
- evidence that industry continues to seek pre-market assessment for substances added to infant formula products where it is required (based on recent applications and enquiries made to FSANZ).

FSANZ stands by this decision and notes the number of recent applications for nutritive substances added to infant formula products signifies that the current pre-market assessment requirements are established in regulatory practice. Nevertheless, we have considered where changes could be made as part of this Proposal to clarify or strengthen the current requirements.

Novel foods

Stakeholder comments to previous CPs indicate some regulatory uncertainty around the requirement for pre-market assessment of novel foods used in infant formula products.

Standard 1.1.1 of the Code imposes a requirement for premarket assessment for novel foods used in infant formula products. Subsections 1.1.1—10 (5) and (6) impose a requirement that a food for retail sale, including infant formula products, must not be a novel food or have a novel food as an ingredient or component unless expressly permitted by the Code.

Permissions for novel foods are listed in Standard 1.5.1 and Schedule 25. Section 1.5.1—3 provides the following permission - a food for retail sale may consist of a novel food or have a novel food as an ingredient or component if the novel food is listed in the table to section S25—2 and any conditions of use specified in that table for that food are complied with.

The table to section S25—2 lists various permitted novel food and their conditions of use. The table currently sets two types of conditions in relation to infant formula products - those that permit a novel food to be added to infant formula products and those that restrict a novel food to be added to infant formula products (Figure 4.1.3). However, some permitted novel foods listed in the table have no conditions of use set or have conditions set that make no reference to infant formula products.

FSANZ's proposed approach in the 1st CFS was to continue with current practice for setting requirements for novel foods, which is to use conditions in the table to S25—2 to indicate which novel foods were permitted for use in infant formula products, and which were not. We also proposed to amend S25—2 for those permitted substances that had not been assessed for the infant population. This change was largely supported by stakeholders (see Appendix 1, Table 9).

In preparing the proposed consequential draft variations, FSANZ identified an alternative approach which would provide greater regulatory certainty around the permissions for novel foods in infant formula products.

FSANZ now proposes to amend section 1.5.1—3 so that it states that novel foods must not be added to infant formula products unless an express permission is stated in the table to S25—2. There is no net regulatory effect of this change as it relates only to a clarification and reflects the current intent of permissions for novels foods added to infant formula products. The proposed revision would emphasise that infant formula products have specific pre-market assessment requirements that go beyond the requirements for general foods.

The proposed amendment to section 1.5.1—3 would require consequential amendments to the table to S25—2. That is, to amend that table so that it states expressly which novel foods listed in it may be used in infant formula products.

S25—2 Sale of novel foods

For section 1.5.1—3, the permitted *novel foods and their conditions for use are:

Sale of novel foods

Permitted novel food	*Conditions of use*
α-cyclodextrin	1. The name 'alpha cyclodextrin' or 'α- cyclodextrin' must be used when declaring the ingredient in the statement of ingredients.
γ-cyclodextrin	1. The name 'gamma cyclodextrin' or 'γ- cyclodextrin' must be used when declaring the ingredient in the statement of ingredients.
Diacylglycerol oil (DAG-Oil)	1. The name 'Diacylglycerol oil' must be used when declaring the ingredient in the statement of ingredients.
Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	
Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1. May only be added to infant formula products in accordance with Standard 2.9.1.
Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	
Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)	
Isomalto-oligosaccharide	1. Must not be added to: (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children.

Condition that permits the addition

Condition that restricts the addition

Figure 4.1.3 - Excerpt of the current Schedule 25 showing conditions of use for infant formula products

Used as a nutritive substance

Regulation of nutritive substances are covered by subsection 1.1.1—10 (6) which requires that a food for sale must not have as an ingredient or a component, a substance that is 'used as a nutritive substance' unless expressly permitted by the Code.

Section 1.1.2—12 provides a substance is 'used as a nutritive substance' in relation to a food

if it is added to the food to achieve a nutritional purpose. The definition includes any substance that has been concentrated, refined or synthesised to achieve a nutritional purpose.

Permissions for approved nutritive substances are listed in the relevant food standard, which for infant formula products is Schedule S29—5. Permitted nutritive substances are required to be listed in the nutrition information statement (NIS) (see SD3 for further discussion on this topic).

The current Division 4 IFPSDU states that a compositional requirement does not apply to the extent that it would prevent the sale of an infant formula product that has been specifically formulated for premature or low birthweight infants (section 2.9.1–13) or to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions (section 2.9.1–14). The intent of this clause is to ensure that products formulated for a medical condition are accessible for the infants that require them. This approach has been retained in the proposed consequential draft variation at Attachment A.

FSANZ is unaware of additional changes that would strengthen or clarify the existing requirements for nutritive substances added to infant formula products. FSANZ also considers that the increase in recent applications requesting to add nutritive substances to infant formula products, such as *A1253 - Bovine lactoferrin in infant formula products* (FSANZ 2022j), demonstrates that the current regulation is clear and functioning effectively.

4.1.4 Conclusion

In 2016, the regulatory framework for novel foods and nutritive substances was being considered through two proposals in parallel: P1028 for infant formula products and P1024 for general foods. In 2017, P1024 was put on hold pending a review of the FSANZ Act. It was anticipated at that time that changes to the FSANZ Act would enable FSANZ to have greater latitude to establish a risk proportionate framework for substances added to general foods. There is no objective or intention that a risk proportionate framework for general foods would enable substances for infant formula products to by-pass the pre-market assessment requirements. When P1024 is restarted, the scope of the Proposal will include infant formula products but only to ensure that they are not captured within a less rigorous approval process applicable to general food categories. Given the vulnerable infant population, pre-market assessment would always be required for substances added to infant formula products.

To clarify the existing requirement that novel foods must obtain pre-market assessment for use in infant formula products, FSANZ proposes to amend section 1.5.1—3 to provide that an infant formula product food for retail sale may consist of, or have as an ingredient or a component, a novel food only if: the novel food is listed in the table to section S25—2; and the presence of that novel food in the infant formula product is expressly permitted by that table; and any conditions of use specified in the corresponding row of that table are complied with. FSANZ also proposes to amend the table to section S25—2 to expressly permit the presence in the infant formula product of those novel foods currently permitted to be added to such products.

This amendment does not change the regulatory requirements for novel foods used in infant formula products. However, it has implications for existing Schedule 25 permissions and the preferred option at 1st CFS, which is discussed below.

4.2 Schedule 25 permissions

4.2.1 Background

The 1st CFS proposed to clarify existing permissions in Schedule 25 for infant formula products. The preferred option was to amend Schedule 25 to include conditions for α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, D-tagatose, and trehalose that would restrict these substances from being used in infant formula products (i.e. infant formula and follow-on formula). The conditions would not be applied to formulated supplementary food for young children (FSFYC).

4.2.2 Stakeholder comments

Regarding the proposed amendments to Schedule 25 permissions, most submitters agreed with the preferred option at the 1st CFS. Responses to specific submitter comments are provided in Appendix 1, Table 10.

4.2.3 Discussion and conclusion

In considering drafting changes as part of the development of this CFS, FSANZ has reconsidered its approach to clarifying the Schedule 25 permissions for novel foods added to infant formula products.

As explained above, FSANZ proposes to amend section 1.5.1—3 to state a novel food must not be added to infant formula products unless an express permission is listed in the table to section S25—2. As a result, the changes to section S25—2 proposed at 1st CFS would be unnecessary as the only novel foods permitted in infant formula products would be those that have an existing express permission or novel foods that have been assessed as part of this Proposal. Only two novel foods in Schedule 25 meet this criteria - (1) Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) and (2) Trehalose (see below).

4.3 Permission for trehalose in S25

4.3.1 Background

In the 2016 CP (FSANZ 2016b), FSANZ proposed to amend permissions for those substances listed in Schedule 25 that had not been assessed for the infant population. We also asked industry stakeholders for information if these substances were currently used in infant formula products. One stakeholder provided information about the use of trehalose as a cryo-preservative for LAM added to foods, including infant formula products.[4] FSANZ has now reviewed available information regarding the use of trehalose in infant formula products, as summarised below.

4.3.2 Technological purpose of trehalose in foods and in infant formula products

Trehalose is a disaccharide consisting of two glucose units. According to the FSANZ Final Assessment Report for trehalose as a novel food (FSANZ 2003), trehalose is primarily used to replace sucrose where it is desirable to reduce the level of sweetness for a more balanced or improved taste profile. It was also noted that trehalose may be used as a stabiliser and cryo-preservative. Trehalose was approved in 2003 to be used in a range of cakes, confectionary, instant noodles and rice, and processed fruit. Consistent with the novel food

[4] The permission for use of L(+) lactic acid producing microorganisms to infant formula products is discussed in Section 5.

permissions implemented at that time, no conditions (such as restricting its use in infant formula products) were included.

Trehalose is a permitted novel food. Trehalose performs a processing aid function when used as a cryo-preservative for LAM. Although Schedule 18 lists processing aids for certain purposes, the list is not prescriptive and may include processing aids that have additional purposes. Under section 1.1.2—13 and Standard 1.3.3, the Code does not prohibit the use of foods (including permitted novel foods) as processing aids. Additionally, labelling requirements under section 1.2.4—3 mean that any food used as a processing aid does not need to be labelled in the statement of ingredients (except when other declaration requirements or mandatory statements prevail, e.g. if a listed allergen is present in the food for sale). Therefore, the current use of trehalose as a cryo-preservative in infant formula products or other foods is not prohibited under current Code requirements.

4.3.3 International approvals for trehalose

Trehalose is permitted to be added as an ingredient to foods in the USA, Canada, Japan, Singapore, Taiwan, Malaysia, the EU, Indonesia and India. Most of these permissions do not specifically relate to its function as a cryoprotectant for microorganism preservation. The Joint FAO/WHO Expert Committee on Food Additives (JEFCA) established an acceptable daily intake of “not specified” (JEFCA 2000). The Codex Index of Processing Aid (IPA) maintained by the Codex Committee on Food Additives recognises cryoprotection as a functional use for trehalose.

4.3.4 Nutrition and safety assessment - trehalose used as cryo-preservative in manufacture of infant formula products

According to industry stakeholders, trehalose is specifically used for LAM that require cryo-preservation (or freeze drying) in the manufacture of powdered infant formulas.

The safety of trehalose for infants was documented in the developmental and reproductive toxicology studies referenced by JECFA and reported in the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh) dossier (JECFA 2000, REACh 2020). Other reviews on the safety of trehalose have also been published (Richards et al. 2002, Chen et al. 2022).

Confidential information given to FSANZ provided an exposure estimate for trehalose when present in infant formula products as a cryo-preservative for LAM. The exposure estimate showed that 0–12 month old infants consuming infant formula supplemented with LAM would consume an amount of trehalose that is approximately 2000 times less than the No-Observed-Effect-Level of 5 g/kg BW/day (JECFA 2000) and, if the trehalose was converted to glucose, approximately 20 times less than the glucose exposure from human milk.

The estimated trehalose exposure is also insignificant compared to total carbohydrate content in infant formula products. Carbohydrate content is not specified in Standard 2.9.1 but is derived from the difference between the total energy amount and the energy equivalents for protein and fat amounts. On this basis, trehalose used as a cryo-preservative for LAM added to infant formula products would contribute an insignificant amount to the total carbohydrate content.

4.3.5 Conclusion

FSANZ concludes that the use of trehalose as a cryo-preservative in infant formula products 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 infant formula 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.

Therefore, the permission for trehalose in Schedule 25 should be retained. However, it is proposed that a condition that its use be restricted to a cryo-preservative purpose (and not as a carbohydrate source) would also be included.

5 L(+) Lactic acid producing microorganisms (LAM)

5.1 Background

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

5.2 Stakeholder comments

Detailed comments from submitters and FSANZ's response are listed in Appendix 1, Table 11.

Many submitters expressed divergent views on this issue. Industry strongly opposed the proposed clarification of the existing permission. This was based on the significant impact a restricted permission will likely have on current products on the market, along with the fact that the existing permission has been in place for more than 20 years with no evidence of harm and can be considered safe and traditional for infants. Industry submitters also commented that FSANZ's proposed restriction runs counter to international regulations, scientific literature and FSANZ's risk assessment published in the 2021 CP for P1028 (FSANZ 2021e).

Several submitters supported an approach that would 'grandfather in' permissions for specific strains of LAM purposes such as a probiotic purpose. This approach was proposed to provide regulatory certainty for both industry and enforcement agencies, and better align with the approach under Codex regulations. Other submitters indicated that specific strains are novel foods and as such must undergo pre-market assessment in line the Ministerial Policy Guideline. If this is the case, submitters commented that many new applications are likely to be submitted to FSANZ seeking approval for specific strains that are currently already in products on the market. Two jurisdictional submissions opposed FSANZ's preferred option and raised a new issue not considered in P1028. This issue relates to microorganisms producing bioactive metabolites during the fermentation process ('postbiotics').

5.3 Discussion

5.3.1 Safety assessment conclusions

FSANZ's microbiological risk assessment reviewed the potential risks associated with (1) supplementation with live microorganisms and (2) fermented formulas (FSANZ 2021e).

For addition of live microorganisms to infant formula products, FSANZ concluded that, in healthy full term infants, infant formula products supplemented with non-pathogenic, non-toxigenic L- and DL-lactic acid producing bacteria does not pose a risk to public health and safety. For infants with underlying clinical complications (including pre-term, low birth weight and immuno-compromised infants), there are case reports of sepsis and bloodstream infections associated with dietary supplementation with non-pathogenic L- and DL-lactic acid producing bacteria. However, due to a lack of sufficient data on infectivity and exposure, FSANZ was unable to assess the level of the risk in these circumstances.

FSANZ also concluded that formula fermented with LAM—where no viable bacteria are present in the final product—does not present a risk to public health and safety in healthy full term infants.

Some submissions provided in confidence information related to safety of their proprietary strains of LAM. FSANZ's safety assessment covered the traditionally defined LAM to the order Lactobacillales; bifidobacteria belonging to the genus *Bifidobacterium*; and spore forming LAM belonging to the genus *Bacillus.* The use of specific strains as named in industry submissions were included in FSANZ's safety assessment.

FSANZ's 2021 conclusion in regards to safety of LAM added in infant formula products is unchanged.

5.3.2 Current use and international regulatory requirements

Many submitters who opposed the preferred option cited the ubiquitous use of LAM in infant formula products and in other foods. Some submitters provided detailed data on the strains used and products in which they were added.[5] This evidence has not been provided in previous rounds of consultation. Based on a review of this evidence, FSANZ understands that the preferred option to restrict the existing permission 'for acidification' would significantly disrupt the availability of domestically and internationally manufactured infant formula products. Large reformulation costs, decreased product availability (possibly permanent), or a large influx of applications to FSANZ seeking permissions would all be factors that would be potentially detrimental to Australian and New Zealand infants requiring infant formula products.

International standards

The justification for the preferred option in the 1st CFS was based in part on Australian and New Zealand regulations in place prior to the development of the joint Code. As noted in submissions, requirements for the addition of LAM to infant formula products have been set in international standards and warrants consideration. Relevant international standards are summarised below.

- Codex – Clause 3.2.4 of CXS72-1981 states that "Only L(+) lactic acid producing cultures may be used"; for infant formula and formulas for special medical purposes intended for infants.
- EU – the European Union's list of food additives (Annex II to Regulation No 1333/2008 of the European Parliament and of the Council[6]) allows the use of non-pathogenic L(+) lactic acid producing cultures for the manufacture of acidified milks

[5] Data provided in confidence.

[6] EU Commission Regulation No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives

for infant formula and Dietary foods for infants for special medical purposes and special formulae for infants. EU 2016/17 for compositional and information requirements for infant formula and follow-on formula allows LAM added as optional ingredients as long as safety and suitability demonstrated by generally accepted scientific data.

- United States – *Generally Recognised as Safe* (GRAS) status for some strains and species (e.g. species of *Bifidobacterium*, *Lactobacillus,* and *Streptococcus*).
- China – maintains a positive list of microbial species allowed to be added to foods.

FSANZ considers that alignment with the Codex standards for infant formula and follow-on formula is justified within the objectives of this Proposal. Regarding consistency with the EU regulation, the current Standard 2.9.1 does not include a generic permission for optional ingredients as listed in Article 3 of EU 2016/17. Such a permission has not been considered in P1028 and would reduce regulatory clarity around requirements for optional substances. Establishment of a positive list of permitted LAM would have broader implications in the Code where LAM are permitted to be used in other foods. Consideration of the broader permission is out of scope for P1028.

5.3.3 Purposes of LAM in infant formula products

Several submitters were of the view that specific strains currently in use should be 'grandfathered in' because of their history of use and purported beneficial health effects. These health effects include improvements in gut microbiota and reduction in transient gut disorders (e.g. regurgitation, constipation colic).

FSANZ's view is that permissions for specific strains added for probiotic purposes should not be 'grandfathered in' as their beneficial health effects have not been assessed. Throughout P1028, FSANZ has maintained that the scope of P1028 does not include assessing new permissions for substances or nutrients to be added to infant formula products, or assessing existing permitted substances intended to be used for a new purpose. Such permissions should be sought through the application process.

FSANZ also notes current requirements in the Code. Subsection 1.1.1—10 (6) requires that substances added for a nutritive purpose require pre-market assessment. Subsection 1.1.2—12 (1) requires that a substance is *used as a nutritive substance* in relation to a food if it is added to the food to achieve a nutritional purpose. LAM added for a 'probiotic' purpose would constitute a substance that is being added to achieve a nutritive purpose. The existing permission in Standard 2.9.1 does not include addition of LAM as a nutritive substance. 'Grandfathering in' such a permission would be beyond the scope of P1028 and inconsistent with the Policy Guideline.

5.3.4 Labelling of LAM in infant formula products

LAM added as an ingredient to infant formula products must be listed in the statement of ingredients. Section 1.2.4—4 requires ingredients to be described by a name by which the ingredient is commonly known or that describes the true nature of the ingredient. Prescribing certain terms for the declaration of LAM in the statement of ingredients is not being considered in P1028 (see SD3 B.1).

The NIS is proposed to be mandated for format and content (see SD3 Sections 5 and 6). As LAM have not been approved for use as a nutritive substance, any words indicating LAM in the NIS will be prohibited. Further, nutrition content and health claims about LAM (including as 'probiotics') will also be prohibited.

5.3.5 Other restrictions that apply to LAM in infant formula products

FSANZ notes other restrictions that currently apply to the use of LAM in infant formula products:

- The current Standard 2.9.1 provides that only microorganisms producing the L(+) form of lactic acid are permitted.
- Paragraphs 1.1.1—10(5)(c) and (6)(g) of Standard 1.1.1 require that, unless expressly permitted, a food for sale must not be a *food produced using gene technology*, or have as an ingredient or component of a *food produced using gene technology*. This requirement is applicable to all infant formula products and any food, ingredient or component produced using gene technology must be assessed for safety through FSANZ pre-market assessment before it can be sold in Australia and New Zealand.
- Addition of LAM for a probiotic purpose cannot be included on the label of infant formula or follow-on formula as Standard 1.2.7 prohibits the use of a nutrition content claims.

There is no change proposed for any of these Code requirements as applied to infant formula products.

5.4 Conclusion

FSANZ proposes to amend its preferred option at 1st CFS and retain the current permission for the addition of LAM to infant formula products based on the following reasons:

(1) No safety concerns
(2) Long history of use and ubiquitous in products currently on market
(3) Alignment with Codex
(4) Removal of permission would cause large reformulation cost to industry (for minimal benefit), loss of products from the market (possibly permanently) and potentially a large influx of applications to FSANZ seeking permission to add LAM to infant formula products.

The existing permission does not include the addition of LAM for a novel or nutritive purpose and FSANZ is not proposing to 'grandfather in' such a permission into Standard 2.9.1. Although the current unrestricted permission does not exclude LAM added for probiotic function, restrictions on labelling and claims preclude any indication of this purpose unless approved as a novel food or nutritive substance through the application process. In this case, if approved, the use of LAM in infant formula products would trigger the requirement to be listed in the NIS.

6 Food Technology for Infant Formula Products (SD1)

FSANZ had proposed a number of approaches to such permissions during the 1st Call for Submissions and its SD1 of April 2022, which built on the consideration of stakeholder views expressed in response to FSANZ's 2021 Consultation Paper 1 – Safety and Food Technology (FSANZ 2021 CP1), as well as previous consultations.

In this 2nd CFS, FSANZ is proposing a number of regulatory/risk management amendments to the various standards related to the regulation of food additives and contaminants in infant formula products. Proposed amendments have been prepared with consideration to the objectives of the Proposal, the requirements of the FSANZ Act and relevant risk management principles. These proposed amendments are summarised below while more detail is provided in SD1.

6.1 Food additives

Nine submissions were received to the 1st CFS on issues relating to food additive permissions. The major issues raised by submitters related to the:

- technological justification for the use of the additive
- carry-over principle[7]
- international alignment of permissions to Codex and EU Regulations.

FSANZ considered following criteria in relation to the technological justification for food additives in infant formula products. They are where there was no existing:

- permission in the Code
- provisions in relevant Codex standards, or
- EU Regulations for equivalent products to SMPPi.

Applying these criteria for new food additives, only phosphoric acid required a separate assessment of technical function. FSANZ concluded that the use of phosphoric acid is technologically justified as an acidity regulator, to assist in preventing aggregation and coagulation of milk proteins used as an ingredient in infant formula products.

FSANZ maintains its preferred proposal is to remove carry-over permissions for food additives to be consistent with Codex and the European regulations. This position is consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population. FSANZ has proposed an appropriate transitional period that ensures continuous supply of these products.

FSANZ is proposing to update the food additive permissions for infant formula products to align as best as possible with relevant international regulations, especially Codex standards and EU Regulations. As a part of the harmonisation process FSANZ has considered the available evidence on safety and technological function of the food additives. Table 6.1 below summarises FSANZ's proposed amendments to permissions for food additives and Maximum Permitted Level (MPL) for the different food classes. Information provided in parentheses relates to how the permissions align with relevant international standards.

Table 6.1 – P1028 proposed MPL for infant formula products and SMPPi as amendments to current Code permissions

Food additive (INS #)	P1028 MPL (mg/L)	
	Infant Formula Products (includes follow-on formula)	SMPPi
Calcium carbonates (170)	NP	GMP (EU 13.1.5.1)
Ascorbic acid, L- (300)	50 (Codex FUF)	NP
Sodium ascorbate (301)	50 (Codex FUF)	NP
Calcium ascorbate (302)	50 (Codex FUF)	NP
Ascorbyl palmitate (304)	50 (Codex FUF)	100 (EU 13.1.5.1)

[7] The 'carry-over principle' refers to the presence of food additives in a final food, as a result of them having been added (as permitted) to ingredients used in the production of that food. Whilst they provide a technological function in the raw materials or ingredients used to produce the final food, they do not provide a technological function in that final food.

Tocopherols concentrate, mixed (307b)	30 (Codex FUF)	unchanged (10)
Gamma-tocopherol (308)	10 (EU 13.1.1)	
Delta-tocopherol (309)	10 (EU 13.1.1)	
Calcium citrates (333)	NP	GMP (EU 13.1.5.1)
Phosphoric acid (338) Sodium phosphates (339) Potassium phosphates (340)	450 (aligns EU 13.1.1)	-
Phosphoric acid (338) Sodium phosphates (339) Potassium phosphates (340) Calcium phosphates (341)	-	450 (EU 13.1.5.1)
Sodium alginate (401)	NP	1000 (EU 13.1.5.1)
Locust bean (carob bean) gum (410)	Unchanged (1000)	5000 (reduced cf EU 13.1.5.1)
Guar gum (412)	Unchanged (1000)	10,000 (EU 13.1.5.1)
Xanthan gum (415)	NP	1000 (Codex) 1200 (EU 13.1.5.1)
Pectins (440)	10000 (Codex FUF)	2000 (Codex) 5000 (reduced cf EU 13.1.5.1)
Sodium carboxymethylcellulose (466)	Not proposing to permit use in any infant formula product	
Citric and fatty acid esters of glycerol (CITREM) (472c)	9000 for liquid products, 7500 for powdered products, (Codex and EU).	
Diacyltartaric and fatty acid esters of glycerol (472e)	Remove the permission in the Code (Codex and EU).	
Sucrose esters of fatty acids (473)	NP	120 (EU 13.1.5.1)
Sodium carbonates (500)	2000 (Codex)	
Potassium carbonates (501)	2000 (Codex)	
Sodium hydroxide (524)	2000 (Codex)	
Potassium hydroxide (525)	2000 (Codex)	
Calcium hydroxide (INS 526)	2000 (Codex and EU)	
Silicon dioxide (amorphous) (551)	10 (EU)	
Starch sodium octenylsuccinate (1450)	NP	20,000 (Codex and EU 13.1.5.1)

Notes
NP= Not Permitted
FUF= Codex Follow-Up Formula
GMP= Good Manufacturing Practice
EU 13.1.1 = EU Regulation food category 13.1.1 (comparable to infant formula products)
EU 13.1.5.1 = EU Regulations food category 13.1.5.1 (comparable to SMPPi)

6.2 Contaminants

Nine submissions were received to the 1st CFS on issues relating to chemical contaminants. The major issue raised related to having a single ML for aluminium of 0.05 mg/100 mL for

infant formula, including soy-based. After consideration of all submissions received, FSANZ remains of the view that, in the absence of any new data or information, the rationale presented in FSANZ 2016 CP, FSANZ 2021 CP1 and the 1st CFS is still valid. Specifically:

- The HBGV established by JECFA in 2011 is relatively low and remains unchanged.
- Occurrence data from the 23rd and 24th ATDSs indicated that the upper range for aluminium approached the ML of 0.05 mg/100 mL (23rd ATDS). As such, retaining the ML will keep dietary exposure within safe levels for those contaminants that present a significant risk to public health and safety.
- Whilst the 2016 risk profile calculated exposures as less than 40-50% of the PTWI (in 9 month olds), it concluded that the maximum limits in Standard 2.9.1 were protective (i.e. removal of the MLs could lead to higher exposures).
- Lowering the ML for soy-based infant formula and having a single ML for aluminium in the Code is protective and FSANZ has received no indication that this level cannot be met by manufacturers.

Therefore, FSANZ's preferred option is to progress with the FSANZ 2021 CP1 approach, which is to retain a single ML of 0.05 mg/100 mL for infant formula products including soy-based formula. FSANZ remains of the view that having only one ML for aluminium, which is lower than the current one for soy-based infant formula products, will help ensure the safety of infant formula products.

A summary of FSANZ's proposed amendments for the maximum levels (MLs) for the thirteen chemicals or chemical group contaminants is provided in Table 6.2 below. No changes are proposed to the current MLs for three contaminants, no MLs are proposed for eight contaminants, and changes for the MLs for aluminium and lead are proposed consistent with the 1st CFS and FSANZ 2021 CP. More detail is provided in SD1.

Table 6.2 –P1028 proposed MLs for infant formula products and SMPPi

Contaminant	Proposed draft variation
Acrylonitrile	No change to the ML of 0.02 mg/kg for all foods including infant formula products.
Aluminium	Move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19. Retain single ML of 0.5 mg/kg for aluminium for infant formula products.
	Retain ML of 0.2 mg/kg in SMPPi formulated for pre-term infants
Arsenic	No ML for infant formula products. Monitor and review (for rice that may be used as an ingredient in infant formula)
Cadmium	No ML to be established.
Lead	Lower ML from 0.02 mg/kg to 0.01 mg/kg and apply to infant formula.
Melamine	No ML to be established.
Tin & inorganic tin	No change to the ML of 250 mg/kg.
Vinyl chloride	No change to the ML of 0.01 mg/kg.
Aflatoxins B1 and M1	No ML to be established.
Ochratoxin A	No ML to be established.
Polycyclic aromatic hydrocarbons (PAH)	No ML to be established.
Perchlorate	No ML to be established.
Chloropropanol, glycidol and their esters	No MLs to be established.

6.3 Processing aids

No changes to the Code related to processing aids is required, in line with the 1st CFS.

7 Nutrient Composition for Infant Formula Products (SD2)

The nutrient composition of infant formula products must be safe for formula-fed infants to consume, and must be appropriately prescriptive to ensure the formula provides sufficient energy and nutrients to promote normal growth and development of formula-fed infants, without posing a risk to infant health.

Stakeholder comments from the 1st CFS are considered in detail within SD2, alongside FSANZ conclusions and subsequent proposed amendment. SD2 addresses each regulatory requirement that relates to the composition of infant formula and follow-on formula including the nutrient ranges, sources, equivalents, permitted forms, conversion factors and ratios for macronutrients, micronutrients and nutritive substances. SD2 also considers general requirements such as units of measure, definition for GUL, standardisation of the measuring scoop, vitamin and mineral supplementation and modified formulas.

FSANZ's current proposed regulatory approach for infant formula and follow-on formula nutrient composition is summarised below in Table 7 and incorporated into the draft variations at Attachment A.

Table 7 –P1028 proposed infant formula and follow-on formula nutrient composition

Nutrient	Unit	Infant formula		Follow-on formula	
		Min	Max	Min	Max
Energy	kJ/L	2510	2930	2510	2930
Carbohydrates	g/100 kJ	NS	NS	NS	NS
Total fat	g/100 kJ	1.1	1.4	1.1	1.4
Linoleic acid (LA)	mg/100 kJ	90	335*	90	335*
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1
Docosahexaenoic acid (DHA)^	mg/100 kJ	NS	7*	NS	7*
Trans fatty acid^	% total fatty acid	NS	4	NS	4
Phospholipids^	mg/100 kJ	NS	72	NS	72
Protein (milk)	g/100 kJ	0.43	0.72	0.38	0.72
Protein (soy)	g/100 kJ	0.54	0.72	0.54	0.72
L-amino Acids					
Histidine	mg/100 kJ	10	NS	10	NS
Isoleucine	mg/100 kJ	22	NS	22	NS
Leucine	mg/100 kJ	40	NS	40	NS
Lysine	mg/100 kJ	27	NS	27	NS
Cysteine	mg/100 kJ	9	NS	9	NS
Methionine	mg/100 kJ	6	NS	6	NS
Phenylalanine	mg/100 kJ	19	NS	19	NS
Threonine	mg/100 kJ	18	NS	18	NS
Tryptophan	mg/100 kJ	8	NS	8	NS
Tyrosine	mg/100 kJ	18	NS	18	NS
Valine	mg/100 kJ	22	NS	22	NS
Vitamins					
Vitamin A	µg RE/100 kJ	14	43	14	43
Vitamin B_6	µg/100 kJ	8	42*	8	42*
Vitamin B_{12}	µg/100 kJ	0.02	0.36*	0.02	0.36*
Vitamin C	mg/100 kJ	1.7	17*	1.7	17*
Vitamin D	µg/100 kJ	0.24	0.63	0.24	0.63
Vitamin E	mg α-TE/100 kJ	0.14	1.2*	0.14	1.2*
Vitamin K	µg/100 kJ	0.24	6*	0.24	6*
Biotin	µg/100 kJ	0.24	2.4*	0.24	2.4*

Niacin	µg/100 kJ	70	359*	70	359*
Riboflavin	µg/100 kJ	14.3	120*	14.3	120*
Pantothenic acid	µg/100 kJ	96	478*	96	478*
Folic acid	µg/100 kJ	2.4	12*	2.4	12*
Thiamin	µg/100 kJ	10	72*	10	72*
Minerals					
Calcium	mg/100 kJ	12	35*	12	43*
Magnesium	mg/100 kJ	1.2	3.6*	1.2	3.6*
Iron	mg/100 kJ	0.14	0.48	0.24	0.48
Sodium	mg/100 kJ	4.8	14	4.8	14
Chloride	mg/100 kJ	12	38	12	38
Potassium	mg/100 kJ	14	43	14	43
Phosphorus	mg/100 kJ	6	24*	6	24*
Manganese	µg/100 kJ	0.24	24*	0.24	24*
Zinc	mg/100 kJ	0.12	0.36*	0.12	0.36*
Copper	µg/100 kJ	8	29*	8	29*
Iodine	µg/100 kJ	2.4	14*	2.4	14*
Selenium	µg/100 kJ	0.48	2.2*	0.48	2.2*
Nutritive substances					
Choline	mg/100 kJ	1.7	12*	NS	12*^
Myo-inositol	mg/100 kJ	1.0	10*	NS	10*^
L-Carnitine	mg/100 kJ	0.3	0.8*	0.3^	NS^
Fluoride	µg/100 kJ	NS	17	NS	17
2′-fucosyllactose^	mg/100 kJ	NS	961	NS	961
Taurine^	mg/100 kJ	NS	2.9	NS	2.9
Lutein^	µg/100 kJ	1.5	5.0	1.5	5.0
Lactoferrin ^	mg/100 kJ	-	40	-	40
Nucleotides					
Adenosine-5′-monophosphate^	mg/100 kJ	NS	0.36	NS	0.36
Cytidine-5′-monophosphate^	mg/100 kJ	NS	0.6	NS	0.6
Guanosine-5′-monophosphate^	mg/100 kJ	NS	0.40	NS	0.40
Inosine-5′-monophosphate^	mg/100 kJ	NS	0.24	NS	0.24
Uridine-5′-monophosphate^	mg/100 kJ	NS	0.42	NS	0.42
Total free nucleotide 5'-monophosphates^	mg/100 kJ	NS	3.8	NS	3.8
Ratios					
LA : ALA	ratio	5 : 1	15 : 1	5 : 1	15 : 1
Ca : P	ratio	1 : 1	2 : 1	1 : 1	2 : 1
Vitamin E : fatty acids	ratio	0.5 mg : 1 g	NS	0.5 mg : 1 g	NS
Arachidonic acid^	ratio	≥ DHA	NS	≥ DHA	NS
Eicosapentaenoic acid	ratio	NS	≤ DHA	NS	≤ DHA
Zn : Cu	ratio	Removed			
Sources					
Protein	Cow's milk protein, goat's milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins				
Carbohydrate	Sucrose and/or fructose should not be added, unless needed as a carbohydrate source in infant formula or follow-on formula manufactured from protein hydrolysates, and provided the sum of these does not exceed 20% of available carbohydrates.				
Permitted forms and equivalents					
Vitamin A	***Retinol forms***: vitamin A (retinol), vitamin A acetate (retinyl acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate ***Provitamin A forms***: beta-carotene				
Vitamin C	L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate				
Vitamin D	Vitamin D2, vitamin D3 and vitamin D (cholecalciferol-cholesterol)				
Thiamin	Thiamin hydrochloride, thiamin mononitrate				
Riboflavin	Riboflavin, riboflavin-5′-phosphate, sodium				
Niacin	Niacinamide (nicotinamide)				
Vitamin B_6	Pyridoxine hydrochloride, pyridoxine-5′-phosphate				
Folic acid	Naturally occurring folate will not be included in the permitted range for folic acid				
Pantothenic Acid	Calcium pantothenate, dexpanthenol, D-panthenol, calcium D-pantothenate, sodium D-pantothenate				
Vitamin B_{12}	Cyanocobalamin, hydroxocobalamin				
Biotin	d-biotin				
Vitamin E	dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate mixed, d-α-				

	tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate
Vitamin K	Vitamin K1 as phylloquinone (phytonadione)
Calcium	Calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate, dibasic, calcium phosphate, monobasic, calcium phosphate, tribasic, calcium sulphate
Chloride	Calcium chloride, magnesium chloride, potassium chloride, sodium chloride
Copper	Copper gluconate, cupric sulphate, cupric citrate, cupric carbonate
Iodine	Potassium iodate, potassium iodide, sodium iodide
Iron	Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate, ferric citrate, ferrous bisglycinate and ferrous sulphate
Magnesium	Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium oxide, magnesium phosphate dibasic, magnesium phosphate tribasic, magnesium sulphate, magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid
Manganese	Manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate
Phosphorus	Calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic).
Potassium	Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate, dibasic, potassium phosphate, monobasic, potassium phosphate, tribasic, potassium L-lactate
Selenium	Seleno methionine, sodium selenate, sodium selenite
Sodium	Sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate
Zinc	Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate, zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate)
Choline	Choline chloride and choline bitartrate, choline, choline citrate and choline hydrogen tartrate
L-Carnitine	L-carnitine hydrochloride and L-carnitine tartrate
Units of expression	
Vitamin A	µg RE/100 kJ
Folic acid	µg/100 kJ
Vitamin E	α-TE/100 kJ
Niacin	µg/100 kJ
Linoleic acid (LA)	mg/100 kJ
α-Linolenic acid (ALA)	mg/100 kJ
Docosahexaenoic acid (DHA)^	mg/100 kJ
Conversion factors	
Nitrogen Conversion Factor (NFC)	Removed
Potential Renal Solute Level (PRSL)	Removed

NS = Not Specified * = GUL ^ = Voluntary Addition

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

SD2 also addresses stakeholder comments on the overarching approach applied to SMPPi composition, composition of different medical conditions and pre-market assessment of SMPPi. FSANZ's proposed regulatory approach for SMPPi nutrient composition is summarised below and incorporated into the primary draft variation at Attachment A to the 2nd CFS.

The proposed variations:

- add a definition for *special medical purpose products for infants* to the Code
- amend Division 4 Infant formula products for special dietary use to reflect the following changes:
    - amend the title to Special medical purpose products for infants;

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

8 Labelling for Infant Formula Products (SD3)

Label information about an infant formula product is important for assisting caregivers to identify and purchase the correct product for their infant and for instructing how to safely prepare and use it. FSANZ's statutory objectives in developing or reviewing food standards and variations thereof (as set out in subsection 18(1) of the FSANZ Act) - the protection of public health and safety, provision of adequate information relating to food to enable informed choices, and prevention of misleading or deceptive conduct - are each particularly relevant for infant formula products.

FSANZ has considered submitter comments to the 1st CFS along with additional risk assessment for some provision of information labelling issues. FSANZ's conclusions have been presented for each labelling issue.

Labelling matters in SD3 are split into three parts. Part A addresses the safety-related labelling requirements for infant formula and follow-on formula. These requirements include directions for preparation and use, representations about food as an infant formula or a follow-on formula, prescribed names, the requirement for a measuring scoop, storage instructions, print size, warning statements, age-related statements, the protein source statement, statements related to dental fluorosis, date marking and general legibility requirements.

A summary of the proposed regulatory approach for these safety-related labelling requirements, including a comparison compared with existing requirements (if any), is provided in Table 8.

Table 8 - Comparison between existing and new safety-related labelling requirements for infant formula and follow-on formula

Existing labelling requirements	Draft variation in Attachment A to the 2nd CFS
Directions for preparation and use	
(a) each bottle should be prepared individually.	Direction varied by replacing the word 'should' with 'must'.
(b) if a bottle of made up formula is stored prior to use, it must be refrigerated and used within 24 hours.	Direction varied by replacing the word 'made up' with 'prepared'.
(c) potable, previously boiled water should be used.	Direction varied by adding the word 'cooled' and replacing the word 'should' with 'must'.
(d) if a package contains a measuring scoop—only the enclosed scoop should be used.	Direction varied by replacing the word 'should' with 'must'.
Warning statements to follow instructions exactly	New directions (e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice

Existing labelling requirements	Draft variation in Attachment A to the 2nd CFS
	(f) for ready-to-drink formula—do not dilute or add other food except on medical advice.
(g) formula left in the bottle after a feed must be discarded.	Direction varied by adding the words 'within 2 hours'
	New provisions • directions (a), (b), and (c) do not apply to ready-to-drink formula • direction (d) does not apply to concentrated formula and ready-to-drink formula.
Other specific labelling requirements in Standard 2.9.1	
Representations about food as an infant formula product.	• Provision varied to refer to food as infant formula or a follow-on formula
Prescribed names 'infant formula' and 'follow-on formula'.	New provision • for the existing name of the food (the prescribed name) to be stated on the front of the package.
Requirement for measuring scoop for an infant formula product.	Provision varied to apply to infant formula or follow-on formula.
Storage instructions must cover the period after the package has opened.	Provision varied to apply to infant formula or follow-on formula.
Print size is specified for warning statements, based on net weight.	Provision varied to apply to infant formula or follow-on formula.
Warning statement about following instructions exactly, by product type (e.g., powdered, concentrated and ready-to-drink)	Single warning statement applicable for all product types.
Warning statement 'Breast milk is best for babies'.	Retained
Statement that infant formula may be used from birth.	• Statement varied by replacing the words 'infant formula product' with 'infant formula' New provision • require the statement to appear on the front of the package.
Statement that follow-on formula should not be used for infants aged under 6 months.	• Statement varied by replacing the words 'infant formula product' with 'infant formula' New provision • requiring the statement to appear on the front of the package.
Statement about age to offer foods in addition to formula.	Statement varied by clarifying it applies to infant formula and follow-on formula only.
Protein source statement.	• Provision varied to require the specific animal or plant source(s) of protein and replace the word 'product' with 'food' • Retained requirement for protein source statement to be included in the statement of the name of the food New provision • requiring this information to be stated on the front of the package.
Statements relating to dental fluorosis.	Removed.
Application of certain general labelling requirements in Part 1.2 of the Code	
Date marking requirements in Standard 1.2.5	Retained.
General legibility requirements in Division 6 of Standard 1.2.1	Retained.

Part B addresses provision of information labelling requirements for infant formula and follow-on formula. These requirements include (but are not limited to) general requirements for the statement of ingredients, allergen declaration requirements, labelling of genetically modified food, requirements to declare nutrition information, requirements for 'lactose free' and 'low lactose' formulas and partially hydrolysed formula, stage labelling, product differentiation and prohibited representations (including proxy advertising).

Table 8.1 summarises the proposed regulatory approach for labelling requirements that provide information about infant formula and follow-on formula to enable caregivers to make informed choices and assist health professionals when providing infant feeding advice. These requirements have been compared against existing labelling requirements (if any).

Table 8.1 - Comparison between existing and new provision of information labelling requirements for infant formula and follow-on formula

Existing labelling requirements	Draft variations in Attachment A to the 2nd CFS
General requirements for statement of ingredients in Standard 1.2.4.	Retained. New provision • permitting an optional format for declaring added vitamins and minerals that are required nutritive substances in the statement of ingredients • if optional format used, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients lists all added vitamins together under the subheading 'Vitamins' and lists all added minerals together under the subheading 'Minerals'.
Allergen declaration requirements in Division 3 of Standard 1.2.3.	Retained.
Requirement for the statement 'genetically modified' in Standard 1.5.2.	Retained.
Declaration of nutrition information in the nutrition information statement (NIS)	
Requirement to declare energy, protein, fat, carbohydrate, vitamins, minerals, permitted nutritive substances, inulin-type fructans, galacto-oligosaccharides (or a combination of inulin-type fructans and galacto-oligosaccharides).	Retained. New provision • requiring choline, inositol, and L-carnitine to be declared in the NIS for infant formula.
	New provision • permitting declaration of specified fatty acids and whey and casein in the NIS • if declared, these sub-group nutrients must appear in the NIS in the prescribed format.
Nutrition information declared per 100 mL made up formula; guidance indicates per 100 mL concentrated or per 100 g powder also permitted.	Provision varied to require the unit quantity of food expressed in per 100 mL.
Nutrition information must be expressed in terms of the product as reconstituted according to directions on the package.	Provision varied to clarify it applies to powdered and concentrated formula.
Average energy content, average amount.	• Retained average energy content • Provision varied to require the average quantity for nutrients, substances, and nutritive substances New provision • for how average quantity must be calculated.

Existing labelling requirements	Draft variations in Attachment A to the 2nd CFS
	New provision • requiring a prescribed format for the NIS • include subheadings 'Vitamins,' 'Minerals', 'Additional' in the NIS for infant formula and follow-on formula; and the subheading 'Other nutrients' in the NIS for infant formula • subheadings must be printed in a size of type that is the same or larger than the nutrient names in the NIS.
Weight of one scoop (for powdered formula), the proportion of powder or concentrate required to reconstitute formula according to directions (for powdered and concentrated formula).	Provision varied to prohibit this information from appearing in the NIS, and to apply to infant formula or follow-on formula.
Other information requirements	
Prohibition for nutrition content and health claims, and therapeutic claims	New Note • Explains that existing prohibitions for nutrition content and health claims, and therapeutic claims in Standard 1.2.7 apply to infant formula and follow-on formula.
Requirements for lactose free and low lactose formulas.	• Provision varied to apply to infant formula that is represented as lactose free or low lactose • Removed permission for follow-on formula to be represented as lactose free or low lactose • Retained requirement to declare lactose and galactose in the NIS. New provisions • requiring the words 'lactose free' or 'low lactose' to be included with the name of the food on the front of the package • an explicit prohibition for the words 'lactose free' and 'low lactose' elsewhere on the label.
Partially hydrolysed protein.	New provision • for infant formula that is represented as partially hydrolysed, requiring the words 'partially hydrolysed' immediately adjacent to the statement of protein source • permitting the words 'partially hydrolysed' or any word or words having the same or similar effect in the statement of ingredients • The requirement applies to infant formula only. Representations about partially hydrolysed follow-on formula would not be permitted.
Stage labelling.	New provisions • permit the use of the number '1' on infant formula and the number '2' on follow-on formula to identify for consumers that the product is infant formula or follow-on formula, respectively • if used, the number must appear on the front of the package of the product and immediately adjacent to the relevant age statements for infant formula and follow-on formula.
Product differentiation.	New provision • requiring that a food represented as infant formula or follow-on formula must not be also represented as another food.

Existing labelling requirements	Draft variations in Attachment A to the 2nd CFS
Prohibited representations (including proxy advertising).	Retained existing prohibited representations New provisions • Unless expressly permitted or required by the Code, prohibiting representations made in infant formula or follow-on formula about: – information relating to another product (a name, number, picture, image, word or words). – ingredients – animal or plant sources of protein – the words 'partially hydrolysed' (or any word or similar words in the statement of ingredients) – the words 'lactose free' or 'low lactose' – a number used to identify for consumers that the product is infant formula or follow-on formula. Included a Note to clarify existing prohibition for nutrition content and health claims, and therapeutic claims apply.

Part C of SD3 addresses new labelling requirements for SMPPi. FSANZ has summarised the proposed regulatory approach in Table 8.2 below. Table 8.2 lists the FSMP, Standard 2.9.5, Standard 2.9.1 and Chapter 1 labelling requirements that would or would not apply to SMPPi. Given significant labelling changes have been made for the new SMPPi category, a labelling comparison of these requirements with new SMPPi requirements has not been provided.

Table 8.2 - New labelling requirements for SMPPi

Draft variation in Attachment A to the 2nd CFS
Standard 2.9.5 food for special medical purposes (FSMP) labelling requirements applied to SMPPi
Requirements that a food may only be represented as an SMPPi if it complies with Division 4 in Standard 2.9.1 Mandatory labelling information: • name of the food • lot identification • information on irradiated food • ingredient labelling • date marking • directions for use or storage • legibility requirements • Mandatory statements and declarations • Nutrition information about any other nutritive substance added to the product to achieve its intended medical purpose Inner package requirements Transportation outer requirements.
Standard 2.9.1 labelling requirements applied to SMPPi
Permission for information on the source or sources of protein Prohibited representations: • a picture of an infant • the word 'humanised' or 'maternalised' or any word or words having the same or similar effect • the words 'human milk oligosaccharide,' 'human milk identical oligosaccharide' or any word or words having the same or similar effect • the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect • information relating to another food.
Other Chapter 1 labelling requirements applied to SMPPi

Draft variation in Attachment A to the 2nd CFS
Existing prohibition for nutrition content and health claims, and therapeutic claims (a Note included in Division 4 of the primary draft variation) Information relating to foods produced using gene technology.
Labelling requirements <u>not</u> applied to SMPPi (Chapter 1, Standard 2.9.1 and Standard 2.9.5 FSMP)
Name and address of supplier Labelling requirements relating to infant formula and follow-on formula in new Division 3 would not apply to SMPPi. For example: • Directions for preparation and use for infant formula and follow-on formula • Warning statements for infant formula and follow-on formula – 'Follow instructions exactly' – 'Breast milk is best' • Age-related statements for infant formula and follow-on formula Requirements for lactose and gluten claims for FSMP A prescribed name for SMPPi.

9 Risk communication

9.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. All submissions received are considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

Prior to this CFS, FSANZ held several rounds of public consultation. These are noted in Section 1.6 and comments summarised throughout this CFS and accompanying SDs.

The release of this 2nd CFS is supported by a media release, updated website information and public notification via Food Standards News and social media channels.

FSANZ has prepared a communication strategy for this Proposal, which includes extensive targeted communication strategies with key stakeholders and information for the broader community. We envisage a significant amount of targeted consultation during the development and finalisation of the Approval Report. FSANZ will ensure comprehensive information for consumers and industry about the changes is developed in consultation with the relevant enforcement agencies, well in advance of them coming into effect.

9.2 World Trade Organization (WTO)

Australia and New Zealand are members of the World Trade Organization (WTO) and therefore are legally obliged to follow the rules of WTO trade related agreements. The Technical Barriers to Trade (TBT) Agreement recognises countries' rights to adopt standards for the protection of human health at the level it considers appropriate provided that such measures are in accordance with that Agreement (WTO, 1995).

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

There are relevant overseas standards for infant formula products discussed above in Section 1.5.2, and throughout the SDs. Amending the Code to update the regulation of infant

formula products in line with the latest scientific evidence, and where possible, with international regulations may have a significant effect on international trade due to differences in labelling and composition and in turn require manufacturers to reformulate and update labels specifically for the Australia and New Zealand markets. FSANZ considers that in the majority of the assessment, where there was no risk to public health or safety of Australian and New Zealand infants, international alignment has been sought. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement has been made to enable other WTO members to comment on the proposed amendments.

10 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

10.1 Section 59

10.1.1 Consideration of costs and benefits (SD4)

The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59(2)(a) of the Act).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers the revisions of standards related to infant formula in the Code that preferred options will require, if approved. FSANZ is unaware of any more cost effective measures.

Exemption from CRIS requirements, development of DRIS

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a formal Consultation Regulation Impact Statement (CRIS) in relation to the regulatory change proposed.[8]

A CRIS is not required because the function of the CRID has been achieved by an appropriate alternative mechanism. This includes the statutory consultation under the FSANZ Act for the 1st CFS and this second CFS. FSANZ also undertook ongoing consultation prior to the development of the 1st CFS.

A Decision Regulation Impact Statement (DRIS) will be prepared and presented to the FSANZ Board ahead of their meeting to inform the Boards decision on whether approve, amend or reject the proposed draft variations described and set out in this call for submissions. The DRIS will be based on the analyses presented in this CFS, updated based on stakeholder feedback.

Although a formal CIA is not required, FSANZ has given consideration to the costs and benefits that may arise from the proposed measure. This analysis satisfies the requirements of:

Section 59 of the FSANZ Act and
the Regulatory Impact Analysis Guide of for Ministers' and National Standard Setting Bodies (May 2020).

[8] The Office of Impact Analysis (OIA) was formerly known as the Office of Best Practice Regulation (OBPR). To review the exemption, refer to the OIA website under reference number 25089

For the full analysis, refer to Supporting Document (SD4).

Conclusions from cost and benefit analysis in SD4

Following consideration of the costs and benefits, FSANZ considers that the proposed changes to the Code will, on balance, have the largest net benefit and is therefore the preferred option.

The biggest potential impact of the proposed amendments Proposal are improved, life-long, health impacts for formula-fed infants. A large number of infants are fed formula, and therefore only a small benefit for each of those infants are likely to outweigh the costs identified in this assessment.

FSANZ expects that this benefit is likely to outweigh the costs, which is primarily the cost for industry to reformulate products and update labels.

Therefore, the proposed changes represent the greatest net benefit to the community. However, information received through this consultation process may result in FSANZ arriving at a different conclusion.

10.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

10.1.3 Any relevant New Zealand standards

This Proposal proposes to amend the current joint Australia New Zealand standards that regulate infant formula products. There are no other relevant New Zealand standards.

10.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

10.2.1 Protection of public health and safety

Infant formula products are a safe alternative to breast milk. Standard 2.9.1 and Schedule 29 (and other related standards) set specific compositional and labelling requirements to ensure these products are safe and suitable. The proposed draft variations prepared by FSANZ aim to update these standards where possible or necessary to ensure products remain safe. Where relevant, FSANZ has assessed scientific evidence related to the protection of the health and safety of infants who consume infant formula products. Our conclusions from these assessments (listed throughout the CFS and SDs) underpin the risk management options and the proposed draft variations to the Code.

10.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Labelling requirements to ensure adequate information is provided to caregivers is currently covered in Divisions 4 and 5 of Standard 2.9.1. The assessment for Proposal P1028 included a review of these requirements which was covered in the 1st CFS.

10.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements in Standard 2.9.1 include provisions to prevent misleading or deceptive conduct. The assessment for Proposal P1028 included a review of these requirements which was covered in the 1st CFS SD3.

10.3 Subsection 18(2)

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to assess this Proposal. Where evidence was lacking, particularly in the relation to consumer behaviour, FSANZ commissioned or undertook research reviews and utilised these reviews in the assessment:

- Consumer research in relation to safe preparation and use of infant formula (FSANZ 2021h)
- NZ MPI research (NZFS 2020)
- Microbiological safety of powdered infant formula: Effect of water temperature on risk (FSANZ 2022c)
- Consumer research on infant formula labelling (FSANZ 2022f).
- Rapid Systematic Evidence Summary on Infant Formula Stage Labelling and Proxy Advertising (Attachment 1 to SD3)
- Analysis of Current Stage Labelling and Proxy Advertising Practices of Infant Formula Products in Australia and New Zealand (Attachment 2 to SD3).

- **the promotion of consistency between domestic and international food standards**

A primary objective of this Proposal is to align with international regulations where possible. Codex standards are the main regulations to which FSANZ has compared requirements. This along with other international regulations are referenced through this assessment.

- **the desirability of an efficient and internationally competitive food industry**

The proposed draft variations, if adopted, will clarify and update to current standards, and align with international standards where appropriate. This supports efficiency and competitiveness in the food industry.

- **the promotion of fair trading in food**

Amending standards regulating the infant formula product industry can have implications for domestically manufactured products in both the domestic and international markets, and for internationally manufactured products for the domestic market.

- **any written policy guidelines formulated by the Forum on Food Regulation**

Two Ministerial Policy Guidelines apply to this application:

- Regulation of Infant Formula Products
- Intent of Part 2.9 – Special Purpose Foods

FSANZ considers these Ministerial Policy Guidelines have been addressed in its assessment and in its decision to prepare the proposed draft variations for the reason summarised in this

2nd CFS and the SDs. SD6 to the 1st CFS included detail on the FSANZ's assessment against the Ministerial Policy Guidelines (FSANZ 2022i).

11 Implementation

11.1 Transitional arrangements

The draft variations prepared by FSANZ provide transitional arrangements.

In developing these transitional arrangements, FSANZ considered the complex and diverse regulatory changes proposed. FSANZ also further considered the range of products on the market required to adopt the proposed labelling and composition requirements, the costs and practicalities of transition for industry, stakeholder views, precedents for transitional arrangements and other relevant FSANZ proposals and applications.

At the 1st CFS, industry stakeholders suggested the transitional arrangements for this Proposal should be considered as a major factor in minimising the cost of labelling changes and reformulation. Some industry groups recommended a five year transition plus a two year stock-in-trade period. During targeted consultation, other industry stakeholders noted that a four year transition period would also be appropriate and indicated this timing would be sufficient to incorporate new labelling and composition requirements into routine labelling and reformulation updates.

Under previous FSANZ proposals, such as *P1050 – Pregnancy warning labels* and *P1059 – Energy labelling on alcoholic beverages*, a three year transition period with stock-in-trade provisions specific to the product type were applied. These two proposals were reflective of a mandatory labelling change only. An example of a proposal with both compositional and labelling changes is FSANZ Proposal *P242 - Food for Special Medical Purposes* which considered the development of *Standard 2.9.5 – Food for Special Medical Purposes*. This Standard included sale, composition and labelling requirements for complex medical and formula foods, with the changes in effect two years after gazettal. P242 is the most comparable regulatory change to those specified within *P1028 – Infant Formula*, as it considered a whole standard including the sale, labelling and composition of medical and formula foods.

FSANZ acknowledges that the draft variations are one of the largest regulatory changes the agency has proposed and also understands the complexities associated with infant formula and its use as sole source of nutrition for a considerably vulnerable population.

Given the above, the proposed draft variations provide for a five year transitional arrangement, commencing on the gazettal date of the draft variations, if approved. During that five year period, infant formula products may be sold if they either comply with: the Code as in force as if the variation had not taken effect; or the Code as amended by the draft variations. After the transition period, all infant formula products available in the Australia and New Zealand markets would need to comply with the Code as amended by the draft variations.

The default standard transition arrangements provided by section 1.1.1—9 of the Code would not apply. This section provides for a 12 month stock-in-trade period for variations to the Code, commencing on the date of the variations' gazettal.

FSANZ is also not proposing to apply a separate two year stock-in-trade period sought by some submitters to the 1st CFS. This is because a five year transition period inclusive of stock-in-trade provides more flexibility to manufactures and food business than a three year transition period plus a two year stock-in-trade period. Allowing manufacturers and food

business to comply with either the Code as currently in force or with the Code as amended by the variations provides opportunity for individualised reformulation and labelling changes that are fit for purpose for each manufacturer. Industry stakeholders noted differing views of which transition period would be more effective for their business, not all responses aligned with a five year transition plus a two year stock-in-trade period. Some stakeholders noted an extended transition and stock-in-trade-period may incur additional expenses attributed to the continued production of additional SKU. FSANZ also notes that as infant formula products currently on the ANZ market are safe and suitable, extending the time for industry to comply with the current standard poses no risk to the health of ANZ infants. The proposed transitional arrangements take account of stock-in-trade and the fact that the proposed changes will be affecting products with a longer shelf life (up to 24 months).

A five year transition period would allow sufficient time for industry to adopt new labelling and composition requirements and minimise costs associated with labelling changes and reformulation. The transition period would not unduly impact consumers as the label information or updated composition has previously not been available, however a transition period greater than five years would unreasonably delay optimum nutrition to infants and the provision of information to consumers.

In summary, FSANZ proposes a five year transition period for infant formula products that will take effect on the date of gazettal.

12 Draft Standard

The primary and consequential draft variation to the Code is at Attachment A and is intended to take effect on gazettal, with a five year transition period.

A draft explanatory statements are at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

12.1 Exclusive use permissions

The draft variations include the compositional variations proposed in *Application A1251 - 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products* and *Application A1253 - Bovine lactoferrin in infant formula products* due to their anticipated gazettal. However, the conditional exclusive use periods have not been included within the draft variations for the above two applications, or for other exclusive use periods currently in the Code. It is expected that these exclusive use periods will no longer be applicable at the time of gazettal of the draft variation at Attachment A. Where required, FSANZ will address any current exclusive use permissions at the Approval Report.

12.2 Numbering issue

The primary draft variation will insert new sections 2.9.1—2 to 2.9.1—43 into Standard 2.9.1. The new sections do not include a section numbered as section 2.9.1— 34. This omission is deliberate and is a result of renumbering and restructuring that occurred in drafting and preparing that proposed draft variation. FSANZ will review the numbering of the new sections after responses to this 2nd Call for Submissions have been received.

The proposed variation

The proposed primary draft variation (see Attachment A) amends Standard 2.9.1 to reflect the following divisions:

- Division 1 deals with preliminary matters including outline of the standard, definitions and interpretation.

- Division 2 sets out compositional requirements for infant formula and follow-on formula.
- Division 3 sets out labelling and packaging requirements for infant formula and follow-on formula.
- Division 4 sets out all requirements for special medical purpose products for infants including, sale, representation, composition and labelling.

The proposed consequential draft variation includes amendments to the following three Standards and four Schedules including:

- Amendments to Standard 1.1.2 *Definitions used throughout the Code* which include the definitions of infant formula products, infant formula, follow-on formula and SMPPi. The definition for pre-term formula is also repealed.
- Amendments to Standard 1.3.1 *Food additives,* Schedule 8 *Food additive names and code numbers (for statement of ingredients)* and Schedule 15 *Substances that may be used as food additives* to clarify food additive permissions which do and do not apply to infant formula products.
- Amendments to Standard 1.5.1 *Novel Foods* and to Schedule 25 *Permitted novel foods* to clarify that an infant formula product may only have a novel food component or ingredient added if the presence of that novel food in that infant formula product has been expressly permitted.
- Amendments to Schedule 19 *Maximum levels of contaminants and natural toxicants* set or clarify Maximum Levels (MLs) for certain substances in infant formula products.
- Amendments to Schedule 29 – Special Purpose foods which prescribe calculations, permitted nutritive substances, amino acid minimums, required amounts and permitted forms of vitamins, minerals, and electrolytes, fatty acid limits, and guidelines.

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Appendix 1: Submitter comments and FSANZ responses to the 1st CFS

The following tables compile submitter comments and FSANZ responses for issues discussed in Sections 2 through to 5 of this CFS. Submitter comments related specifically to food technology (SD1), nutrient composition (SD2), labelling (SD3), and costs and benefits (SD4) are provided in the SDs.

List of tables

Table 1: Regulatory framework – Structure and categorisation of products

Issue	Comment	Submitter(s)	FSANZ Response
High level comments on the regulatory framework *FSANZ preferred option at the CFS was to structure and categorise products as:* • *Category 1: infant formula and follow-on formula and infant formula and follow-on formula with compositional modifications, including hydrolysed protein and lactose free/low lactose* • *Category 2: SMPPi*			
Yes, the preferred option is supported.	Supports infant formula product and categories of infant formula and follow-on formula (i.e. the current framework) for healthy infants.	FCG, INC, DAN, NZFS, A2M	Noted. See Section 2.3.1 FSANZ further explains its preferred option that products represented as or formulated for a medically diagnosed disease, disorder or condition of an infant would be categorised as SMPPi. Formulas for transient gastrointestinal conditions may meet infant formula or follow-on formula compositional requirements or not (e.g. they could require higher levels of thickeners). If the latter, products would be categorised as SMPPi.
	Supports removal of current subcategories for IFPSDU and creation of SMPPi category, however not modified infant formula products. Support removal of IFPSDU and current associated sub-categories.	DA, QLDH	
	Supports SMPPi and supports approach that includes a subcategory for modified infant formula products to capture low risk products used for transient gastro conditions.	NZMoH	
	Supports the option that IFPSDU remain in Standard 2.9.1. Supports the creation of the new category SMPPi within 2.9.1 whilst providing a clear distinction from other products for special dietary use.	AAA	
No, the preferred option is not supported.	This submitter does not support FSANZ's preferred option on the following grounds: 1. All infant formula products (including special purpose products) should be retained under the umbrella term infant formula products 2. Ensure the regulations recognise breastfeeding is the preferred way to feed infants by actively limiting the development of unnecessary formulas and associated marketing that undermine breastfeeding 3. Ensure pre-market assessment requirements for any new substance in infant formula products is clear in the regulations	VICDoH	FSANZ notes the submitter comments and provides the following responses: 1. FSANZ agrees and has modified the preferred option. Modulatory/supplementary products have been removed from the scope of the Proposal and in turn the definition of SMPPi has been modified to make clear that SMPPi are a subcategory of infant formula products. 2. Breast milk is the primary reference for composition of infant formula. In line with the Ministerial Policy Guidelines, any new substances proposed to be added to infant formula products are required to

Issue	Comment	Submitter(s)	FSANZ Response
	4. Make it clear infant formula is suitable for infants 0 to 12 months 5. Phase out follow-on formula 6. Address the imbalanced regulatory framework for optional ingredients 7. Ensure standard formula can be clearly delineated from valid special formula for the dietary management of medical conditions.		undergo rigorous pre-market assessment process which includes comparison to breast milk and assessment of benefit. The current framework does not allow exemptions from this process and there is no proposal to diminish these requirements. As such, the process limits development of unnecessary formulas. In terms of marketing, SD3 discusses aspects of marketing which have been considered in the Proposal. 3. See above (2) and Section 4 for discussion on novel foods and nutritive substances. 4. FSANZ has addressed this issue in Section 3 above. 5. FSANZ notes international regulations including Codex, the EU, UK, US, Turkey, China and South East Asia (SEA) include regulations and guidelines which prescribe separate composition for follow-on formula. To remove follow-on formula from the Code would be out of step internationally and inconsistent with the purpose of the Proposal to align with international regulations unless safety concerns have been identified. 6. FSANZ does not agree that the regulatory framework of optional ingredients is imbalanced. This is discussed in Section 4 above. 7. We agree that specialised infant formula products (defined as SMPPi) should have separate regulatory requirements in comparison to infant formula and follow-on formula. The proposed draft variations prepared by FSANZ seek to achieve this through restriction of sale (see Section 2.3.6) and strengthened labelling restrictions of standard infant formula products (such as nutrients that would be permitted to be listed on the NIS – see SD3).

Issue	Comment	Submitter(s)	FSANZ Response
	This submitter did not support FSANZ preferred option, and instead recommends that infant formula, follow-on formula and SMPPi products categories are all captured under the infant formula product definition. SMPPi creates two product categories under Standard 2.9.1 each with different rules applied to each category. This is inconsistent with MPGI.	NSWFA	The proposed primary draft variation prepared by FSANZ provide that SMPPi would be a subcategory of infant formula products, and therefore regulated under the same standard. In the 1st CFS, the SMPPi category was separated from infant formula products to allow modulatory and supplementary products be included under the SMPPi definition. FSANZ is no longer proposing this (see Section 2 above).
	This submitter supports the concept to regulate low risk modified products for dietary management of transient gastro conditions, however suggests there should be clear differentiation between products to avoid manufacturers positioning their products wherever they want. This submitter request further explanation to demonstrate how the regulatory framework will prevent low-risk products from being represented as SMPPi.	NZFS	See Section 2.3.1 for clarification about modified products. There are only two types of products that come under the 'low risk' modified concept. These are infant formulas represented as low lactose, or lactose-free or as partially hydrolysed. Both are permitted under the current standard. Under the proposed variations, these products would be subject to specific requirements to label as 'partially hydrolysed', 'lactose free' or 'low lactose'. SMPPi products would also have specific labelling requirements that prevent them from being represented as a general infant formula product or a low risk product. See sections 2.3.5 and subsection 2.9.1—37 and 2.9.1—38 in the primary draft variation. FSANZ has proposed that only SMPPi are restricted from sale in grocery stores and this provides additional differentiation (i.e. in addition to labelling requirements) from products intended for healthy infants. Regarding manufacturers deliberately positioning their products as SMPPi, it is difficult to see why manufacturers would do this as these products will be restricted to be sold only at pharmacies. An SMPPi product cannot be 'positioned' as 'low risk' as there will be mandatory labelling information (see proposed primary draft variation section 2.9.1 – 38) that specifies that they must be used under medical supervision and

Issue	Comment	Submitter(s)	FSANZ Response
			include a statement indicating the medical purpose of the food. There are also requirements that are analogous to those required for FSMP foods and are not consistent with low risk foods. SMPPi may deviate from baseline infant formula composition only when required by and for the special medical purpose of the product, i.e. for a specific disease, condition, or disorder (see section 2.9.1 – 32(2)). Despite flexibility provided in the primary draft variation, all food including SMPPi must meet Australian State and Territory and New Zealand Food Act requirements to be safe and suitable.
	These submitters do not support FSANZ's preferred option, on the basis that it delivers little benefit and/or there are few products that would actually qualify under this modification and most would fall into the SMPPi.	INC, NZFGC	See Section 2.3.1. FSANZ agrees that this may be the case. As noted above, there are only two types of products that come under the 'low risk' modified concept. These are infant formulas represented as low lactose, or lactose-free or as partially hydrolysed. Both are permitted under the current standard. Under the proposed primary draft variation, such products could continue to fall under general infant formula or follow on formula, as long as they meet the compositional requirements for those product types.
	These submitters do not support FSANZ preferred option as the modified category creates confusion between products suitable for healthy infants and those for special conditions to be used under medical supervision. These submitters noted that formula for transient gastrointestinal conditions should only be used under medical supervision, however should not have restricted sale due to implications relating to access and availability. These submitters recommend that specialised products should be categorised as SMPPi, however with no sale restriction applied.	INC, SAN, AFGC	See Section 2.3.1 that discusses how low risk and high risk products are differentiated under the proposed framework. FSANZ also notes that if products addressing transient dietary conditions are to be used under medical supervision, then restricted sale is justified on public health and safety grounds. By restricting SMPPi products from sale in grocery stores, products are not prohibited from sale but would be geographically separated from general infant formula products which assists in enforcement of the standard. FSANZ notes that FSMP that are regulated in Standard 2.9.5 also have an overarching restricted sale

Issue	Comment	Submitter(s)	FSANZ Response
			requirement (Division 2 of Standard 2.9.5). That is, restricted sale applies to all medical purpose products regulated by the Code. This is a particularly appropriate risk mitigation strategy given that infants are considered vulnerable population. Further discussion and FSANZ's position on the restriction of sale is included in Section 2.3.6.
	This submitter does not support the modified category and notes there should only be two categories of infant formula products: those for healthy infants healthy infant and those for unhealthy infants, both under Standard 2.9.1.	NSWFA	See Section 2.3.1.
	This submitter considers reflux is not a medical condition and does not need medical treatment.	DA	Noted. The regulatory framework includes definitions to enable products to be unambiguously captured under the appropriate category so that compositional and labelling requirements can apply.
Other issues raised.	**Pre-market assessment** The submitter questions whether an application could be made to FSANZ for a new modification to be incorporated under the modified category. If so what evidence would be required to demonstrate safety and efficacy.	NZFS	Manufacturers may apply to amend the Code and the compositional requirements that apply to IFP. The requirements relating to any such application and its assessment are explained in Chapter 3 of the Application Handbook
	Optional ingredients The departments have previously requested that FSANZ considers optional ingredients in its review of the regulatory framework in responses to consultations conducted in 2012, 2016 and 2021. FSANZ has not provided an assessment, nor consulted on this issue, and is proposing maintaining the current approach…. The current regulatory framework for optional ingredients in Standard 2.9.1, which permits substances to be optional indefinitely without review (or remain optional on the basis there is no evidence of toxicity) is predisposed towards supporting broad industry innovation for the purposes of	VICDoH	FSANZ does not routinely reconsider a decision by it to permit the use of a substance after an evidence based risk assessment has confirmed that the substance and its use is safe. Mechanisms exist whereby permissions and standards can be reviewed when warranted (e.g. by new evidence).

Issue	Comment	Submitter(s)	FSANZ Response
	product differentiation (and associated misleading marketing) rather than ensuring infants are the beneficiaries of industry innovation.		

Table 2: Regulatory framework – Specific comments on infant formula products with compositional modifications, such as low lactose or lactose free and partially hydrolysed protein sources

Issue	Comment	Submitter(s)	FSANZ Response
Specific comments on compositionally modified infant formula products *FSANZ preferred option at the CFS was to:* • *include the following as infant formula products(note that this was not proposed to be a defined category in Standard 2.9.1)* • *nutritionally complete infant formula products with a modified formulation relating only to partially hydrolysed protein and/or low lactose/lactose free which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.*			
Yes, the preferred option is supported.	Supports the categorisation of infant formula products that contain hydrolysed protein and/or are low lactose/lactose free as 'infant formula' rather than SMPPi. These products are not formulated to treat a medical condition as such in inborn error of metabolism, prematurity or any disease or other serious medical condition. This categorisation would prevent claims currently made by these products (e.g. 'comfort', 'sleep').	AWAW	Noted. The intended outcome for the proposed option at 1st CFS was that infant formula products in the general category need to comply with the composition and labelling requirements of that category. Thus, the general prohibition on claims for infant formula products would apply.
	Supports the concept to regulate low-risk modified protein and/or lactose content products as standard infant formula products. Products with these modifications are currently available and represented for the dietary management of transient gastrointestinal conditions (e.g. to help with digestion and colic). However, the proposed modified infant formula products and SMPPi categories need to be clearly differentiated within the Code.	NZFS	Under the measures proposed by FSANZ, infant formula represented as partially hydrolysed and/or lactose free/low lactose would have mandated labelling information that would differentiate these products from other infant formula (see Sections 7 and 8 of SD3). However, these low risk products would still be categorised as, and subject to the requirements for, infant formula. The specific elements that would enable differentiation of infant formula from SMPPi are described in Section 2.3.1.
	Supports the proposed approach to include a subcategory for modified infant formula products to capture low risk products that are for the dietary management of a transient condition (refer to Section 2.4.2-CFS). But support only if the inclusion of partially hydrolysed formula products is based on a clear role for these products based on scientific evidence. We note that partially hydrolysed formulas are no longer	NZMoH	Low risk products based on partially hydrolysed protein are currently available for feeding healthy infants and have been permitted in the Code for many years. There is no evidence that these products are unsafe for healthy infants when used for the dietary management of a transient condition.

Issue	Comment	Submitter(s)	FSANZ Response
	recommended for the primary prevention of allergic disease in high-risk infants, nor are they recommended for the dietary management of cow's milk allergy (ASCIA 2020).		FSANZ has proposed appropriate labelling of such products (see SD3 Section 8) to allow them to be differentiated. There is no scope to indicate a medical purpose unless the product is categorised as a SMPPi. For infant formula and follow-on formula, any label that suggests these products are recommended for prevention of allergic disease (or any other disease) is not permitted.
	While it is not ideal to present a modified formula as a standard infant formula, the departments agree to include lactose free and any partially hydrolysed protein products as standard formula as this would prevent claims made on some pseudo-medical formulas.	VICDoH	This comment is addressed in Section 2.3
No, the preferred option is not supported.	INC opposes the proposed new subcategory of infant formula products based on modified protein or lactose free/low lactose and makes the following points: • Does not resolve stakeholder issues and there is no benefit from industry's perspective • Creates confusion between products suitable for healthy infants and products for serious conditions • Infant formula for transient conditions should only be used under medical supervision and must communicate its purpose so that receive infant formula product they need. • Modified protein does not include all formulas designed for dietary management of functional transient gastro conditions • "Purpose not labelled" • "Consumers will be frustrated" • "No dairy-based lactose free products on the market" • "Product labels must communicate adequate information to carers" • Ignores broader application of these products to the SMPPi category. If this sub-category is pursued, additive permissions under SMPPi may need to be considered. This submitter also notes there needs to be a way to convey necessary information to allow caregivers to select the correct product (communication of adequate information), with potential health risks if	INC	See Section 2.3.1. The proposed primary draft variation prepared by FSANZ will permit infant formula represented as partially hydrolysed and/or low lactose or lactose-free and allow them to be appropriately labelled through mandated wording in the Standard. As low risk-type formulas, i.e. suitable for otherwise healthy infants, it is not appropriate to allow such products flexibility in providing information on a specified medical purpose, as is afforded to SMPPi. The objectives here are to protect public health and safety and (with mandated wording) to provide clarity that will enable enforcement and compliance. Infant formulas based on partially hydrolysed protein and/or low lactose/lactose free have been permitted in the Code for over 25 years. If an infant formula that is represented as partially hydrolysed and/or low lactose/lactose free, and • it requires higher quantities of food additives (for example) to make a functional formula, or

Issue	Comment	Submitter(s)	FSANZ Response
	incorrect product is used.		• it's formulation deviates from baseline infant formula composition to address a specified medical purpose then the product would fall under the SMPPi category with requirements as listed in the proposed new Division 4. FSANZ notes the labelling of infant formula that is represented as partially hydrolysed and/or low lactose/lactose free is addressed in Section 2.3.5.
	These submitters do not support a 'modified' category as it represents a way to market modified products to infants that do not need them. Any product that is needed for medical purpose should be categorised as SMPPi.	WADoH, DA	Agreed, see Section 2.3.1.
	This submitter does not support FSANZ preferred option as it adds complexity and confusion about products for healthy infants versus products that should only be used under medical supervision. Infant formula for transient gastrointestinal conditions must be able to state conditions it is used for to provide adequate information for healthcare professionals and carers.	AFGC	In this CFS the structure has been adjusted so the SMPPi would be a subcategory of infant formula products. See also Section 2.3.1. See Section 2.3.5, FSANZ has stated previously that the Code is clear that nutrition content and health claims must not be made about an infant formula product.
	This submitter does not support the proposed option for modified infant formula products as presented. As these products are formulated for the dietary management of infants with a functional gastrointestinal condition, often a transient condition, and are based on generally accepted scientific evidence. These products should be used following advice from a healthcare professional. This submitter suggests that these products are readily identified by a statement "For the Dietary Management of" to minimise self-selection. Dose not agree that limiting access to pharmacy is likely to reduce retail competition with result of increased price and minimal impact on	NES	As above, FSANZ reiterates that if an infant formula product is represented as being formulated for a condition it will be categorised as an SMPPi. For the reasons summarised in this CFS, SMPPi regulation includes mandated labelling and a restriction of sale. The proposed primary draft variation allows infant formula with certain compositional modifications to be represented as such. See section 7 and 8 in SD3 for further details. These products would still be able to be sold on the grocery shelf, however they would not be able to label for a condition.

Issue	Comment	Submitter(s)	FSANZ Response
	consumers self-selecting these products.		The restriction of sale is discussed in detail in Section 2.3.6.
	This submitter does not support lactose free products on open market and should be categorised as SMPPi. Caution should be exercised as there is “limited evidence” on long term growth impact”. Therefore, infants that require these formulas should be under recommendation of health professionals, under medical supervision and available at pharmacy only.	DA, WADoH	As above, FSANZ reiterates that if an infant formula products is represented as being formulated for a condition (such as lactose intolerance or an allergy) it would be categorised as an SMPPi. Products that are represented as low lactose or lactose free will only be categorised as SMPPi if they represent themselves as formulated for a medically diagnosed disease, disorder or condition of an infant. While there is limited evidence regarding low lactose or lactose free infant formulas and their impact on long term growth and development, studies that have been conducted have concluded that absence of lactose in milk-based formula does not adversely affect normal growth in term infants (Jacobs 2011).
	This submitter recommends to account for ‘low lactose’, ‘lactose free’ and ‘partially hydrolysed’ formulas in the modified infant formula product category need specific definitions to provide appropriate legal clarity for where these products can differ from standard composition and where they cannot.	NSWFA	As noted above, FSANZ clarifies that there is not a defined modified category of infant formula products. However infant formula can have compositional modifications such as partially hydrolysed protein and/or low lactose/lactose free. These compositional modifications are permitted through compositional requirements and the following labelling requirements: • Infant formula represented as low lactose/lactose free which will be delineated by a mandatory statement (see 2.9.1—21) • Infant formula represented as partially hydrolysed which will be delineated by the words “partially hydrolysed’ adjacent to the

Issue	Comment	Submitter(s)	FSANZ Response
			mandatory protein source statement (see 2.9.1—20).
	This submitter requests further commentary on the functional purpose of 'partial hydrolysis' of proteins in infant formula products. This submitter also requests a definition for partial hydrolysis to enable clear differentiation between infant formula products and SMPPi.	NSWFA	This issue is addressed above in Section 2.3.3. There is no internationally agreed definition for partial hydrolysis so it would be difficult to do this and remain internationally consistent. The categorisation of general infant formula for healthy infants versus SMPPi stems from the product's ability to meet specified compositional requirements for infant formula. If an infant formula is represented as partially hydrolysed and is unable to meet general composition requirements (e.g. requires a higher level of thickeners which is a safety issue for healthy infants), then it is SMPPi.
	This submitter noted that the extent of hydrolysis will be difficult to enforce and queries how partially and extensively hydrolysed infant formula products will be differentiated, for example when degree of hydrolysation of may cross over both infant formula products and SMPPi. Please address how infant formula products that contain partially hydrolysed proteins as general infant formula products will be differentiated from extensively hydrolysed products (which would be SMPPi).	SAH	See Section 2.3.1 and 2.3.3. The degree of hydrolysis of a protein source is not definable and prescribing a degree would be out of step with international jurisdictions, and thus potentially be a trade barrier. Differentiation between partially hydrolysed and extensively hydrolysed proteins is subject to the food additives needed to produce a functional, stable product for infants, e.g. additional thickeners and stabilisers. If a product is based on a hydrolysed protein source to the degree that higher levels of thickeners or other additives are needed, then these would no longer be suitable for healthy infants and would be categorised as SMPPi.
	This submitter notes that without a definition for modified infant formula products, other risk management aspects of the regulation (e.g. food additive permissions) are needed to self-limit products produced under	NZFS	See Section 2.3.1. Infant formula products can have compositional modifications (such as partially hydrolysed protein and/or low lactose/lactose free) in

Issue	Comment	Submitter(s)	FSANZ Response
The submitter(s) provided a new proposed option.	each of the modified infant formula product and SMPPi categories. This submitter requests FSANZ further strengthens and clarifies the risk management strategies applied to modified infant formula products so that the intended low-risk products are captured and regulated as standard infant formula products.		prescribed circumstances. In these cases, specific labelling requirements apply.
	This submitter does not support the permission for allowing partially hydrolysed protein. As there is no evidence that partially hydrolysed formula is suitable to treat or manage any medical/health condition, consideration may be required for the need for this product at all.	QLDH	FSANZ notes that partially hydrolysed protein is permitted in international regulations and under the current Standard 2.9.1. This issue has been discussed in Section 4.4 in SD2 to the 1st CFS and is further discussed above in Section 2.3.3.
	This submitter suggests an independent expert advisory group review of the evidence for the modified formula products category and its use in the dietary management of a transient gastrointestinal condition would assist in strengthening the rationale to support decision making.	WADoH	FSANZ acknowledges how an expert panel could improve regulatory clarity. However, the FSANZ Act does not allow the Code to establish such an independent expert panel as it does not come within the list of matters that can be included in a proposed draft variation as per section 16 of the FSANZ Act. This is a matter for the jurisdictions to consider.

Table 3: Regulatory framework – Specific comments on proposed SMPPi

Issue	Comment	Submitter(s)	FSANZ Response
Specific comments on the SMPPi category *FSANZ preferred option at the CFS was to include the following as SMPPi:* • *Products which are nutritionally complete with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, when used under medical supervision in accordance with the manufacturer's instructions, may constitute the sole or principal liquid source of nourishment for the infants for whom it is intended.* • *Products which are nutritionally incomplete with a nutrient-adapted formulation specific for a disease, disorder or medical condition that is supplementary and is not suitable to be used as the sole source of nourishment.*			
Yes, the preferred option is supported.	Supports the category and proposed definition for SMPPi in principle. Requests further detail e.g. on labelling restrictions.	A2M, NAS	Please see Section 2 above for further discussion on the regulatory framework, including requirements for SMPPi.
	Supports rice based formulas included as SMPPi.	NAS	Noted, FSANZ agrees.
	Supports SMPPi comply with allergen declaration requirements in Standard 1.2.3.	NAS	Noted, FSANZ agrees.
	Support category of SMPPi, however recommends a tighter definition.	AWAW	Noted, the SMPPi definition is discussed in Section 3.2 above.
	Use for older infants (>12 years) Support removal of IFPSDU category and replace with SMPPi & to regulate any special medical purpose formulas for infants< 12 months under St 2.9.1 noting caveat that some of these products due to their specialty nature may be used for older infants. All FSMP for > 12 months regulated by St 2.9.5. Decision to use specialised formula (SMPPi) at >12 months lies with medical practitioner to advise on case-by-case basis and is not a standards matter. But concern that labelling to permit consumption past 12 months blurs the lines between Standards 2.9.1 and 2.9.3. (See suggested alternative below).	DA NSWFA	Noted. The proposed primary draft variation states, in relation to SMPPi, that 'if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group'. This is required to enable accurate information provided to the caregiver and/or medical professional. FSANZ notes the drafting is consistent with Article 5(2)(c) of European Regulation (EU) 2016/128. SMPPi are intended to mirror a medical purpose food regulated under Standard 2.9.5. Standard 2.9.3 does not regulate medical purpose foods nor do foods covered under Standard 2.9.3 address a condition or

Issue	Comment	Submitter(s)	FSANZ Response
			require use under medical supervision. Further, 'Formulated supplementary food for young children' (FSFYC) is a prescribed name and these products are covered under Standard 2.9.3. The Code specifically states this name must appear on the label of the food (Standards 1.1.2, 1.2.2 and 2.9.3). If the infant formula product (which serves as sole or principal liquid source of nourishment) is formulated for a medically diagnosed disease, disorder or condition of an infant, and manufacturer wishes to represent or label it as such, the product can only be SMPPi under the revised Standard 2.9.1. Standard 2.9.5 specifically excludes infant formula products.
	These submitters support FSANZ preferred option for the new category for SMPPi, which includes supplementary and modular products such as human milk fortifiers,	MoH, NZFS	Noted. For the reasons stated in section 2.3.2 of this CFS, the proposed regulatory approach is to exclude modular and supplementary products (including human milk fortifiers) from the scope of the review of Standard 2.9.1.
	Considers that the principles listed in section 2.4.3 of the CFS should be "incorporated into the regulation in SMPPi"	NZFS	Those principles listed in section 2.4.3 of the 1st CFS that can be incorporated into a clear and enforceable standard have been, and are reflected in the proposed variations. See, for example, the definition of SMPPi (see Section 3.1) in the proposed variations and the conditions that would apply to SMPPi.
	Supported further discussion on prescribed name for SMPPi.	NZFS	For a response on this issue please see Table 7 of SD3.
	This submitter supported FSANZ preferred option for restricted sale as this provides a level of protection against inappropriate use of products that should have medical supervision. However, considered the approach will not prevent access through warehouse-type pharmacies or online sales.	NZFS	The proposed regulatory approach to restrict access to SMPPi is consistent with FSMP. SMPPi are intended to be used under medical supervision and all stakeholders have acknowledged these products are unsuitable for healthy infants. Regulation of e-commerce (online sales) of food is a matter for the Australian and New Zealand food laws

Issue	Comment	Submitter(s)	FSANZ Response
			that apply the Code. E-commerce is not within the scope of this Proposal, or the remit of FSANZ. However, FSANZ is aware that products sold online that are to be used under a medical professional are typically accompanied by an online declaration and/or wavier that outlines this important information to consumers at the point of purchase.
No, the preferred option is not supported.	These submitters did not support the SMPPi category and raised the following concerns: 1. Inclusion of other specialty foods from Standard 2.9.5. These products have not been raised in previous consultations and risks specialty products for infants from being imported. 2. That nutrient sources, additives and other refined ingredients have not been considered, how the products is used and the intended consumer group. 3. That there is no principle of international alignment for highly specialised SMPPi that must be imported. 4. Restriction on sale is inequitable and unsafe for those in need particularly due to limited access in rural and remote communities.	INC with support from A2M, CMA, DAN, FCG, NZFGC, AFGC	Submitter comments have been addressed as numbered: 1. Addressed in Section 2.3.2 2. Addressed in SD2 part D and throughout SD1. Please see the proposed primary draft variation. The intent is that no SMPPi that is required for an infant with a medically diagnosed disease, disorder or condition be blocked from importation 4. Addressed in Section 2.3.6.
	These submitters do not support inclusion of modulatory and other supplementary products (i.e. all specialty infant foods) which currently fall under Standard 2.9.5. SMPPi only includes foods that form the sole or principle liquid source of nourishment, and specifically formulated for the nutritional requirements of infant with diagnosed disease disorder or medical condition.	DAN, AFGC, NZFGC, NES, NSWFA	FSANZ has revised the regulatory framework and has excluded supplementary and modular products from the proposed SMPPi category. This is discussed in Sections 2 and 3.2 above.
	'Generally accepted scientific data' does not provide adequate certainty for enforcement and instead provides means for current IFPSDU to relabel as SMPPi with no product reformulation. It may also lead to products to meet consumer demand rather than specific medical purposes.	NSWFA	FSANZ agrees that a requirement for *generally accepted scientific data* would be unenforceable. This has not been included in the proposed drafting/definition for SMPPi. FSANZ notes that, under the proposed primary draft variation, a manufacturer could choose to position IFPSDU as SMPPi. However, to do so, the manufacturer would need to ensure that the product met the relevant restricted access, composition and labelling

Issue	Comment	Submitter(s)	FSANZ Response
			requirements.
	Segregation of SMPPi from pre-market assessment requirements on basis of 'generally accepted scientific data' will allow manufacturers to subvert the pre-market assessment requirements for additional nutritive substances, food additives etc.	NSWFA	The proposed primary draft variation would segregate SMPPi from pre-market assessment requirements in the same way as FSMP currently are and only to the extent that the permitted deviation from compositional requirements is required by and for a particular medical purpose. Subjecting SMPPi products to the pre-market assessment requirements would introduce long delays in getting those products to infants that would need them.
	The absence of a prescribed name for SMPPi will be challenging for health professionals to identify specific products.	NSWFA	SMPPi cannot have a prescribed name as this will prevent import of some SMPPi products not manufactured in Australia and New Zealand, which is a health and safety risk to infants who require those particular products. There are other labelling requirements for SMPPi that will enable health professionals to correctly identify a product. Refer to FSANZ's response on the issue of not applying a prescribed name to SMPPi in item C.10 in Table 7 of SD3.
The submitter(s) provides a new proposed option.	• Two categories: general and special medical purpose (SMP) • Prescribed name for SMP (to assist health professionals to identify specific product. • Definition to include 'medically determined' – will assist in getting recognised products on the PBS	NSWFA	Noted. The FSANZ Act does not allow the Code to establish such an independent expert panel to conduct pre-market assessments of SMPPi. FSANZ is also not

Issue	Comment	Submitter(s)	FSANZ Response
	• Pre-market assessment required for SMP • Level of evidence to support SMP: clear, un-ambiguous, and unequivocal • Independent expert panel established to conduct pre-market assessment (expeditiously and separate to normal application process) • Approved SMP to be listed on a Positive List • Positive List to be part of CoP that sits beside Standard 2.9.1 (as a reference point) • Place an express offence in Std. 2.9.1 if product represents itself as SMP and not on Positive List • Additional regulatory controls similar to 'Schedule 3 (Poisons Standards)' to prevent SMP purchased in error online. • Explanatory Statement to outline the range of health conditions known to warrant production of SMP formulas.		resourced to develop and implement a premarket assessment mechanism that effectively sits parallel to the standard setting process. The Code does not, and cannot, contain offence provisions. Offence provisions are provided in the application Acts. The proposed regulatory framework (see Figure 2.4) will delineate infant formula and follow-on formula from SMPPi for regulatory purposes (which is not the case under the existing Standard 2.9.1).
	Non-trade restricted SMPPi to require specific clear and consistent labelling, and located in a prominent place, so that products are not misused.	AFGC	As per the primary draft variation, all SMPPi would be subject to a restriction of sale and would have clear labelling. This is consistent with FSMP.
	Trade restricted SMPPi permitted to have flexible labelling to enable continued supply of imported products. It is not commercially feasible to create specific labels and formulations of these products for ANZ.	AFGC	FSANZ notes that the mandatory statements and declarations are for public health and safety reasons. Caregivers and medical professionals need accurate information to be able to decide whether a product is appropriate for the infant.

Table 4: Definition of infant formula products

Issue	Comment	Submitter(s)	FSANZ Response
Definition of infant formula product *FSANZ preferred option at CFS was to:* • *Retain existing definition where **infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.*			
Yes, the preferred option is supported.	These submitters supported and did not provide reasons other than views that the current definition was working well.	DA, FCG, NZFS	Noted.
No, the preferred option is not supported.	These submitters support alignment with Codex as much as possible and note it is important to include 'based on milk or other edible food constituents of animal or plant origin'.	CMA, INC, DAN	FSANZ will not be aligning the definition to that of Codex, due to the difference between Codex as a guideline and the Code as a legislated instrument. FSANZ will retain the wording 'based on milk or other edible food constituents of animal or plant origin', however has prescribed set protein sources for infant formula and follow-on formula.
	This submitter suggests simplifying the definition for infant formula product to state an infant formula product is an infant formula and/or follow-on formula. Then refer to more detailed definitions proposed for infant formula and follow-on formula. The basis for this is to remove definition for 'infant' as the age limit of 12 months is written into definitions for infant formula product, infant formula and follow-on formula.	SAH	FSANZ does not consider this suggestion to be appropriate or fit for purpose, as it does not solve any current regulatory problems or aid clarity.
	This submitter requests a slight amendment so that the definition includes partial source of nourishment and is therefore able to capture all SMPPi's, including fortifiers: *'An infant formula product means a product that is based on milk or other edible food constituents of animal or plant origin which **serves as a partial or sole liquid source** of nourishment for infants depending on the age or **medical nutrition requirements** of the infant'*	VICDoH	Since FSANZ has changed the regulatory framework from the 1st CFS, partial sources of nutrition have been scoped out and this definition amendment is no longer relevant.

Issue	Comment	Submitter(s)	FSANZ Response
The submitter(s) provides an new proposed option.	These submitters request ‘proven to be safe’ be included in the definition.	A2M, INC	Australian and New Zealand food laws already expressly require that all food sold - including infant formula - must be safe and must be suitable. The added benefit of restating in the Code an existing requirement imposed by those Acts (i.e., through mandating that the food also 'be proven to be safe') appears unclear, noting the requirement imposed on FSANZ by paragraph 59(b) of the FSANZ Act.
	This submitter proposed amended wording to the definition which stated more specific compositional parameters, such as ‘ based on milk of cows’.	CMA	FSANZ has not incorporated this wording into the proposed definition as protein source compositional parameters would be prescribed in the composition Division of the revised Standard.
Other issues raised.	This submitter supports the approach for no definition for modified products as these products should captured under the infant formula product definition.	NZFS	The 1st CFS did not propose to set a definition for modified infant formula products. The term ‘modified’ was used as a descriptor and the types of products that would fit into this description would be set in compositional parameters.

Table 5: Definition of infant formula

Issue	Comment	Submitter(s)	FSANZ Response
Definition of infant formula *FSANZ preferred option at CFS was:* *Retain existing definition where* ***infant formula*** *means an infant formula product that:* *(a) is represented as a breast milk substitute for infants; and* *(b) satisfies by itself the nutritional requirements of infants under the age of 6 months.*			
Yes, the preferred option is supported.	These submitters supported FSANZ preferred option at the 1st CFS.	A2M, DA, NZFS, SO	FSANZ notes this support. The definition for infant formula is discussed in Section 3.1 above.
No, the preferred option is not supported.	These submitters did not support for the following reasons: Changing the age from under the age of 4 – 6 month to under the age of 6 months, does not: • accurately represent the product • reflect the ministerial policy guidelines • align with ANZ nutrition polices and guidance • align with intentional regulations	DAN, FCG, INC, NZMoH, VICDoH	Noted. Based on the submitter comments provided and how this preferred option would affect the representation of infant formula and alignment with Australian and New Zealand ministerial polices and guidelines, FSANZ has not included this amendment in the proposed draft variations. The proposed definition of infant formula in the draft variations refers to 'under the age of 6 months'.
The submitter(s) provides an new proposed option	These submitters proposed alternatives: Infant formula means an infant formula product that • 'is represented as a breast milk substitute for infants; and satisfies by itself the nutritional requirements for infants for the first months of life up to the introduction of complementary food'. • 'is represented as a breast milk substitute for infants; and satisfies by itself the nutritional requirements for infants for the first months of life up to the introduction of complementary food' • 'is represented as a breast milk substitute for infants; and satisfies by itself the nutritional requirements of infants under the age of six months; and suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months'.	FCG, INC, NZMoH	While FSANZ appreciates the suggestions submitters have provided, FSANZ has not incorporated these suggestions into the draft variations. FSANZ has discussed the definition for infant formula in Section 3.

Table 6: Definition of SMPPi

Issue	Comment	Submitter(s)	FSANZ Response
Definition of special medical purpose product for infants *FSANZ preferred option at CFS was:* • *New definition for SMPPi where a **special medical purpose product for infants** means a food that is* *(a) specially formulated for the dietary management of infants* *(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and* *(ii) whose dietary management cannot be completely achieved without the use of the food; and* *(b) intended to be used under medical supervision; and* *(c) represented as being* *(i) a food for special medical purposes intended for infants; or* *(ii) for the dietary management of a disease, disorder or medical condition in infants.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	A2M, DA, NZMoH	FSANZ notes this support. The definition for SMPPi is discussed in Section 3.2 above.
	These submitters suggested the definition be amended to include the following statements: • *must be safe, beneficial and effective* • *based on generally accepted scientific data.*	VICDoH, NZFS	Noted. FSANZ does not support use of the suggested additional statements. The inclusion of such statements would introduce ambiguity into the definition which in turn would undermine compliance and enforcement. Australian and New Zealand food laws already expressly require that all food sold - including infant formula - must be safe and must be suitable. The added benefit of restating in the Code an existing requirement imposed by those Acts (i.e., through mandating that the food also 'be proven to be safe') appears unclear, noting the requirement imposed on FSANZ by paragraph 59(b) of

Issue	Comment	Submitter(s)	FSANZ Response
			the FSANZ Act. Please see the discussion within section 3 of this CFS on the use of definitions to set substantive compositional requirements. As explained, definitions should not include or set substantive requirements. Instead the proposed draft variations would set compositional requirements to ensure safety and suitability (for the product's intended purpose). See, for example, the proposed Division of the revised Standard 2.9.1 that relates to composition.
No, the preferred option is not supported.	This submitter did not support the preferred option as the proposed definition is not tight enough and needs to clearly describe the medical conditions that products under SMPPi are for.	AWAW	Noted. The draft variations includes a refined definition that accurately captures SMPPi. This definition does not include specific medical conditions which SMPPi are formulated for, however does note an SMPPi means an infant formula product that is 'for the dietary management of a medically diagnosed disease, disorder or condition of an infant'. The objective in creating the SMPPi category is to add clarity to the Standard about where products should be positioned (as an infant formula or, follow-on formula, or as a SMPPi). The current Division 4 of Standard 2.9.1 doesn't include definitions of specific conditions or clearly delineate whether products are positioned as an infant formula, follow-on formula or IFPSDU. The proposed definition for SMPPi clarifies where SMPPi products are positioned and makes clear what the regulatory requirements are depending on whether the product is infant formula, follow-on formula or SMPPi.

Issue	Comment	Submitter(s)	FSANZ Response
	This submitter did not support FSANZ preferred option as the SMPPi definition extends to other special medical infant products that are not sole source of nutrition or formulated in alignment with the base composition of infant formula. These submitters noted this definition extends past infant formula products, creates ambiguity for products that should sit under Standard 2.9.5 and extends the scope of the PG which covers infant formula, follow-on formula, and IFPSDU. The definition is ambiguous for enforcement and does not align internationally.	DAN, INC, NES	FSANZ notes this comment and clarifies that the regulatory framework and definition of SMPPi have been amended to exclude supplementary and modular products. The definition for SMPPi has changed to reflect only medical purpose products that are considered sole or principal liquid source of nourishment. The definition for SMPPi is discussed in Section 3.2 above.
The submitter(s) provides an new proposed option.	This submitter recommended the following amendments be made to the definition: • a)(i) the words 'medically determined' should appear twice, to read: *by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose medically determined capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and* • (b) require mandatory use under medical supervision and delete the word 'intended' to read: *to be used under medical supervision* This will make line (b) consistent with Regulation (EU) No 609/2013 (see table 3.2.1 p. 26), given that most SMPPi consumed in Australia are manufactured in Europe.	AWAW	Noted. FSANZ does not support use of the suggested amendments to the definition. The text proposed would introduce ambiguity into the definition, which in turn would undermine compliance and enforcement and compliance. FSANZ notes that the Standard appropriately imposes labelling requirements to inform consumers that SMPPi should be used under medical supervision. The majority of SMPPi products are also prescription based.
	This submitter noted that modified infant formula products should be covered by requirements for standard infant formula products and to ensure this the definition for SMPPi should expressly exclude those products for dietary management of transient gastrointestinal conditions. This submitter supports the definition being based on Standard 2.9.5 FSMP definition.	NZFS	The term 'modified infant formula products' is used to denote the modification to protein and lactose, not as a prescribed modified infant formula products category. Any product which modifies protein and/or lactose and represents them as such (e.g. as partially hydrolysed or as low lactose or lactose free) will be regulated as standard infant formula and be subject to additional composition and labelling requirements. The proposed definition has been revised in developing the draft variations that are the subject of this 2nd CFS. FSANZ expects the revised definition addresses the concerns about the operation of clauses (i) and (ii) as written in the 1st CFS.

Issue	Comment	Submitter(s)	FSANZ Response
	This submitter suggested a prescribed name of Infant Formula Product for Special Medical Purposes and amending the definition where the focus is on medical determination as the pre-requisite entry requirement to the SMPPi category: **Infant Formula Product for Special Medical Purposes** means an infant formula product that is: i) specially formulated for the dietary management of infants who have **medically determined** nutrient requirements; including limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and ii) whose dietary management **cannot medically be achieved** without use of the food; and iii) intended for use under **medical supervision**; and iv) represented as being for the dietary management of a **medically diagnosed** disease, disorder or **medically diagnosed condition** in an infant; and v) may be provided to **medically diagnosed** infants by way of exclusive or partial feeding.	NSWFA	FSANZ does not support setting a prescribed name for the reasons stated in SD3. As noted in Table 3, there are other labelling requirements for SMPPi that will enable health professionals to correctly identify a product. Refer to FSANZ's response on the issue of not applying a prescribed name to SMPPi in item C.10 in Table 7 of SD3. FSANZ has revised the definition for SMPPi to reflect the FSMP definition and is satisfied that it meets the objectives of a definition in the Code. The SMPPi definition no longer refers to 'partial feeding'. See Section 3.2 above.
	This submitter proposed the following amendments to the definition: A Special Medical Purpose Product for infants *under the age of 12 months* means a food that is a. specially formulated for the dietary management of infants (i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and (ii) whose dietary management cannot be completely achieved without the use of the food; and b. intended to be used under medical supervision; and c. represented as being (i) a food for special medical purposes intended for infants; or (ii) for the dietary management of a disease, disorder or medical condition in infants. a. represented as being (i) a food for special medical purposes intended for infants; or (ii) for the dietary management of a disease, disorder or medical condition in infants. The addition of the underlined phrase removes the need for a definition for 'infant'	SAH	FSANZ notes that the definition of 'infant' applies in multiple places in the Code, not just Standard 2.9.1 (e.g. Standard 2.9.2, Schedule 15). Therefore, FSANZ proposes not to remove the definition for infant. The definition for SMPPi is discussed at Section 3.2 above.

Table 7: Definition of follow-on formula

Issue	Comment	Submitter(s)	FSANZ Response
Definition of follow-on formula *FSANZ preferred option at CFS was:* • *Retain existing definition where **follow-on formula** means an infant formula product that:* *(a) is represented as either a breast milk substitute or replacement for infant formula; and* *(b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	DAN, DA, FCG, INC, NZFS	FSANZ notes this support.
Yes, the preferred option is supported.	This submitters noted support, however stated it should be phased out as it is not supported by national infant guidelines or the scientific literature and therefore not consistent with the Policy Guidelines.	VICDoH	As previously mentioned FSANZ considers follow-on formula to be a necessary product. This view is shared through international regulation including the EU, UK, US, Turkey, China and South East Asia (SEA) and Guidelines such as Codex Alimentations. These regulations and guidelines prescribe separate composition for follow-on formula. To remove follow-on formula from the Code would be out of step internationally and inconsistent with the purpose of the Proposal to align with international regulations unless safety concerns have been identified.
The submitter(s) provides an new proposed option.	This submitter recommended the following amendments be made to the definition: *Follow-on formula means a product that:* *is represented as either a breast milk substitute or replacement for infant formula; and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months to 12 months.*	SAH	FSANZ notes this comment, and that the definition of follow-on formula is discussed in Section 3. FSANZ has not included the proposed submitter amendment as "infant" is already defined in the Code as a person under the age of 12 months. Adding in this additional age parameter to the definition duplicates unnecessary information in the definition for "follow-on formula".

Table 8: Other definitions

Issue	Comment	Submitter(s)	FSANZ Response
Protein substitutes *FSANZ preferred option at the CFS was:* • *Remove the definition for protein substitute as the use of this term is superseded by the categorisation of products as SMPPi.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	DAN, INC, NZFS	FSANZ notes this support.
No, the preferred option is not supported.	The departments previously supported removing definitions for protein substitutes. Now that these products will sit across two categories, with very different regulatory requirements, the department's request FSANZ provides more information for enforcement purposes on how formulas containing partially hydrolysed proteins (to be regulated as standard formulas and subject to a prohibition on health claims) will be differentiated from extensively hydrolysed proteins.	VICDoH and SAH	Further information on this issue has been provided within Section 2 above. Infant formula and follow-on formula containing partially hydrolysed proteins must meet the composition requirements including all restrictions on use of food additives (i.e. the restricted use on thickeners will apply). However, only infant formula would be permitted to be represented as 'partially hydrolysed' on the label. SMPPi may also include partially hydrolysed proteins although would be able to deviate from the base composition of infant formula and follow-on formula to address a medically diagnosed disease, disorder or condition of an infant. Specific labelling requirements would apply to SMPPi (see Section 2.3.5) and they would only be permitted to be sold by a medical practitioner or dietitian; or at a medical practice, pharmacy or responsible institution; or by a majority seller of that special medical purpose product for infants.
	Does not support removal of protein substitute definition as retaining the definition will help in identifying protein sources.	DA	Noted. The proposed primary draft variation prepared by FSANZ would prescribe an explicit list of protein sources for infant formula products. These are cow

Issue	Comment	Submitter(s)	FSANZ Response
			milk protein, goat milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins'. Any protein sources outside of those specified above will be required to undergo a pre-market assessment through FSANZ. See Section 4.4 of SD2.
Soy-based infant formula *FSANZ preferred option at the CFS was:* • *Remove the definition for soy-based infant formula.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	DAN, DA, FCG, INC, NZFS, QLDH, VICDoH	FSANZ notes that, in previous consultation papers, submitters also agreed with the preferred option to remove this definition. The draft variations therefore repeal this definition.
Pre-term formula *FSANZ preferred option at the CFS was:* • *Remove the definition for pre-term as guidance about infant feeding of pre-term and underweight infants should be obtained from medical professionals.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	DAN, DA, INC, NZFS, QLDH, SAH	FSANZ notes that in previous consultation papers, submitters also agreed with the preferred option to remove this definition. The reason it was proposed to retain the definition in the 2021 CP was because it might be needed for further differentiation from human milk fortifiers. This is no longer the case as the SMPPi category is no longer intended to include human milk fortifiers and supplementary products. See Section 2.3.2.
No, the preferred option is not supported.	This submitter agreed with the view expressed in the 1st CFS that 'authoritative medical definitions of these conditions are necessary to help prevent products being developed and marketed for non-medical (e.g. normal behavioural) paediatric conditions and manufacturers making health or therapeutic claims for them'.	AWAW	FSANZ has stated previously in consultation papers and the 1st CFS that it is out of scope to set medical definitions for specific diseases, disorders or conditions in the Code.

Issue	Comment	Submitter(s)	FSANZ Response
	This submitter also considers that authoritative medical definitions should be included for pre-term, low birthweight, inborn errors of metabolism, disease of serious long-term impairment or loss of dietary functions requiring particular nutritional needs. Suggest that there is a need to tighten the definition of what products can be included in the SMPPi category and the need to be specific about the conditions for which an SMPPi product can be formulated to treat.		The basis for this conclusion is that additional definitions are unlikely to add regulatory clarity, medical professionals are best placed to understand the range of severity of conditions that may be included, and such definitions are inappropriate to include in the Code. Changes or updates to definitions would be subject to pre-market assessment timeframes which could affect access of specialised medical purpose infant formula products to infants that need them. There is no international consensus or definitions for these conditions, Code definitions for such terms would potentially create a trade barrier.
	NSWFA is concerned that removal of the definition of 'pre-term formula' from Standard 2.9.1 would not provide the means to appropriately tailor the maximum amount of aluminium (currently set at 0.02mg/100ml) and also guide medium chain triglyceride (MCT) permissions as these are shown to have high water solubility and are more easily absorbed by pre-term infants (pg 11 of SD4).	NSWFA	FSANZ confirms that the aluminium ML for pre-term formulas is retained and included within the proposed consequential draft variation. MCT requirements and permissions for SMPPi including formulas for pre-term infants are subject to the compositional parameters of Division 4 and can deviate where necessary to address the medical purpose of the product. This requirement allows the MCT level to vary depending on the needs of the condition.
The submitter(s) provides an new proposed option.	This submitter considers that specified conditions (such as pre-term) may be a preferable option if suitable risk management strategies are not incorporated into the SMPPi category that adequately regulate these products. Suggested strategies include: • The product clearly stating the purpose or condition it is managing • A semi-prescribed name for infant formula products for medical purposes to clearly identify these products and their purpose both for consumers and for regulators, allowing for variations for imported products. • The requirement in the definition for these products to be effective in their purpose for the dietary management of the proposed condition (in line with EU regulations) • Semi-prescribed labelling for 'use under medical supervision is	VICDoH	Regarding the points raised: • SMPPi must be labelled with a name or description sufficient to indicate the true nature of the food. Other mandatory labelling includes a statement indicating the medical purpose of the food. See Section part C of SD3. • "Prescribed name" is defined in Standard 1.1.2. The Code requires the prescribed name to meet any labelling requirement requiring the name of the food to be state or used. It would be inconsistent with that regulatory regime to prescribe a name and then permit another name to be used to label and identify the product. FSANZ also considers a prescribed name is not necessary because other

Issue	Comment	Submitter(s)	FSANZ Response
	required' • Access limits in line with Standard 2.9.5. • Provisions to manage prohibition of nutrition and health claims within the above requirements to declare the intended condition and modifications.		mandated labelling requirements for SMPPi make the products easily identifiable. • FSANZ addressed similar comments above related to the addition of wording to the definition about the *effectiveness* of the product. FSANZ considers such terminology in a definition as vague and open-ended and does not support the appropriate positioning of products to the SMPPi category. • A statement to the effect that the food must be used under medical supervision is mandated for SMPPi products. The wording of this statement is not prescribed to prevent a trade barrier for imported SMPPi. See item C.6 in Table 7 to Part C of SD3. • Restricted sale in line with Standard 2.9.5 is mandated for SMPPI. See Section 2.3.6. • SMPPi will be prohibited from making nutrition content and health claims.
Medium chain triglycerides (MCT) *FSANZ preferred option at the CFS was:* • *Remove the definition for MCT.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	INC, VICDoH, DAN, NZFS	FSANZ notes this support.
No, the preferred option is not supported.	This submitter does not support the removal of the definition for 'medium chain triglycerides' because MCTs are not recommended as an additive to standard formulas for healthy infants.	DA	FSANZ notes that there is no current or proposed permission for the addition of MCTs to standard formulas for healthy infants.
	Supports retention of the definition for MCT, to ensure its clear that this is defined as saturated fatty acids designated C8:0 and C10:0.	FCG	FSANZ will not be retaining the definition for MCT's, however this does not affect the addition of MCT's to SMPPi by virtue of the permission for these products to vary their composition.
The submitter(s) provides an new proposed option.	These submitters propose amending the definition to the following "MCT oils" means oils commercially manufactured via fractionation and/or esterification to yield a high proportion of medium chain saturated fatty	INC, DAN	

Issue	Comment	Submitter(s)	FSANZ Response
	acids (designated by 8.0 or 10.0)."		MCT are commonly defined as saturated fatty acids of 6–12 carbon chains which include caprylic (C:8) and capric (C:10) acids, the Code does not need to house this definition. This is also consistent with the Codex and EU regulations.
Other issues raised regarding definitions			
New definitions suggested to be included in the Standard 2.9.1.	These submitters suggested including definitions for: gastrointestinal reflux, gastrointestinal disorders, impairment of the gastrointestinal tract and inborn errors of metabolism.	DAN, AAA, DA	As FSANZ has stated above in discussing the term "pre-term infant formula", the varying degree of 'medically determined conditions' that exist would preclude a listing of specific conditions to which SMPPi applies and it is not fit for purpose to detail and specify medical conditions for which SMPPi are intended. If the Code were to specify conditions, any changes or updates to the listed conditions would be subject to pre-market assessment and, if approved, amendment of the Code. The time taken for this process would potentially prevent access to formulas intended for sick infants.
	These submitters recommend that the term "GUL" is used and defined within the Code. Replacing the use of guideline maximum amounts to better align with Codex standards.	INC, AFCG, FCG, A2M, NZFGC	FSANZ notes the term GUL is discussed in SD2 Section 3.2.
	This submitter recommends that as part of P1028, definitions for the term(s) "ferment" and/or "fermentation" are included in section 1.1.2 of the Code by amendment, because of concerns that a lack of a clear definition(s) can lead to different interpretations depending on the specific characteristics of the food.	QLDH	FSANZ considers this out of scope for Proposal P1028, therefore FSANZ has not undertaken a review of definitions aside from those specifically relevant to infant formula products.
	This submitter noted their understanding that FSANZ intends to rely on medically accepted definitions for each condition. Dietitians Australia recommends that FSANZ identify clinical references for such definitions to be included in relevant sections of the regulation. They expect that medical conditions would not include normal infant behaviours (e.g. sleep, reflux, crying or comfort).	DA	FSANZ has addressed this issue above in Table 6 and is not listing conditions in the proposed SMPPi definition.

Table 9: Novel foods and nutritive substances – pre-market assessment requirements

Issue	Comment	Submitter(s)	FSANZ Response
Framework for approval of nutritive substances and novel foods *FSANZ preferred option at the CFS was:* • *requirements for novel foods and nutritive substances in infant formula products are to be considered as part of the broader review of these substances for all food categories in P1024. Therefore, these substances must undergo pre-market approval.*			
Yes, the preferred option is supported.	These submitters supported the preferred option as requirements for infant formula products are best considered in parallel with P1024.	AFGC, INC, A2M, DAN	FSANZ re-iterates, as stated in the 1st CFS: 'In removing the consideration of novel foods and nutritive substances from the scope of P1028, there is no intention to ignore the vulnerable status of the infant population in future reviews of novel foods and nutritive substances regulation for the broader food categories. This has played out repeatedly in recent applications to amend the Code for infant formula products'.
No, the preferred option is not supported.	This submitter noted concerns that substances added to SMPPi for 'medical purpose' do not require pre-market safety assessment, whereas 'nutritive substances' would. This is akin to a self-substantiation pathway for infant formula products.	NSWFA	FSANZ reiterates that SMPPi need to be available for sick infants and used under medical supervision. For that reason there is flexibility for varying the composition to ensure it is suitable for the medical purpose for which it is formulated. Responsibility for evaluating the efficacy of a new substance or changes in composition should lie with the medical specialist supervising or managing the infants' condition. In this regard, it is akin to a 'self-substantiation pathway'. However, this approach is consistent with the Specific Policy Principles for Infant Formula Products for Special Dietary Uses. FSANZ proposes to restrict the sale of SMPPi to sale by a medical practitioner or dietitian, medical practice, pharmacy or responsible institution or a majority seller of that SMPPi and as such, represents an increase in the regulation of these types of products. The number of products sold as SMPPi is likely to be small.

Issue	Comment	Submitter(s)	FSANZ Response
	Pre-market assessment should be required of all nutritive substances, novel foods and nutritive substances added to infant formula products due to the higher risk they may present to infants considering infant formula products may be the sole source of nutrition and infants are a vulnerable population group. There must be clarification through P1028 that pre-market assessment is required for any new substance noting that the requirement in 1.1.1—10 6(1)(b) allows substances present in an ingredient (e.g. cow's milk) to be present in infant formula products but not if it is extracted, purified etc to be added back in an enriched or purified form.	NSWFA, VICDoH, QLDH	FSANZ reaffirms that infant formula products are currently subject to pre-market assessment for nutritive substances and novel foods. There is no suggestion to remove this requirement. Section 2.9.1—5 states that a substance listed in Column 1 of the table to section S29—5 may be used as a nutritive substance in an infant formula products only if: (a) it is in a permitted form listed in Column 2 of the table; and (b) the amount of the substance in the infant formula products (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of the table. In accordance with the Code, any substance not listed in the table to section S29—5 requires an express permission for to be used as a nutritive substance in infant formula products. See section 4.1 for proposed clarification of pre-market assessment requirements for novel foods.
	These submitters noted it is not appropriate to assess the addition of novel foods and nutritive substances as part of the wider food categories assessment. Infant formula is a distinct food category for a vulnerable population and has a separate regulatory framework and an associated Policy Guideline for Infant Formula.	SAH, DA	FSANZ confirms there is no suggestion or plans to assess the addition of novel foods and nutritive substances according to requirements for broader food categories. The current requirements already impose the most stringent assessment processes and require detailed data. The current assessment processes are consistent with policy guidance. Any changes in the future would only be in line with new policy guidance.
Other issues raised.	Submitters request FSANZ provide clarity on next steps for progressing P1024.	INC	According to the FSANZ Work Plan (February 2023), P1024 is on hold pending the outcomes of FSANZ Act 1991 review. No further information is available at this time.

Issue	Comment	Submitter(s)	FSANZ Response
	Submitters request the term 'Optional Ingredients' as used in Codex should replace the term 'Used as a nutritive substance' (as part of P1024).	INC, DAN	FSANZ has proposed to note these ingredients as 'optional nutritive substances' in the draft variations.
	The submitter questions FSANZ's interpretation that α-lactalbumin is a nutritive substance from a strict reading of section 1.1.2 – 12 where the substance is seen as a concentrated, refined, or synthesised part of cows' milk used to achieve a nutritional purpose.	CareA2	FSANZ notes that this issue has been raised in recent applications related to infant formula products. FSANZ consistently applies the definition of a nutritive substance in infant formula products in accordance with section 1.1.2—12 of the Code. A substance "used as a nutritive substance" is defined in section 1.1.2—12 as a substance added to food to achieve a nutritional purpose. Based on this definition, substances such as α-lactalbumin when concentrated, refined and added to infant formula products at a proposed amount, may be regulated as a nutritive substance if added to achieve a purpose other than meeting amino acid requirements. This is consistent with the Ministerial Policy Guideline which states that pre-market assessment should be required for any substance that has a history of safe use but which has a different form or structure. Guidance and requirements related to 'used to achieve a nutritional purpose' are provided in the FSANZ Application Handbook.
Novel food definition *FSANZ preferred option at the CFS was:* • *amend the definition to include 'for the intended population'.*			
Yes, the preferred option is supported.	These submitters provided in principle support, however they noted this change may have implications outside of the infant population. They suggested an amendment to the definition as 'for infants, a novel food is defined as a non-traditional for the intended infant population'.	INC, A2M, FCG	FSANZ agrees that the amendments to the novel foods definition at 1st CFS has potential implications to other populations outside of infants. For further information please see Section 4.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	Submitter considers that the proposed amendment will not achieve the required regulatory certainty for enforcement purposes.	NSWFA, VICDoH	FSANZ agrees that the proposed amendment does not achieve better regulatory certainty and has discussed this in detail in Section 4.

Table 10: Novel foods and nutritive substances – Schedule 25 permissions

Issue	Comment	Submitter(s)	FSANZ Response
Amendments to Schedule 25 *FSANZ preferred option at CFS was:* • *to amend Schedule 25 to include conditions for α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, D-tagatose, and trehalose that restricts these substances from being used in infant formula products.*			
Yes, the preferred option is supported.	These submitters supported the preferred option as substances in S25 that have not been assessed for infant population should not be permitted to be added to infant formula products. These submitters also agreed that these constraints are not applied to FSFYC (for 2 years and older) .	INC, A2M, DAN, QLDH	FSANZ notes this support.
No, the preferred option is not supported.	This submitter did not support the preferred option for the proposed restriction being applied to trehalose as it is a long standing permission in the Code and has history of safe use in infant formula products. The submitter provided safety assessment information to support their views.	Comments provided in confidence.	FSANZ notes that this issue is addressed in Section 4.3 above.
	Concerns that the permission for dried marine micro-algae (Schizochytrium sp.) rich in DHA be used as a non-evidence based marketing opportunity for manufacturers and recommends that FSANZ reviews the use of voluntary ingredients, including DHA and other LCPUFAs. Related to the comment, the submitter recommends FSANZ prohibits the addition of voluntary nutritive ingredients, and instead mandates their addition and declaration if they mimic the composition of breast milk and are proven to benefit infant growth and development.	DA	The submitter notes existing permissions in Schedule 25 as well as reference to voluntary permissions that are in place in Standard 2.9.1/Schedule 29. As noted in the 1st CFS (SD6 Assessment Against Ministerial Policy Guidelines), P1028 has reviewed and proposed updated essential composition and voluntary permissions for infant formula and follow-on formula. The 2016 and 2021 Nutrition Assessments concluded that the proposed composition satisfied the nutritional requirements of Australian and New Zealand infants and ensures normal growth and development. FSANZ considers that the strength, quality and type of evidence supporting the inclusion of these ingredients is appropriate for a voluntary compositional permission, and not mandatory regulation.

Table 11: L(+) lactic acid producing microorganisms (LAM)

Issue	Comment	Submitter (s)	FSANZ Response
LAM *FSANZ preferred option at CFS was:* • *to retain the existing permission, but clarify that LAM may only be added for acidification purposes* • *clarify the permission so that only non-pathogenic or non-toxigenic microorganisms may be used.*			
Yes, the preferred option is supported.	These submitters supported an approach which provides regulatory certainty for both industry and enforcement agencies, and better aligns with the approach under Codex CXS 72-1981 and the draft Codex Standard for FuFOI. These submitters agreed that permission to use LAM for a nutritive purpose should require pre-market assessment	NSWFA, NZFS	FSANZ understands that the current wording proposed for the draft Codex FuFOI has been clarified to state the purposes for which LAM have been added, i.e.: *Only L (+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product should not contain significant amounts of viable L (+) lactic acid producing cultures, and residual amounts should not represent any health risk.* *The safety and suitability of the addition of specific strains of L(+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.* However as we have noted previously in this document, clauses in the Codex standards like that above are not appropriate to state requirements in legislative instruments applied by Australian and New Zealand laws which make failure to comply with those requirements a criminal offenceSection 5.3 provides a

Issue	Comment	Submitter (s)	FSANZ Response
			full discussion of the issues that were raised in submissions. Implementation of the above text into the Code would have an unacceptable impact on products currently on the market.
No, the preferred option is not supported.	These submitters strongly opposed the preferred option for the following reasons: • it is inconsistent with FSANZ's risk assessment and with advances in scientific knowledge about use of probiotics in infant formula • there has been no indication by guidance or enforcement that there was intent to limit addition of LAM for acidification purposes only. • there is no evidence of harm, no evidence of market failure, and there is an extended history of safe use given the permission has been in place for over 20 years. • it lacks international alignment, creates trade barrier and is inconsistent with the stated objectives of the Proposal to not hinder trade or innovation. Will have significant impact on ANZ being efficient and internationally competitive.	FCG, CMA, AS, ChrH, DAN, MMI, NES, NZFGC, AFGC	Noted. The proposed change was based on the original intent of this permission at the time of the development of the joint Code. The scope of the risk assessment was only on the safety of adding LAM to infant formula products. It did not include advances in scientific knowledge on the use of these organism for other purposes (e.g. as a probiotic). The 1st CFS summarises the assessment as required under the FSANZ Act. Prior consultation was conducted to collect information to inform the assessment and did not represent any conclusions of the assessment. Based on those consultations, FSANZ was unaware of the number of products on the market that LAM were being added. Based on FSANZ's risk assessment on the safety of LAM added to infant formula products, FSANZ agrees there is no evidence of harm to infants. We acknowledge data that was provided in some submissions demonstrating the history of safe use. See section 5.3.2 regarding current use and international regulatory requirements.

Issue	Comment	Submitter (s)	FSANZ Response
	Submitter concerned that 'for acidification' will negatively impact a significant sector of the IF category domestically and for exported products. Large number of products already using LAM based on the current permissions which does not restrict its use.	DIFF	FSANZ was not fully aware of the extent of use of LAM in infant formula products currently on the market, and how much this has changed since the start of P1028. We have reviewed market share data provided in confidence and agree that the proposed clarification ('for acidification only') would have a significant economic impact and potentially remove a large number of products from the Australia and New Zealand markets.
	Submitter acknowledges that use of these for probiotic purposes has come about due to what may be misinterpretation of the Code, but this does not equate to a public health and safety risk.	DIFF	FSANZ notes that the issue relates to the health benefits of adding LAM for a probiotic purpose. The Code requires that substances added to infant formula products as a novel food or nutritive substance undergo pre-market assessment. Use of probiotics may be considered as either a nutritive substance and/or a novel food. Pre-market assessment includes regard for the Policy Guideline which included assessment of health benefit. To date, no permissions for LAM for a probiotic purpose have been approved.
	These submitters noted if permission is restricted there is likely to be an influx of applications: 10 or more applications to assess LAM already in use through pre-market assessment process.	ChrH, INC, AFGC	FSANZ understands that this may be the case and approvals for each company's individual strain may impact on supply of products for infants.
	These submitters noted the clarification 'for acidification' will restrict consumption of LAM for this population when older infant 6-12 months will be exposed to LAM through consumption of yoghurt and cheese.	FCG, INC	FSANZ agrees that the proposed amendment 'for acidification' has the effect of restricting the addition of LAM to infant formula products when exposure to LAM may form part of a healthy infant diet once solid foods are introduced (NHMRC Infant Feeding Guidelines). We refer to yoghurt consumption data for 9 month old infants from the InFANT study. Across three days of the survey (210 respondents) 78.1% of infants were reported to have consumed yoghurt (Campbell et al 2008, 2013 and FSANZ 2008).

Issue	Comment	Submitter (s)	FSANZ Response
	These submitters noted use of LAM is established, post-market assessment will be disruptive, potentially interrupt supply with consequential public health impacts, and cast doubt on current safety of infant formula products.	AS, FCG, INC, NES, NZFGC, AFGC, CMA	FSANZ notes that the objective of the proposed approach was not to have significant interruptions to supply and FSANZ agrees that this would have unintended consequences.
	These submitters noted the microbiological testing requirements at the time the Code was written anticipate the presence of live bacteria, this is inconsistent with an intent to have no viable microorganisms present. It suggests that at the time of drafting the scope of the LAM permission in infant formula products was not solely for acidification purposes.	INC	FSANZ agrees with this comment and has reviewed Standard 1.6.1 from a previous version of the Code where it was required that: *The Standard Plate Count (SPC) in powdered infant formula with added lactic acid producing cultures must not exceed the microbiological limits set in the Schedule, prior to the addition of the lactic acid cultures to the food.* That is, it could be viewed that viable microorganisms were intended to be present. Proposal P1039 removed the limit for SPC in powdered infant formula from the Code. Microbiological criteria are now listed in the *Compendium of Microbiological Criteria for Food* (FSANZ 2022k). As noted in the footnote of Table 3.2, the microbiological guideline criteria for powdered infant formula products do not apply to infant formula products with lactic acid cultures.
	Several submitters discussed safety of specific LAM strains and/or provided safety data on specific strains currently in use (as confidential).	AS, FCG, INC, NES	FSANZ understands that the data provides evidence to assess these specific strains for the purpose of listing them in the Code as permitted strains. However, as noted previously, P1028 is not a mechanism to seek new permissions for addition of novel foods or nutritive substances in infant formula products. Manufacturers should seek permission for specific strains through the application process.
	This submitter also opposes the preferred option but for alternative reasons:	VICDoH	FSANZ notes the Code does not define 'postbiotic', although any substance added for the purpose of a

Issue	Comment	Submitter (s)	FSANZ Response
	• The preferred option does not prevent use of LAM as a 'postbiotic' in infant formula products • There is a need to require that no viable bacteria are to be present in the final product. • Acidification is best achieved by addition of the food acids, not LAM. Submitter also acknowledged the impact of removing the general permission for LAM will have on current market and supports an appropriate transition period.		postbiotic effect or outcome could meet the definition of 'used as a nutritive substance' (Standard 1.1.2—12) and would require pre-market assessment. Postbiotics have been defined by the International Scientific Association of Probiotics and Prebiotics as a *preparation of inanimate microorganisms and/or their components that confers a health benefit on the host.* As with LAM added as a probiotic, the current unconditional permission in Standard 2.9.1 does not prohibit addition of LAM as a postbiotic. However, FSANZ's understanding is that, as there is no specific permission to add LAM as a nutritive substance or novel food, inclusion of this substance in the NIS would be prohibited.
Submitters provided a new or amended proposed option.	These submitters suggested 'grandfathering in' permissions for LAM other than for acidification purpose as proposed in the 1st CFS. The suggested permissions included use of existing microorganisms as probiotic, retention of existing permissions, including for probiotic purpose and CCI material provided by some submitters to support claim that specific strains of LAM have history of safe use.	QLDH, CMA, ChrH, NES, MMI	P1028 is not a mechanism to seek new permissions for addition of novel foods or nutritive substances to the Code. There is currently no permission to add probiotics as a novel food or for a nutritive purpose to infant formula products.
	This submitter recommended looking to the Therapeutic Goods Administration (TGA) for appropriate assessment mechanisms for microorganisms/probiotic strains, given highly specific nature of probiotic purpose.	CMA	FSANZ considers that the existing pre-market assessment process for substances used for a nutritive purpose would apply to probiotics added to infant formula products. We have also clarified how nutritive substances and novel foods for infant formula products (which may include specific strains of LAM) could be regulated in the Code (see section 4.1.4).
	This submitter noted the regulatory status of specific strains of LAM added to infant formula products for a nutritive purpose requires further consideration, to identify these strains and then specifically permit in the Code.	NZFS	It is FSANZ's view that specific strains of LAM added for a nutritive purpose (e.g. a desired health effect) requires pre-market assessment. Companies currently seeking a permission for a specific strain should do this via the application process. If approved, permitted nutritive substances are required to be listed in the NIS (See SD3).

Issue	Comment	Submitter (s)	FSANZ Response
Other issues raised.	This submitter supported a positive list of registered LAM rather than by pre-market assessment a process, as adopted in other international jurisdictions (US, China). Since these registration requirements are quite severe, submitter suggests that these registration lists can be helpful in order to skip or shorten the pre-assessment process by FSANZ.	MMI	Establishment of a positive list could only apply to infant formula products. Introducing new requirements in the Code that would apply to general foods is not in scope for P1028. Under the FSANZ Act, FSANZ has limited ability to adopt regulations from international regulations without undertaking a pre-market assessment process.
	Submitters requested FSANZ consider that there are many infant formula products containing probiotics in international jurisdictions and these have been consumed by infants for many years. Suggests FSANZ consider a more appropriate mechanism for assessment or exemption on the novel food assessment for current probiotics already used in infant formula products.	ChrH, CMA	This is out of scope for P1028. FSANZ has consistently maintained that new permissions will not be assessed thought P1028 and require application through that process. An exemption from assessment as a novel food would be inconsistent with Ministerial Policy Guidance.
	The submitter seeks information on how the proposed drafting will also ensure the safety of any fermentation by-products and that the permission is not used to bypass pre-market assessment requirements to add novel substances to infant formula, such as human milk oligosaccharides.	VICDoH	FSANZ has clarified the requirements for novel food permissions for infant formula products. See Section 4.1.3. Human milk oligosaccharides are added for a nutritive purpose and as such requires pre-market assessment that would include assessment of by-products in the production of the microbially produced substance.
LAM in SMPPi *FSANZ preferred option at CFS was:* • *use of LAM for acidification in SMPPi should only be used if supported by generally accepted scientific data.*			
Yes, the preferred option is supported.	This submitter supported, however suggested 'generally accepted' be replaced by 'strong' and explicitly define the strength of evidence needed.	DA	The use of 'generally accepted' within the draft variation has been discussed in Table 3. It is implicit that the efficacy, safety and suitability of foods would be based on scientific data and/or manufacturers would have formulated products based on scientific advice and evidence and have that available when and if asked by regulators to demonstrate that their product is safe, and suitable and complies with regulatory requirements, including compositional requirements. Note that FSANZ Act only relates to assessment of

Issue	Comment	Submitter (s)	FSANZ Response
			applications and proposals.
No, the preferred option is not supported.	This submitter did not support as it serves same purpose as the addition to standard infant formula products where pre-market safety assessment is required. Without this correction, it presents means for subversion of pre-market safety assessment requirements in Standard 2.9.1 and is not consistent with the Ministerial Policy Guideline.	NSWFA	FSANZ reiterates the intention for SMPPi to deviate from baseline infant formula composition only as required for the special medical purpose of the product, i.e.a medically diagnosed disease, disorder or condition of an infant (see section 2.9.1 – 32(2) of the primary draft variation). This is critical to enable timely access to medical purpose products for those infants who need them.
Non-pathogenic or non-toxigenic microorganisms. *FSANZ preferred option at CFS was:* • *Clarify the permission that only non-pathogenic or non-toxigenic microorganisms may be used.*			
Yes, the preferred option is supported.	These submitters supported the preferred option because it provides regulatory clarity and minimises risk of pathogenic microorganisms being added to infant formula products, rather than relying on the 'safe and suitable' provision.	DA, NZFS	As noted in the QLDH submission, including the clarification 'only non-pathogenic or non-toxigenic' would need a clear and unambiguous definition to avoid potential misinterpretation. Such definitions would have implications across the Code, and therefore is a regulatory change that is out of scope for P1028. The clarification 'only non-pathogenic or non-toxigenic' has not been included in the proposed draft variations.
	This submitter noted the overarching requirements in the Code for all foods to be safe a suitable. This submitter is not opposed to this change if there is a strong preference by other stakeholders.	FCG	
	This submitter noted a specific requirement that added LAM must be non-pathogenic (and/or non-toxigenic) could add clarity, strengthen requirements and minimise risk. However, the caveat was if specific criteria defining "non-pathogenic" is also provided.	QLDH	

Attachments

A. Draft variations to the Australia New Zealand Food Standards Code

B. Draft Explanatory Statement

Attachment A – Draft variations to the Australia New Zealand Food Standards Code

Food Standards (Proposal P1028 – Infant Formula) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The instrument commences on gazettal.

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*;

(b) the **transition period** means the period commencing on the variation's date of commencement and ending 60 months after the date of commencement.

Schedule

Standard 2.9.1

[1] Sections 2.9.1—2 to 2.9.1—25

Repeal the sections, substitute:

2.9.1—2 Outline of Standard

(1) This Standard regulates various types of infant formula products.

(2) Division 1 deals with preliminary matters.

(3) Division 2 sets out compositional requirements for infant formula and follow-on formula.

(4) Division 3 sets out labelling and packaging requirements for infant formula and follow-on formula.

(5) Division 4 sets out compositional and labelling requirements for special medical purpose products for infants.

2.9.1—3 Definitions

Note In this Code (see sections 1.1.2—2 and 1.1.2—3):

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

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

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 4 to 6 months.

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

inner package, in relation to special medical purpose food for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

special medical purpose product for infants means an infant formula product that is:

(a) represented as being:

(j) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(iii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(b) intended to be used under medical supervision; and

(c) not suitable for general use.

soy-based formula means an infant formula product in which soy protein isolate is the sole source of protein.

2.9.1—4 Interpretation

Interpretation of compositional requirements

(1) Compositional requirements in this Standard apply to:

(a) a powdered or concentrated form of infant formula product that has been reconstituted with water according to directions; and

(b) an infant formula product in 'ready to drink' form.

Calculation of energy, and protein

(2) In this Standard:

(a) energy must be calculated in accordance with section S29—2; and

(b) protein content must be calculated in accordance with section S29—2A; and

(c) vitamin A content for infant formula and follow-on formula must be calculated in accordance with section S29—2B.

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

2.9.1—5 General requirements

(1) Infant formula and follow-on formula must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

(2) Subject to subsection (3), infant formula and follow-on formula must not contain added fructose and/or added sucrose.

(3) Infant formula manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:

(a) the fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and

(b) the sum of the added fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in the formula.

(4) Infant formula and follow-on formula must not exceed a fluoride content of 17 µg/100kJ.

2.9.1—6 Protein requirements

(1) Infant formula and follow-on formula must be only derived from one or more of the following proteins:

(a) cow milk;

(b) goat milk;

(c) sheep milk;

(d) soy protein isolate;

(e) a partially hydrolysed protein of one or more of the above.

(2) Infant formula must have a protein content of:

(a) for a milk-based infant formula—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for all other infant formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(3) Follow-on formula must have a protein content of:

(a) for a milk-based follow-on formula—no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for all other follow-on formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(4) The L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level no less than the corresponding minimum level specified in the table.

(5) Infant formula must have a ratio of methionine to cycteine of no more than 3 to 1.

(6) Despite subsection (4), L-amino acids listed in the table to section S29—3 must only be added to infant formula or follow-on formula in an amount necessary to improve protein quality.

2.9.1—7 Fat requirements

(1) Infant formula and follow-on formula must:

(a) have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(ba) have no less than:

(i) 90 mg/100kJ of linoleic acid; and

(ii) 12 mg/100kJ of α-linolenic acid; and

Note. It is recommended that infant formula and follow-on formula contain not more than 335 mg/100 kJ of linoleic acid. This amount is a Guidance Upper Level and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. This Guidance Upper Level should not be exceeded unless a higher nutrient level cannot be avoided due to high or variable contents in constituents of infant formulas and follow-on formula or due to technological reasons.

(c) have an arachidonic acid (20:4) content of equal to or more than docosahexaenoic acid (22:6 n-3) content; and

(d) contain no less than 0.5 mg of vitamin E/g of polyunsaturated fatty acids; and

(e) for any long chain *polyunsaturated fatty acids that are present—have an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content; and

(f) for a fatty acid listed in Column 1 of the table to section S29—4 and present in the formula—contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

Note It is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 3 of the table. An amount specified in Column 3 is a Guidance Upper Level and is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

(2) Infant formula and follow-on formula may only contain medium chain triglycerides that are:

(a) a natural constituent of a milk-based ingredient of that formula; or

(b) for a fat soluble vitamin that is specified in a following table—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula:

(i) for infant formula—the table to section S29—5; and

(ii) for follow-on formula—the table to section S29—6.

(3) Infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ.

2.9.1—8 Required nutritive substances

(1) Infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that infant formula contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

(2) Follow-on formula must contain each substance listed in Column 1 of the table to section S29—6 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels, which are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

2.9.1—9 Optional nutritive substances

(1) A substance listed in Column 1 of the table to section S29—7 may be *used as a nutritive substance in infant formula, provided that the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount specified in Column 3 of the table.

(2) A substance listed in Column 1 of the table to section S29—8 may be *used as a nutritive substance in follow-on formula, provided that is the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

2.9.1—10 Required forms for nutritive substances

A substance *used as a nutritive substance in infant formula or follow-on formula must be in the permitted form listed in:

(a) if a vitamin, mineral or electrolyte—the table to section S29—23; and

(b) in any other case— the table to section S29—9.

2.9.1—11 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to infant formula and follow-on formula.

2.9.1—12 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

(1) If an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only *inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only *galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

(i) no more than 110 mg/100 kJ of inulin-type fructans; and

(ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

(2) Infant formula and follow-on formula to which an inulin-type fructan or a galacto-oligosaccharide is added must not contain lacto-N-neotetraose as an added substance.

2.9.1—13 Restriction on levels of other substances

Infant formula and follow-on formula must not contain:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates.

Note Section S19—4 contains the maximum level (ML) of lead contaminant in infant formula products.

2.9.1—14 Compositional requirements for infant formula represented as lactose free and low lactose

(1) If infant formula is represented as lactose free, it must contain no detectable

lactose.

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

(3) A compositional requirement of this Standard, other than a requirement imposed by this section, applies to infant formula that is represented as lactose free formula or low lactose formula.

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

2.9.1—15 Representations about food as infant formula or a follow-on formula

(1) A food may only be represented as infant formula or follow-on formula if it complies with this Standard.

(2) A food represented as infant formula or follow-on formula must not be also represented as another food.

Example A food represented as infant formula must not be also represented as, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

2.9.1—16 Prescribed names

(1) 'Infant formula' is the *prescribed name for infant formula.

(2) 'Follow-on formula' is the *prescribed name for follow-on formula.

Note Under the labelling provisions in Standard 1.2.1 and section 1.2.2—2, if a food has a prescribed name, that prescribed name must be used in the labelling of the food.

2.9.1—17 Requirement for measuring scoop

(1) A package of infant formula or follow-on formula in a powdered form must contain a scoop to enable the use of the formula in accordance with the directions contained in the label on the package.

(2) Subsection (1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

2.9.1—18 Storage instructions

For the labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—19 Requirement for the name of the food

For the labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—20 Statement of protein source

(1) For the labelling provisions, the specific animal or plant source or sources of protein in infant formula and follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19.

Examples 'Infant Formula based on cows' milk'. 'Follow-on Formula based on goat's milk. 'Infant Formula based on 'soy protein'.

Note The labelling provisions are set out in Standard 1.2.1.

(2) If a label of infant formula represents that the formula is partially hydrolysed, the

words 'partially hydrolysed' must be used immediately adjacent to the statement of protein source required by subsection (1).

Example 'Partially hydrolysed Infant Formula based on cows' milk'.

2.9.1—21 Labelling requirements for food represented as lactose free and low lactose formulas

(1) For the labelling provisions, if a label represents that an infant formula is lactose free or low lactose:

(a) for a formula represented as lactose free—the words 'lactose free' must be included in the statement of the name of the food required by section 2.9.1—19; and

Example 'Lactose free infant formula from cows milk'.

(b) for a formula represented as low lactose—the words 'low lactose' must be included in the statement of the name of the food required by section 2.9.1—19; and

Example 'Low lactose infant formula from cows milk'.

(c) the average quantity of lactose and galactose, expressed in grams, must be included in the statement required by section 2.9.1—25 and in the same format as specified in the table to section S29—10 for those substances.

Note The labelling provisions are set out in Standard 1.2.1.

(2) A labelling requirement of this Standard, other than a requirement imposed by subsection (1), applies to an infant formula that is represented as lactose free formula or low lactose formula.

2.9.1—22 Requirement for warning statements and directions

Warning statements

(1) For the labelling provisions, the following *warning statements are required for infant formula and follow-on formula:

(a) 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.'; and

(b) a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.'.

Note The labelling provisions are set out in Standard 1.2.1.

Required statements on use

(2) For the labelling provisions, the required statements for infant formula and follow--on formula are ones indicating that:

(a) for infant formula—the infant formula may be used from birth; and

(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and

(c) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

Location of warning statements and required statements

(3) The statements required by paragraphs (2)(a) and (b) must appear on the front of the package of the product.

(4) Subsection (3) does not prevent a statement required by subsection (2) from appearing more than once on the label.

Directions on preparation and use

(5) For the labelling provisions, directions on preparation and use are required for infant formula and follow-on formula which instruct (in words and pictures) that:

(a) each bottle must be prepared individually; and

(b) if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and

(c) previously boiled and cooled potable water must be used; and

(d) if a package contains a measuring scoop—only the enclosed scoop must be used; and

(e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice; and

(f) for ready-to-drink formula—do not dilute or add other food except on medical advice; and

(g) formula left in the bottle after a feed must be discarded within 2 hours.

Note The labelling provisions are set out in Standard 1.2.1.

(6) Paragraphs (5)(a), (b) and (c) do not apply to ready-to-drink formula.

(7) Paragraph (5)(d) does not apply to concentrated formula and ready-to drink formula.

(8) For the labelling provisions, the following must be declared for a powdered or concentrated form of infant formula and follow-on formula:

(a) the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(b) for a product in powdered form—the weight of one scoop.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—23 Print size

The statements required by subsection 2.9.1—22(1) must be in a *size of type of at least:

(a) if the package of infant formula or follow-on formula has a net weight of more than 500 g—3 mm;

(b) if the package of infant formula or follow-on formula has a net weight of 500 g or less—1.5 mm.

2.9.1—24 Optional format for the statement of ingredients – added vitamins and minerals

(1) Despite section 1.2.4—5, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients not need list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients also:

(a) lists all added vitamins together under the subheading ‘Vitamins’; and

(b) lists all added minerals together under the subheading ‘Minerals’.

Note See Standard 1.2.4 for other ingredient labelling requirements.

(2) Section 1.2.4—8 does not apply to a statement of ingredients referred to in subsection (1).

2.9.1—25 Declaration of nutrition information

Statement of nutrition information

(1) For the labelling provisions, a statement of the following nutrition information is required for infant formula and follow-on formula:

(a) the *unit quantity of the food expressed in per 100 mL; and

(b) the *average energy content expressed in kilojoules; and

(c) the *average quantity of protein, fat and *carbohydrate expressed in grams and as 'protein', 'fat' and 'carbohydrate', respectively; and

(d) the average quantity of each vitamin or mineral expressed in micrograms or milligrams (including any naturally-occurring amount); and

(e) for infant formula—the average quantity of choline, inositol and L-carnitine expressed in milligrams (including any naturally-occurring amount);

(f) if added, the average quantity of the following, expressed in micrograms or milligrams:

(i) any substance *used as a nutritive substance (including any naturally-occurring amount); or

(ii) inulin-type fructans; or

(iii) galacto-oligosaccharides; or

(iv) a combination of *inulin-type fructans and galacto-oligosaccharides.

Note The labelling provisions are set out in Standard 1.2.1.

(2) If one of the following substances is present in the infant formula or follow-on formula, the statement required by subsection (1) may include the average quantity of that substance (including any naturally-occurring amount), expressed in milligrams or grams:

(a) docosahexaenoic acid; and

(b) eicosapentaenoic acid; and

(c) arachidonic acid; and

(d) whey; and

(e) casein.

(3) If the infant formula and follow-on formula is in a powdered or concentrated form, the information mentioned in subsections (1) and (2) must be expressed in terms of the product as reconstituted according to the directions on the package.

(4) Unless expressly provided elsewhere in this Code, the statement required by this section must not contain any other information.

2.9.1—26 Required form for the declaration of nutrition information

(1) A reference to 'the table' in this section is a reference to the table to section S29—10.

(2) The statement required by section 2.9.1—25 must:

(a) be in the same format as specified in the table; and

(b) state the nutrition information in the order specified in the table; and

(c) be titled 'Nutrition Information'; and

(d) have the following subheadings printed in a size of type that is the same or larger than the nutrient names in the statement:

(i) for infant formula and follow-on formula—'Vitamins', 'Minerals' and 'Additional'; and

(ii) for infant formula only—'Other nutrients';

(e) state nutrients and subgroup nutrients using the names and units of measurement specified in that table for that nutrient and subgroup; and

(f) not include a *unit quantity other than per 100 mL.

(3) If the statement includes the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide, that average quantity must be included in the statement:

(a) under the subheading 'Additional'; and

(b) in the same format as specified in the table for that substance.

(4) If the statement includes the average quantity of choline, inositol or L-carnitine, that average quantity must be included in the statement:

(a) for infant formula—under the subheading 'Other Nutrients'; and

(b) for follow-on formula—under the subheading 'Additional'; and

(c) in the same format as specified in the table for that substance.

(5) If the statement includes the average quantity of a substance listed in subsection 2.9.1—25(2), that average quantity must be included in the statement in the same format as specified in the table for that substance.

2.9.1—27 How average quantity is to be calculated

Despite section 1.1.1—6, the method in paragraph 1.1.1—6(3)(c) must not be used to calculate the average quantity of a substance in infant formula or follow-on formula.

2.9.1—28 Requirements for use of stage numbers

(1) The following numbers may be used on the label on a package of infant formula or follow-on formula to identify for consumers that product is infant formula or follow-on formula:

(a) if the product is infant formula—the number '1'; and

(b) if the product is follow-on formula—the number '2'.

(2) A number used in accordance with subsection (1) must appear:

(a) on the front of the package of the product; and

(b) immediately adjacent to:

(i) for infant formula—the statement required by paragraph 2.9.1—22(2)(a); and

(ii) for follow-on formula—the statement required by paragraph 2.9.1—22(2)(b).

2.9.1—29 Prohibited representations

(1) The label on a package of infant formula or follow-on formula must not contain:

(a) a picture of an infant; or

(b) a picture that idealises the use of infant formula or a follow-on formula; or

(c) information relating to another product; or

Example The label on a package of infant formula must not refer to, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

(d) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or

(e) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or

(f) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

(g) words claiming that the formula is suitable for all infants; or

(h) information relating to the nutritional content of human milk; or

(i) information relating to the presence of a substance listed in subsection (3), except for a reference in:

(i) a statement of ingredients; or

(ii) a declaration or statement expressly permitted or required by this Code; or

(j) information relating to ingredients, except for a reference in:

(i) a statement of ingredients; or

(ii) a declaration or statement expressly permitted or required by this Code; or

(k) information relating to the animal or plant source or sources of protein in the infant formula or follow-on formula, except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(1); or

(l) the words 'partially hydrolysed' or any word or words having the same or similar effect, except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(2); or

(m) the words 'lactose free' or 'low lactose', except for a declaration or statement required by section 2.9.1—21; and

(n) a number used to identify for consumers that the product is infant formula or follow-on formula, except where required by section 2.9.1—28.

Note *S*tandard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about an infant formula product - must not be therapeutic in nature.

(2) For the purposes of subsection (1), 'information' includes a reference by means of a name, a number, a picture, an image, a word or words.

(3) For the purposes of paragraph (1)(i), the following substances are listed:

(a) an inulin-type fructan; and

(b) a galacto-oligosaccharide; and

(c) a nutrient; and

(d) a substance *used as a nutritive substance'.

Note Section 2.9.1—25 expressly requires or permits these substances to be declared or stated in the declaration of nutrition information required by that section.

Division 4 Special medical purpose products for infants

2.9.1—30 Application of other Standards

The following provisions do not apply to special medical purpose product for infants:

(a) paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods); and

(b) unless the contrary intention appears:

(i) Part 1.2 of Chapter 1 (labelling and other information requirements); and

(ii) Division 3 of this Standard.

2.9.1—31 Restriction on the sale of special medical purpose products for infants

(1) A special medical purpose product for infants must not be sold to a consumer, other than from or by:

(a) a medical practitioner or dietitian; or

(b) a medical practice, pharmacy or responsible institution; or

(c) a majority seller of that special medical purpose product for infants.

(2) In this section:

medical practitioner means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

majority seller means, in relation to a special medical purpose product for infants, a person who:

(a) during any 24 month period, sold that special medical purpose product for infants to any of the following:
  (i) a medical practitioner;
  (ii) a dietitian;
  (iii) a medical practice;
  (iv) a pharmacy;
  (v) a responsible institution; and
(b) the sales mentioned in paragraph (a) represent more than one half of the total amount of that special medical purpose product for infants sold by the person during that 24 month period.

2.9.1—32 Compositional requirements for special medical purpose products for infants

(1) A special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and
(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that a special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of special medical purpose products for infants or due to technological reasons.

(2) However, the food is not required to comply with subsection (1) to the extent that a variation from a maximum or minimum amount:

(a) is required for a particular medical purpose; or
(b) would otherwise prevent the sale of the food.

2.9.1—33 Representations about food as a special medical purpose product for infants

A food may only be represented as a special medical purpose product for infants if it complies with this Division.

2.9.1—35 Prohibited representations

The label on a package of a special medical purpose product for infants must not contain:

(a) a picture of an infant; or
(b) the word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect; or
(c) the words ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ or any word or words having the same or similar effect; or
(d) the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect; or
(e) information relating to another food.

Note *S*tandard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products, including a special medical purpose product for infants. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about a special medical purpose product for infants - must not be therapeutic in nature.

2.9.1—36 Labelling and related requirements

(1) This section applies to a food for sale that is a special medical purpose product for infants.

(2) If the food for sale is in a package, it is required to *bear a label that complies with section 2.9.1—37.

(3) If the food for sale is in an *inner package:

(a) the inner package is required to *bear a label that complies with section 2.9.1—42; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

(4) If the food for sale is in a *transportation outer:

(a) the transportation outer or package containing the food for sale is required to *bear a label that complies with section 2.9.1—43; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

2.9.1—37 Mandatory labelling information

(1) The label that is required for a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) if the sale of the food for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies:

(i) information relating to *foods produced using gene technology (see section 1.5.2—4); and

(ii) information relating to irradiated food (see section 1.5.3—9);

(d) any required advisory statements, *warning statements, other statements, and declarations (see section 2.9.1—38);

(e) information relating to ingredients (see section 2.9.1—39);

(f) date marking information (see section 2.9.1—40);

(g) directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons;

(h) nutrition information (see section 2.9.1—41).

(2) The label must comply with Division 6 of Standard 1.2.1.

2.9.1—38 Mandatory statements and declarations— special medical purpose products for infants

(1) For paragraph 2.9.1—37(1)(d), the following statements are required:

(a) a statement to the effect that the food must be used under medical supervision;

(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food;

(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been

formulated;

(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c);

(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group;

(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition;

(g) if the food is represented as being suitable for use as a sole source of nutrition:

(i) a statement to the effect that the food is not for parenteral use; and

(ii) if the food has been modified to vary from the compositional requirements of section 2.9.1—32 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable):

(A) a statement indicating the nutrient or nutrients which have been modified; and

(B) unless provided in other documentation about the food—a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.

(2) For paragraph 2.9.1—37(1)(d), the required advisory statements and declarations are any that are required by:

(a) items 1, 4, 6 or 9 of the table to section S9—2; or

(b) subsection 1.2.3—2(2); or

(c) section 1.2.3—4.

(3) For paragraph 2.9.1—37(1)(d), the *warning statement referred to in section 1.2.3—3, if applicable, is required.

2.9.1—39 Information relating to ingredients—special medical purpose products for infants

For paragraph 2.9.1—37(1)(e), the information relating to ingredients is:

(a) a statement of ingredients; or

(b) information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or

(c) information that complies with 21 CFR § 101.4.

2.9.1—40 Date marking information—special medical purpose products for infants

(1) For paragraph 2.9.1—37(1)(f), the required date marking information is date marking information in accordance with Standard 1.2.5.

(2) Despite subsection (1), for subparagraph 1.2.5—5(2)(a)(ii), the words ‘Expiry Date’, or similar words, may be used on the label.

2.9.1—41 Nutrition information—special medical purpose products for infants

(1) For paragraph 2.9.1—37(1)(h), the nutrition information required for a special medical purpose product for infants is the following, expressed per given amount of the food:

(a) the minimum or *average energy content; and

(b) the minimum amount or *average quantity of:

(i) protein, fat and carbohydrate; and

(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and

(c) any other substance:

(i) *used as a nutritive substance in that product; and

(ii) added to that product to achieve that product's intended medical purpose as described in the statement required by paragraph 2.9.1—38(1)(c).

(2) The label that is required for a special medical purpose product for infants may state information relating to the source or sources of protein in that product.

2.9.1—42 Labelling requirement—special medical purpose products for infants in inner package

(1) The label on an *inner package that contains a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) any declaration that is required by section 1.2.3—4;

(d) date marking information (see section 2.9.1—40).

(2) The label must comply with Division 6 of Standard 1.2.1.

(3) To avoid doubt, this section continues to apply to the label on the *inner package if a *responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

2.9.1—43 Labelling requirement— a special medical purpose product for infants in transportation outer

(1) If packages of a special medical purpose product for infants are contained in a transportation outer, the information specified in subsection (2) must be:

(a) contained in a label on the transportation outer; or

(b) contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

(2) For subsection (1), the information is:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2); and

(b) lot identification (see section 1.2.2—3); and

(c) unless it is provided in accompanying documentation—the name and address of the *supplier (see section 1.2.2—4).

Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and position of the Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

(1) The Schedules to this instrument vary Standards in the *Australia New Zealand Food Standards Code*.

(2) Each Standard that is specified in a Schedule to this instrument is amended as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

3 Commencement

This instrument commences immediately after the commencement of the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula) Variation*;

(b) the **transition period** means the period commencing on this instrument's date of commencement and ending 60 months after the date of commencement.

Schedule 1

Schedule 29—Special purpose foods

[1] Sections S29—2 to S29—10

Repeal the sections, substitute:

S29—2 Infant formula products—calculation of energy content

(1) For paragraph 2.9.1—4(2)(a), the energy content of infant formula product must be calculated using:

(a) the energy contributions of the following *components only:

(i) fat; and

(ii) protein; and

(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

(2) The energy content of infant formula product must be expressed in kilojoules.

S29—2A Infant formula products—calculation of protein content

For paragraph 2.9.1—4(2)(b), the protein content of infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen-to-protein conversion factor of 6.25.

S29—2B Infant formula products—calculation of vitamin A content in infant formula and follow-on formula

For paragraph 2.9.1—4(2)(c), the vitamin A content of infant formula and follow-on formula must be calculated using only the retinol forms of vitamin A prescribed in column 1 of Table S29—23.

S29—3 Infant formula products—L-amino acids that must be present in infant formula and follow-on formula

For subsection 2.9.1—6(4), the table is:

L-amino acids that must be present in infant formula and follow-on formula

L-amino acid	*Minimum amount per 100 kJ*
Cysteine	9 mg
Histidine	10 mg
Isoleucine	22 mg
Leucine	40 mg
Lysine	27 mg
Methionine	6 mg
Phenylalanine	19 mg
Threonine	18 mg
Tryptophan	8 mg
Tyrosine	18 mg
Valine	22 mg

S29—4 Infant formula products—limits on fatty acids that may be present in infant formula and follow-on formula

For paragraph 2.9.1—7(1)(f), the table is:

Limits on fatty acids that may be present in infant formula and follow-on formula

Column 1	*Column 2*	*Column 3*
Substance	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Docosahexaenoic acid		7 mg
Long chain omega 6 series fatty acids (C> = 20)	Not more than 2% of the total fatty acids	
Long chain omega 3 series fatty acids (C> = 20)	Not more than 1% of the total fatty acids	
Total *trans* fatty acids	Not more than 4% of the total fatty acids	
Erucic acid (22:1)	Not more than 1% of the total fatty acids	

Note It is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 3 of the table. An amount specified in Column 3 is a Guidance Upper Level and is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

S29—5 Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose products for infants

For subsection 2.9.1—8(1) and section 2.9.1—32, the table is:

Vitamins, minerals, electrolytes and nutritive substances required in infant formula and special medical purpose products for infants

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.63 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	70 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		35 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.14 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	
Other essential substances			

Choline	1.7 mg	12 mg
L-carnitine	0.30 mg	0.80 mg
Myo-inositol	1.0 mg	10 mg

Note It is recommended that infant formula and a special medical purpose product for infants contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or special medical purpose products for infants; or due to technological reasons.

S29—6 Vitamins, minerals and electrolytes required in follow-on formula

For subsection 2.9.1—8(2), the table is:

Vitamins, minerals and electrolytes required in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***
Vitamin, mineral or electrolyte	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.63 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	70 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid (not including naturally occurring folate)	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		43 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.24 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	

Sodium	4.8 mg	14 mg
Potassium	14 mg	43 mg

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in column 4 of the table. The amounts specified are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow on formula or due to technological reasons.

S29—7 Optional nutritive substances in infant formula

For subsection 2.9.1—9(1), the table is set out below.

Optional nutritive substances in infant formula

Column 1	***Column 2***	***Column 3***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose
Adenosine-5′-monophosphate		0.36 mg
Cytidine-5′-monophosphate		0.60 mg
Guanosine-5′-monophosphate		0.40 mg
Inosine-5′-monophosphate		0.24 mg
Lactoferrin		40 mg
Lutein	1.5 µg	5.0 µg
Taurine		2.9 mg
Uridine-5′-monophosphate		0.42 mg

S29—8 Optional nutritive substances in follow-on formula

For subsection 2.9.1—9(2), the table is set out below.

Optional nutritive substances in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg	
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose	
Adenosine-5′-monophosphate		0.36 mg	
L-carnitine	0.30 mg		

Choline			12 mg
Cytidine-5′-monophosphate		0.60 mg	
Guanosine-5′-monophosphate		0.40 mg	
Inosine-5′-monophosphate		0.24 mg	
Lactoferrin		40 mg	
Lutein	1.5 µg	5.0 µg	
Myo-inositol			9.5 mg
Taurine		2.9 mg	
Uridine-5′-monophosphate		0.42 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons.

S29—9 Permitted forms of nutritive substances in infant formula and follow-on formula

For paragraph 2.9.1—10(b), the table is set out below.

Infant formula products—substances permitted for use as nutritive substances

Substance	***Permitted forms***
2′-fucosyllactose permitted for use by Standard 1.5.2	2′-fucosyllactose
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2	2′-fucosyllactose and lacto-N-neotetraose
Adenosine-5′-monophosphate	Adenosine-5′-monophosphate
L-carnitine	L-carnitine L-carnitine hydrochloride L-carnitine tartrate
Choline	Choline chloride Choline bitartrate Choline Choline citrate Choline hydrogen tartrate
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate Guanosine-5′-monophosphate sodium salt
Inosine-5′-monophosphate	Inosine-5′-monophosphate Inosine-5′-monophosphate sodium salt
Lactoferrin	Bovine lactoferrin
Lutein	Lutein from *Tagetes erecta L.*
Myo-inositol	Inositol

Taurine	Taurine
Uridine-5′-monophosphate	Uridine-5′-monophosphate sodium salt

Note Section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products.

S29—10 Required format for a nutrition information statement

The table to this section is:

NUTRITION INFORMATION	
	Average quantity per 100 mL prepared formula
Energy	kJ
Protein	g
— Whey*	g
— Casein*	g
Fat	g
— Long chain polyunsaturated fatty acids*	
— Docosahexaenoic acid*	mg
— Eicosapentaenoic acid*	mg
— Arachidonic acid**	mg
Carbohydrate	
— Lactose*	g
— Galactose*	g
Vitamins	
Vitamin A	µg
Vitamin B_6	µg
Vitamin B_{12}	µg
Vitamin C	mg
Vitamin D	µg
Vitamin E	µg
Vitamin K	µg
Biotin	µg
Niacin	mg
Folate	µg
Pantothenic acid	µg
Riboflavin	µg
Thiamin	µg
Minerals	
Calcium	mg
Copper	µg
Iodine	µg
Iron	mg
Magnesium	mg

Manganese	µg
Phosphorus	mg
Selenium	µg
Zinc	mg
Chloride	mg
Potassium	mg
Sodium	mg
Other nutrients*	
Choline*	mg
Inositol*	mg
L-carnitine*	mg
Additional	
(insert any other substance used as a nutritive substance; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)	g, mg, µg

Note: *See the following.

Entries and amounts for the following only need be included when stated in accordance with subsection 2.9.1—25(2): whey; casein; long chain polyunsaturated fatty acids; docosahexaenoic acid; eicosapentaenoic acid; arachidonic acid.

Entries and amounts for lactose and galactose only need be included when stated in accordance with paragraph 2.9.1—21(1)(c).

The heading 'Other nutrients' only need be included when required by subparagraph 2.9.1—26(2)(d)(ii).

Entries and amounts for choline, inositol, L-carnitine are included under the heading 'Other nutrients' when required by paragraph 2.9.1—26(4)(a) and under the heading 'Additional' when required by paragraph 2.9.1—26(4)(b).

[2] After section S29—22

Insert

S29—23 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

For sections 2.9.1—10(a), 2.9.2—4, 2.9.2—5, 2.9.2—6, 2.9.3—3(2)(c)(iii) and 2.9.5—6, the table is:

Permitted forms of vitamins, minerals and electrolytes in infant formula products, etc

Vitamin, mineral or electrolyte	***Permitted forms***
Vitamin A	
Retinol forms	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)
	vitamin A palmitate (retinyl palmitate)
	retinyl propionate
Provitamin A forms	beta-carotene
Vitamin C	L-ascorbic acid
	L-ascorbyl palmitate
	calcium ascorbate
	potassium ascorbate

	sodium ascorbate
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
	vitamin D (cholecalciferol-cholesterol)
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5′-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
	pyridoxine-5′-phosphate
Folic acid	Folate (excluding naturally occurring folate)
Pantothenic acid	calcium pantothenate
	dexpanthenol
	D-panthenol
	calcium D-pantothenate
	sodium D-pantothenate
Vitamin B_{12}	cyanocobalamin
	hydroxocobalamin
Biotin	d-biotin
Vitamin E	dl-α-tocopherol
	d-α-tocopherol concentrate
	tocopherols concentrate, mixed
	d-α-tocopheryl acetate
	dl-α-tocopheryl acetate
	d-α-tocopheryl acid succinate
	dl-α-tocopheryl succinate
Vitamin K	Vitamin K_1 as phylloquinone (phytonadione)
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate
	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	calcium sulphate
Chloride	calcium chloride

	magnesium chloride
	potassium chloride
	sodium chloride
Chromium	chromium sulphate
Copper	copper gluconate
	cupric sulphate
	cupric citrate
	cupric carbonate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Iron	ferric ammonium citrate
	ferric pyrophosphate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
	ferric citrate
	ferrous bisglycinate
	ferrous sulphate
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
	magnesium hydroxide carbonate
	magnesium hydroxide
	magnesium salts of citric acid
Manganese	manganese chloride
	manganese gluconate
	manganese sulphate
	manganese carbonate
	manganese citrate
Molybdenum	sodium molybdate VI
Phosphorus	calcium glycerophosphate
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic

	magnesium phosphate, dibasic
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	potassium L-lactate
Selenium	seleno methionine
	sodium selenate
	sodium selenite
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium chloride iodised
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Zinc	zinc acetate
	zinc chloride
	zinc gluconate
	zinc oxide
	zinc sulphate
	zinc lactate
	zinc citrate (zinc citrate dehydrate or zinc citrate

trihydrate)

Schedule 2

Standard 1.1.2—Definitions used throughout the Code

[1] Subsection 1.1.2—2(3)

Insert:

inner package, in relation to special medical purpose products for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

[2A] Subsection 1.1.2—2(3) (definition of *medium chain triglycerides*)

Repeal the definition.

[2] Subsection 1.1.2—2(3) (definition of *protein substitute*)

Repeal the definition.

[3] Subsection 1.1.2—2(3) (paragraph (c) of the definition of *warning statement*)

Repeal the paragraph, substitute:

(c) subsection 2.9.1—22(1) (warning statements for infant formula product);

[4] Subsection 1.1.2—3(2) (definitions—particular foods)

Insert:

special medical purpose product for infants means an infant formula product that is:

(a) represented as being:

(i) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(ii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(b) intended to be used under medical supervision; and

(c) not suitable for general use.

[5] Subsection 1.1.2—3(2) (definition of *follow-on formula*)

Repeal the definition, substitute:

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

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

[6] Subsection 1.1.2—3(2) (definition of *infant formula*)

Repeal the definition, substitute:

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 4 to 6 months.

[7] Subsection 1.1.2—3(2) (definition of *infant formula product*)

Repeal the definition, substitute:

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

[8] Subsection 1.1.2—3(2) (definition of *pre-term formula*)

Repeal the definition.

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

[9] Paragraph 1.2.3—6(4)(b)

Repeal the paragraph, substitute

(b) a special medical purpose product for infants.

[10] Note 2 to subsection 1.2.3—6(4)

Repeal the note, substitute:

Note 2 Division 4 of Standard 2.9.1 applies to special medical purpose products for infants and sets out compositional and labelling requirements for such food.

Standard 1.3.1—Food Additives

[11] Subsection 1.3.1—3(2)

After 'any food', insert '(other than an infant formula product)'

[12] Paragraph 1.3.1—4(6)(k)

Repeal the paragraph, substitute:

(k) rosemary extract is calculated as the sum of carnosic acid and carnosol;

(l) phosphoric acid and phosphates are calculated as phosphorus.

Standard 1.5.1—Novel Foods

[13] Section 1.5.1—3

Omit the section, substitute:

1.5.1—3 Sale of novel foods

(1) Despite paragraphs 1.1.1—10(5)(b) and (6)(f), a food offered for retail sale (other than an infant formula product) may consist of, or have as an ingredient, a *novel food if:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are complied with.

Note Novel foods are added to the table to section S25—2 by variations to the Code. When added for the first time, the conditions may include some that apply to the novel food only during the first 15 months after gazettal of the variation. Conditions may also deal with matters such as the following:

- the need for preparation or cooking instructions, warning statements or other advice;
- the need to meet specific requirements of composition or purity;
- the class of food within which the food must be sold;
- during the first 15 months after gazettal, the brand under which the food may be sold.

(2) An infant formula product food for retail sale may consist of, or have as an ingredient or a component, a novel food only if:

(a) the novel food is listed in the table to section S25—2; and

(b) the presence of that novel food in the infant formula product is expressly permitted by that table; and

(c) any conditions of use specified in the corresponding row of that table are complied with.

Standard 2.9.2—Food for infants

[14] Section 2.9.2—4

Omit **'**section S29—7' (wherever occurring), substitute 'section S29—23'.

[15] Section 2.9.2—5

Omit **'**section S29—7' (wherever occurring), substitute 'section S29—23'.

[16] Subsection 2.9.2—6(3)

Omit **'**section S29—7', substitute 'section S29—23'.

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

[17] Subparagraph 2.9.3—3(2)(c)(iii)

Omit **'**section S29—7', substitute 'section S29—23'.

Standard 2.9.5—Food for special medical purposes

[18] Paragraph 2.9.5—6(1)(b)

Omit **'**section S29—7', substitute 'section S29—23'**.**

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

[19] The table to section S8—2 (food additive names—alphabetical listing)

Insert:

Potassium hydroxide	525
Sodium hydroxide	524

[20] The table to section S8—2 (food additive names—numerical listing)

Insert in numerical order:

524	Sodium hydroxide
525	Potassium hydroxide

Schedule 15—Substances that may be used as food additives

[21] The table to section S15—5 (food classes 13.1, 13.1.1, 13.1.2 and 13.1.3)

Repeal food classes, substitute:

13.1	***Infant formula products***		
270	Lactic acid	GMP	
300	Ascorbic acid	50 mg/L	See Note 1, below.
301	Sodium ascorbate	50 mg/L	See Note 1, below.
302	Calcium ascorbate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
307b	Tocopherols concentrate, mixed	30 mg/L	See Note 1, below
308	Gamma-tocopherol	10 mg/L	
309	Delta-tocopherol	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrates	GMP	
332	Potassium citrates	GMP	
338	Phosphoric acid	450 mg/L	Not for follow-on formula
339	Sodium phosphates	450 mg/L	Not for follow-on formula
340	Potassium phosphates	450 mg/L	Not for follow-on formula
407	Carrageenan	300 mg/L	Only in a liquid product
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	Only in a liquid product that contains hydrolysed protein
440	Pectins	10 000 mg/L	See Note 1, below
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
472c	Citric and fatty acid esters of glycerol	7 500 mg/L	Only in a powdered product
		9 000 mg/L	Only in a liquid product
500	Sodium carbonates	2 000 mg/L	
501	Potassium carbonates	2 000 mg/L	
524	Sodium hydroxide	2 000 mg/L	
525	Potassium hydroxide	2 000 mg/L	
526	Calcium hydroxide	2 000 mg/L	
551	Silicon dioxide (amorphous)	10 mg/L	May only be added as part of a nutrient preparation
1412	Distarch phosphate	5 000 mg/L	See Note 2, below.
1413	Phosphated distarch phosphate	5 000 mg/L	See Note 3, below.
1414	Acetylated distarch phosphate	5 000 mg/L	See Note 4, below.
1422	Acetylated distarch adipate	5 000 mg/L	See Note 5, below.
1440	Hydroxypropyl starch	5 000 mg/L	See Note 6, below.

Note 1. For additives 300, 301, 302, 304, 307b, 440—the additive may only be used in follow-on formula products.

Note 2. Additive 1412 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1413, and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1413, and 1422.

Note 5. Additive 1422 may only be used in soy based follow-on formula, either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in soy based infant formula product (other than follow-on formula), either singly or in combination with one or more of additives 1412, 1413, and 1414.

13.1.1	**Special medical purpose products for infants**		
170	Calcium carbonates	GMP	
304	Ascorbyl palmitate	100	
333	Calcium citrate	GMP	
338	Phosphoric acid	450 mg/L	For pH adjustment only
339	Sodium phosphates	450 mg/L	
340	Potassium phosphates	450 mg/L	
341	Calcium phosphates	450 mg/L	
401	Sodium alginate	1 000 mg/L	Only in a product specifically formulated for both the dietary management of metabolic disorders of infants aged 4 months and above and general tube-feeding of infants aged 4 months and above.
407	Carrageenan	1 000 mg/L	Only in a liquid product that contain hydrolysed proteins and/or amino acids
410	Locust bean (carob bean) gum	5 000 mg/L	Only in a product specifically formulated for reduction of gastro-oesophageal reflux
412	Guar gum	10 000 mg/L	See Note 1, below.
415	Xanthan gum	1 000 mg/L	Only in a powdered hydrolysed protein and/or amino acid based product

		1 200 mg/L	Only in a product that is: based on amino acids or peptides; and formulated for infants with gastrointestinal tract problems, protein mal-adsorption or inborn errors of metabolism
440	Pectins	2 000 mg/L	Only in a liquid product that contain hydrolysed protein
		5 000 mg/L	Only in a product formulated for infants with gastro-intestinal disorders
471	Mono- and diglycerides of fatty acids	5 000 mg/L	Only in product formulated for diets devoid of proteins
473	Sucrose esters of fatty acids	120 mg/L	Only in products that contain hydrolysed proteins, peptides and amino acids
1412	Distarch phosphate	25 000 mg/L	See Notes 2 and 7, below.
1413	Phosphated distarch phosphate	25 000 mg/L	See Notes 3 and 7, below.
1414	Acetylated distarch phosphate	25 000 mg/L	See Notes 4 and 7, below.
1422	Acetylated distarch adipate	25 000 mg/L	See Notes 5 and 7, below
1440	Hydroxypropyl starch	25 000 mg/L	Sees Note 6 and 7, below.
1450	Starch sodium octenylsuccinate	20 000 mg/L	See Note 7, below

Note 1. Additive 412 may only be used in a product that contains one or more of the following: hydrolysed proteins; peptides; amino acids.

Note 2. Additive 1412 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1422.

Note 5. Additive 1422 may only be used in a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413, and 1414.

Note 7. Additives 1412, 1413, 1414, 1422, 1440 and 1450 may only be used in a product that contains hydrolysed proteins, amino acids or both.

Schedule 19—Maximum levels of contaminants and natural toxicants

[22] The table to section S19—4 (Maximum levels of metal contaminants)

Insert:

Aluminium	Infant formula and follow-on formula	0.5
	Special medical purpose products for infants formulated for pre-term infants	0.2

[23] The table to section S19—4 (items dealing with 'Lead')

Insert:

	Infant formula products	0.01

Schedule 25—Permitted novel foods

[24] Subsection S25—2 (table item dealing with "Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)"

Repeal item, substitute:

Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1.	May only be added to infant formula products.

[25] Subsection S25—2 (table item dealing with "Isomalto-oligosaccharide")

Repeal item, substitute:

Isomalto-oligosaccharide	1.	Must not be added to: (a) food for infants; and (b) formulated supplementary food for young children.

[26] Subsection S25—2 (table item dealing with "Rapeseed protein isolate", column headed "*Conditions of use*", condition 2)

Repeal the condition, substitute:

	2.	Must not be added to food for infants.

[27] Subsection S25—2 (table item dealing with "Trehalose")

Repeal item, substitute:

Trehalose	1.	May be added to infant formula products only as a cryo-preservative for L(+) lactic acid producing microorganisms.

Attachment B – Draft Explanatory Statements

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1028 – Infant Formula) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1028 to revise and clarify standards relating to infant formula products. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared two draft variations – the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

This Explanatory Statement relates to the *Food Standards (Proposal P1028 – Infant Formula) Variation* (the draft variation).

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the

FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*. The purpose of both instruments is to amend the Code to revise and clarify the Code's provisions relating to infant formula products, including those relating to category definitions, composition, labelling and representation of infant formula products.

4. Documents incorporated by reference

Section 14 of the *Legislation Act 2003* provides that a legislative instrument may:

- apply, adopt or incorporate provisions of a Commonwealth disallowable legislative instrument, with or without modification, as in force at a particular time or as in force from time to time; and
- incorporate any other document in writing which exists at the time the legislative instrument commences or a time before its commencement.

The Code currently contains provisions that incorporate other legislative instruments and other written documents by reference in accordance with the above section.

The draft variation contains one section that will incorporate a document by reference. New section 2.9.1—39 lists the information relating to ingredients that must be stated on the label of a special medical purpose product for infants. It provides that that information may be:

- information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4. That is, section 101.4 of Title 21 of the United States Code of Federal Regulations.

A copy of the EU Regulation is freely and publicly available online at various websites. These include https://eur-lex.europa.eu/homepage.html and https://www.legislation.gov.uk/eur/2011/1169/contents

A copy of the United States Code of Federal Regulations is freely and publicly available online at https://www.govinfo.gov/app/collection/cfr

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1028 includes two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

Given the broad scope of Proposal P1028, the Authority released a number of consultation papers prior to the first call for public comment, each focused on key aspects of infant formula regulation. The first call for submissions was held between 4 April - 17 June 2022. The second call for submissions (including the draft variation) will be open for a 10-week period.

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a formal Consultation Regulation Impact Statement (CRIS) in relation to the regulatory change proposed. A CRIS is not required because the function of the CRIS has been achieved by an appropriate alternative mechanism. This includes the statutory consultation under the FSANZ Act for the first call for submissions as well as this second call for submissions.

A Decision Regulation Impact Statement (DRIS) will be prepared by the Authority following the second call for submissions.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the Legislation Act 2003.

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the amendments made by the draft variation. See subclause 4(1).

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a five year transition period commencing on the date of gazettal, an infant formula product may be sold if the product complies with either: the Code as in force without the amendments made by the draft variation and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*; or the Code as amended by those two instruments.

8. Variation

The Schedule of the draft variation amends Standard 2.9.1 of the Code.

Item [1] of the Schedule repeals sections 2.9.1—2 to 2.9.1—25 and substitutes them with new provisions as follows.

Section 2.9.1—2: This provision provides an outline for the new standard 2.9.1. The outline explains that the Standard regulates various types of infant formula products and then what each division of the new standard 2.9.1 covers. Division 1 deals with preliminary matters. Division 2 sets out the compositional requirements for infant formula and follow-on formula, while Division 3 sets out their labelling and packaging requirements. Division 4 sets out compositional and labelling requirements for special medical purpose products for infants.

Section 2.9.1—3: The Note to this provision sets out definitions for certain key words used in the Standard. These definitions are contained within sections 1.1.2—2 and 1.1.2—3 of the Code and are restated in Standard 2.9.1 for convenience. S*pecial medical purpose product for infants* is a newly defined term in the Code, and is inserted into Standard 1.1.2 by the *Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments)*

Variation.

The effect of this variation is clarification that Division 4 only applies to products that are represented as special purpose medical products for infants.

Section 2.9.1—4: This provision provides that compositional requirements contained in the Standard apply to both the powdered or concentrated form of infant formula product that has been reconstituted with water as well as infant formula in 'ready to drink' form. The section also prescribes how energy, protein and vitamin A content must be calculated for the purposes of the Standard.

Division 2: Division 2 contains the compositional requirements for infant formula and follow-on formula. Division 2 comprises sections 2.9.1—5 to 2.9.1—14**.**

Section 2.9.1—5: This section sets general compositional requirements for infant formula and follow-on formula.

Subsection 2.9.1—5(1) provides that infant formula and follow-on formula must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L. This amendment will increase the minimum energy content from 2500 kJ/L to 2510 kJ/L for both infant formula and follow-on formula. It will also decrease the maximum energy content from 3150 kJ/L for infant formula, and 3550 kJ/L for follow-on formula to 2930 kJ/L for both products.

Subsection 2.9.1—5(2) prohibits the presence of added fructose and/or added sucrose in infant and follow-on formula.

Subsection 2.9.1—5(3) provides an exception to the prohibition imposed by subsection 2.9.1—5(2). The exception applies only to infant formula manufactured from partially hydrolysed protein. The exception will also only apply to the latter if: the fructose and/or sucrose is added to provide a source of carbohydrate; and the sum of the added fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in that formula.

Subsection 2.9.1—5(4) provides that the fluoride content of infant formula and follow-on formula not exceed 17 µg/100kJ. This is a new requirement.

Section 2.9.1—6: This section sets out the protein requirements for infant formula and follow-on formula.

Subsection 2.9.1—6(1) provides that infant formula and follow-on formula must be only derived from one or more of the proteins listed in that subsection. This is a new requirement. The effect of this variation is to clarify the protein sources that are permitted in infant formula products. This composition requirement is to be interpretated in conjunction with the definition for infant formula products.

Subsection 2.9.1—6(2) provides mandatory protein content requirements for infant formula, specifying different levels for milk-based infant formula and other infant formula. Milk-based infant formula must have a protein content of no less than 0.43 g/100 kJ (down from the current minimum of 0.45 g/100 kJ) and no more than 72 g/100 kJ (up from the current maximum of 0.7 g/100 kJ). Other infant formula must have a higher protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

Subsection 2.9.1—6(3) provides mandatory protein content requirements for follow-on formula specifying different levels for milk-based and other follow-on formula. Milk-based

follow-on formula must have a protein content of no less than 0.38 g/100 kJ (identical to the current minimum) and no more than 0.72 g/100 kJ (down from the current maximum of 1.3 g/100 kJ). Other follow-on formula must have a protein content of no less than 0.54 g/100 kJ (up from the current minimum of 0.45 g/100 kJ) and no more than 0.72 g/100 kJ (down from the current maximum of 1.3 g/100 kJ).

Subsection 2.9.1—6(4) requires that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at specified minimum levels.

Subsection 2.9.1—6(5) is a new requirement that infant formula have a ratio of methionine to cysteine of no more than 3 to 1.

Subsection 2.9.1—6(6) restates the current requirement in clause 2.9.1—10 that, despite the requirement that specific L-amino acids must be present in infant formula and follow-on formula, these L-amino acids may only be added to infant formula and follow-on formula in an amount necessary to improve protein quality.

Section 2.9.1—7: This section provides the fat requirements for infant formula and follow-on formula.

Paragraph 2.9.1—7(1)(a) requires that infant formula and follow-on formula must have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ. This amendment increases the minimum fat content requirement for infant formula and follow-on formula from 1.05 g/100 kJ to 1.1 g/100 kJ and decreases the maximum fat content from 1.5 g/100 kJ to 1.4 g/100 kJ.

Paragraph 2.9.1—7(1)(b) requires that infant and follow-on formula must have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1. This restates the current requirement in paragraph 2.9.1—11(b).

Paragraph 2.9.1—7(1)(ba)(i) requires that infant and follow-on formula must have no less than 90 mg/100 kJ of linoleic acid. This amendment changes the units in which the minimum linolenic acid is expressed from % total fatty acid to mg/100 kJ.

Paragraph 2.9.1—7(1)(ba)(ii) requires that infant and follow-on formula must have no less than 12 mg/100 kJ of α-linolenic acid. This amendment changes the units in which the minimum α-linolenic acid is expressed from % total fatty acid to mg/100 kJ. The current α-linolenic acid maximum limit of no more than 4% of the total fatty acids has also been removed.

The Note to paragraph 2.9.1(7)(1)(ab) identifies and explains for readers that it is recommended infant formula and follow-on formula contain not more than 335 mg of linoleic acid. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amount specified not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

Paragraph 2.9.1—7(1)(c) requires that infant formula and follow-on formula must have an arachidonic acid (20:4) content of equal to or more than docosahexaenoic acid (22:6 n-3) content. This is a new requirement.

Paragraph 2.9.1—7(1)(d) requires that infant formula and follow-on formula contain no less than 0.5 mg of vitamin E/g of polyunsaturated fatty acids. This restates the current requirement in subclause 2.9.1—12(3).

Paragraph 2.9.1—7(1)(e) requires that any long chain polyunsaturated fatty acids that are present in infant formula or follow-on formula must have an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3). This restates the current requirement in paragraph 2.9.1—11(1)(d).

Paragraph 2.9.1—7(1)(f) lists requirements for certain fatty acids present in infant formula and follow-on formula. The paragraph provides that, if a fatty acid listed in the table to section S29—4 is present in infant formula or follow-on formula, that formula must contain the minimum (if any) and maximum (if any) amounts of that fatty acid that are specified in and by that table. Some of the minimum and maximum limits listed in that table have been adjusted and differ from the current limits contained in the table to current section S29—8.

The Note to paragraph 2.9.1— (7)(1)(f) identifies and explains for readers the operation of column 3 of the table to section S29—4. This Note explains that it is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table to section S29—4 in an amount that is not more than the amount (if any) specified for that substance in column 3. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 3 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—7(2) provides that infant formula and follow-on formula may only contain medium chain triglycerides that are either: a natural constituent of a milk-based ingredient of that formula; or (b) for a fat soluble vitamin that is specified in either S29—5 (in the case of infant formula) or S29—6 (in the case of follow-on formula), a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula. The definition of the term “used as a processing aid” can be found in section 1.1.2—13 of the Code. This provision reflects the permission contained in current subclause 2.9.1—11(1).

Subsection 2.9.1—7(3) provides that infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ. This is a new requirement.

Section 2.9.1—8: This section provides that infant formula and follow-on formula must contain certain nutritive substances.

Subsection 2.9.1—8(1) provides that infant formula must contain each substance listed in the table to section S29—5 and in the minimum and maximum amounts specified in that table. The amounts specified in the table are not identical to the amounts specified in the current table to S29—9.

The differences for vitamins in infant formula are:

- a vitamin D minimum of 0.24 µg/100 kJ (down from the current minimum of 0.25 µg/100 kJ);
- a vitamin C guidance upper level of 17 mg/100 kJ (increased from the current guideline maximum of 5.4 mg/100 kJ);
- a thiamin guidance upper level of 72 µg/100 kJ (increased from the current guideline maximum of 48 µg/100 kJ);

- a riboflavin minimum of 14.3 µg/100 kJ (increased from the current minimum of 14 µg/100 kJ), and a riboflavin guidance upper level of 120 µg/100 kJ (increased from the current guideline maximum of 86 µg/100 kJ);
- a niacin minimum of 70 µg/100kJ (down from the current minimum of 130 µg/100 kJ),
- niacin guidance upper level of 359 µg/100 kJ (deceased from the current guideline maximum of 480 µg/100 kJ);
- vitamin B6 minimum of 8 µg/100 kJ (decreased from the current minimum of 9 µg/100 kJ) and guidance upper level of 42 (increased from the current maximum of 36 µg/100 kJ);
- folic acid minimum of 2.4 µg/100 kJ (increased from the current minimum of 2 µg/100 kJ) and guidance upper level of 12 µg/100 kJ (increased from the current guideline maximin of 8 µg/100 kJ);
- pantothenic acid minimum of 96 µg/100 kJ (increased from the current minimum of 70 µg/100 kJ) and maximum of 478 µg/100 kJ (increased from the currently guideline maximum of 360 µg/100 kJ);
- vitamin B12 minimum of 0.02 µg/100 kJ (decreased from the current minimum of 0.025 µg/100 kJ) and upper guidance level of 0.36 µg/100 kJ (increased from the current guideline maximum of 0.17 µg/100 kJ);
- biotin minimum of 0.24 µg/100 kJ (decreased from current minimum of 0.36 µg/100 kJ) and guidance upper level of 2.4 µg/100 kJ (decreased from 2.7 µg/100 kJ);
- vitamin E minimum of 0.14 mg α-TE (increased from current minimum of 0.11 mg) and guidance upper level of 1.2 mg α-TE (increased from current maximum of 1.1 mg); and
- vitamin K minimum of 0.24 µg/100 kJ (decreased from the current minimum of 1 µg/100 kJ) and guidance upper level of 6 µg/100 kJ (increased from the current guideline maximum of 5 µg/100 kJ).

The differences for minerals in infant formula are:

- a calcium guidance upper level of 35 mg/100 kJ (increased from the current guideline maximum of 33 mg/100 kJ);
- phosphorus guidance upper level of 24 mg/100 kJ (increased from the current guideline maximum of 22 mg/100 kJ);
- magnesium guidance upper level of 3.6 mg/100 kJ (decreased from the current maximum of 4 mg/100 kJ);
- iron minimum of 0.14 mg/100 kJ (decreased from current minimum of 0.2 mg/100 kJ) and maximum of 0.48 mg/100 kJ (decreased from current maximum of 5 mg/100 kJ);
- iodine minimum of 2.4 µg/100 kJ (increased from current minimum of 1.2 µg/100 kJ) and guidance upper level of 14 µg/100 kJ (increased from current maximum of 10 µg/100 kJ);
- copper minimum of 8 µg/100 kJ (decreased from current minimum of 14 µg/100 kJ) and guidance upper level of 29 µg/100 kJ (decreased from current maximum of 43 µg/100 kJ);
- zinc guidance upper level of 0.36 mg/100 kJ (decreased from current maximum of 43 mg/100 kJ); and
- selenium minimum of 0.48 µg/100 kJ (increased from current minimum of 0.25 µg/100 kJ) and guidance upper level of 2.2 µg/100 kJ (increased from current maximum of 1.19 µg/100 kJ).

The differences for electrolytes in infant formula are:

- a chloride maximum of 38 mg/100 kJ (increased from current maximum of 35 mg/100 kJ);
- a sodium minimum of 4.8 mg/100 kJ (decreased from current minimum of 5 mg/100 kJ) and maximum of 14 mg/100 kJ (decreased from current maximum of 15 mg/100 kJ); and
- a potassium minimum of 14 mg/100 kJ (decreased from current minimum of 20 mg/100 kJ) and a maximum of 43 mg/100 kJ (decreased from current maximum of 50 mg/100 kJ).

The differences for other essential substances in infant formula are:

- Choline at a minimum of 1.7 mg/100 kJ and guidance upper level of 0.80 mg/100 kJ. Currently choline is an optional ingredient in infant formula with a minimum of 1.7 mg/100 kJ and a maximum of 7.1 mg/100 kJ;
- L-carnitine must have a minimum of 0.30 mg/100 kJ and a guidance upper level of 0.80 mg/100 kJ. Currently L-carnitine is an optional ingredient in infant formula with a minimum of 0.21 mg/100 kJ and maximum of 0.8 mg/100 kJ; and
- Myo-inositol must have a minimum of 1.0 mg/100 kJ and a guidance upper level of 10 mg/100 kJ. Currently myo-inositol is an optional ingredient in infant formula with a minimum of 1.0 mg/100 kJ and maximum of 9.8 mg/100 kJ.

The Note to subsection 2.9.1—8(1) identifies and explains for readers the operation of column 4 of the table to section S29—5. This Note explains that it is recommended that infant formula contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—8(2) provides that follow-on formula must contain each substance listed in the table to section S29—6 and in the minimum and maximum amounts specified in that table. The amounts specified in the table are not identical to the amounts specified in the current table to S29—9.

The differences for vitamins in follow-on formula are:

- a vitamin D minimum of 0.24 µg/100 kJ (down from the current minimum of 0.25 µg/100 kJ);
- a vitamin C guidance upper level of 17 mg/100 kJ (increased from the current guideline maximum of 5.4mg/100 kJ);
- a thiamin guidance upper level of 72 µg/100 kJ (increased from the current guideline maximum of 48 µg/100 kJ);
- a riboflavin minimum of 14.3 µg/100 kJ (increased from the current minimum of 14 µg/100 kJ);
- a riboflavin guidance upper level of 120 µg/100 kJ (increased from the current guideline maximum of 86 µg/100 kJ);
- a niacin minimum of 70 µg/100kJ (down from the current minimum of 130 µg/100 kJ), and niacin guidance upper level of 359 µg/100 kJ (deceased from the current guideline maximum of 480 µg/100 kJ);

- a vitamin B6 minimum of 8 µg/100 kJ (decreased from the current minimum of 9 µg/100 kJ) and guidance upper level of 42 (increased from the current maximum of 36 µg/100 kJ);
- afolic acid minimum of 2.4 µg/100 kJ (increased from the current minimum of 2 µg/100 kJ) and guidance upper level of 12 µg/100 kJ (increased from the current guideline maximin of 8 µg/100 kJ);
- a pantothenic acid minimum of 96 µg/100 kJ (increased from the current minimum of 70 µg/100 kJ) and maximum of 478 µg/100 kJ (increased from the currently guideline maximum of 360 µg/100 kJ);
- a vitamin B12 minimum of 0.02 µg/100 kJ (decreased from the current minimum of 0.025 µg/100 kJ) and upper guidance level of 0.36 µg/100 kJ (increased from the current guideline maximum of 0.17 µg/100 kJ);
- a biotin minimum of 0.24 µg/100 kJ (decreased from current minimum of 0.36 µg/100 kJ) and guidance upper level of 2.4 µg/100 kJ (decreased from 2.7 µg/100 kJ);
- a vitamin E minimum of 0.14 mg α-TE (increased from current minimum of 0.11 mg) and guidance upper level of 1.2 mg α-TE (increased from current maximum of 1.1 mg); and
- a vitamin K minimum of 0.24 µg/100 kJ (decreased from the current minimum of 1 µg/100 kJ) and guidance upper level of 6 µg/100 kJ (increased from the current guideline maximum of 5 µg/100 kJ).

The differences for minerals in follow-on formula are:

- a calcium guidance upper level of 43 mg/100 kJ (increased from the current guideline maximum of 33 mg/100 kJ);
- a phosphorus guidance upper level of 24 mg/100 kJ (increased from the current guideline maximum of 22 mg/100 kJ);
- a magnesium guidance upper level of 3.6 mg/100 kJ (decreased from the current maximum of 4 mg/100 kJ);
- an iron minimum of 0.24 mg/100 kJ (decreased from current minimum of 0.2 mg/100 kJ) and maximum of 0.48 mg/100 kJ (decreased from current maximum of 5 mg/100 kJ);
- an iodnine minimum of 2.4 µg/100 kJ (increased from current minimum of 1.2 µg/100 kJ) and guidance upper level of 14 µg/100 kJ (increased from current maximum of 10 µg/100 kJ);
- a copper minimum of 8 µg/100 kJ (decreased from current minimum of 14 µg/100 kJ) and guidance upper level of 29 µg/100 kJ (decreased from current maximum of 43 µg/100 kJ);
- a zinc guidance upper level of 0.36 mg/100 kJ (decreased from current maximum of 43 mg/100 kJ); and
- a selenium minimum of 0.48 µg/100 kJ (increased from current minimum of 0.25 µg/100 kJ) and guidance upper level of 2.2 µg/100 kJ (increased from current maximum of 1.19 µg/100 kJ).

The differences for electrolytes in follow-on formula are:

- a chloride maximum of 38 mg/100 kJ (increased from current maximum of 35 mg/100 kJ);

- a sodium minimum of 4.8 mg/100 kJ (decreased from current minimum of 5 mg/100 kJ) and maximum of 14 mg/100 kJ (decreased from current maximum of 15 mg/100 kJ); and
- a potassium minimum of 14 mg/100 kJ (decreased from current minimum of 20 mg/100 kJ) and a maximum of 43 mg/100 kJ (decreased from current maximum of 50 mg/100 kJ).

The Note to subsection 2.9.1—8(2) identifies and explains for readers the operation of column 4 of the table to section S29—6. This Note explains that it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Section 2.9.1—9: This section provides that infant formula and follow-on formula may contain certain nutritive substances.

Subsection 2.9.1—9(1) provides that a substance listed in Column 1 of the table to S29—7 may be used as a nutritive substance in infant formula, provided that the amount of the substance in the formula (including any naturally-occurring amount) is: no less than the minimum amount specified in column 2 of the table; and no more than the maximum amount (if any) specified in Column 3 of the table. The phrase “used as a nutritive substance” in relation to a food is defined in section 1.1.2—12 of the Code.

Subsection 2.9.1—9(2) provides that a substance listed in Column 1 of the table to S29—8 may be used as a nutritive substance in follow-on formula, provided that the amount of the substance (including any naturally-occurring amount) is: no less than the minimum amount specified in column 2 of the table; and no more than the maximum amount (if any) specified in Column 3 of the table.

The Note to subsection 2.9.1—9(2) identifies and explains for readers the operation of column 4 of the table to section S29—8. This Note explains that it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

Section 2.9.1—10: This section requires that any substance used as a nutritive substance in either infant formula or follow-on formula must be in the permitted form listed in the table to section S29—23 (for vitamin, mineral or electrolytes) or the table to section S29—9 (in all other cases). The phrase “used as a nutritive substance” in relation to a food is defined in section 1.1.2—12 of the Code.

Section 2.9.1—11: This section permits the addition of L(+) lactic producing microorganisms to infant formula and follow-on formula. This restates current section 2.9.1—6.

Section 2.9.1—12: This section restricts the addition of inulin-type fructans and galacto-oligosaccharides. This restates current section 2.9.1—7.

Subsection 2.9.1—12(1) list the requirements that must be met if an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula. The requirements are that the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only *inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only *galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

  (i) no more than 110 mg/100 kJ of inulin-type fructans; and

  (ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

Subsection 2.9.1—12(2) provides that, if an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula, that formula must not contain added lacto-N-neotetraose.

Section 2.9.1—13: This section provides that infant formula and follow-on formula must not contain: detectable gluten; or more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates. This restates current paragraphs 2.9.1—8 (a) and (b), which apply only to infant formula. The new section extends the restriction to follow-on formula as well.

The Note to section 2.9.1—13 refers the reader to section S19—4 which sets out the maximum level of lead contaminant permitted in infant formula products.

Section 2.9.1—14: This section sets compositional requirements for infant formula which is represented as lactose free and low lactose.

Subsection 2.9.1—14(1) provides that infant formula represented as lactose free must contain no detectable lactose. This restates the current requirement at subsection 2.9.1—14(4).

Subsection 2.9.1—14(2) provides that infant formula represented as low lactose must contain no more than 0.3 g lactose/100 mL of the formula. This restates the current requirement at subsection 2.9.1—14(5).

Subsection 2.9.1—14(3) clarifies that a compositional requirement contained in Standard 2.9.1 (other than a requirement imposed by section 2.9.1—14) also applies to infant formula that is represented as lactose free formula or low lactose formula.

Division 3: Division 3 contains the labelling and packaging requirements for infant and follow-on formula. Division 3 comprises sections 2.9.1—15 to 2.9.1—29.

Section 2.9.1—15: This section restricts the representations that may be made about infant formula or follow-on formula.

Subsection 2.9.1—15(1) provides that a food may only be represented as infant formula or follow-on formula if that food complies with Standard 2.9.1.

Subsection 2.9.1—15(2) provides that a food that is represented as infant formula or follow-on formula must not be also represented as another food. The following example is provided to assist readers: a food represented as infant formula must not be also represented as, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children. The effect of subsection 2.9.1—15(2) is

that infant formula and follow-on formula are differentiated from one another, and from other formula products.

Section 2.9.1—16: This section provides that 'infant formula' and 'follow-on formula' are prescribed names for the purposes of the Code. It restates current section 2.9.1—17. Subsection 2.9.1—16(1) provides that 'infant formula' is the prescribed name for infant formula.

Subsection 2.9.1—16(2) provides that 'follow-on formula' is the prescribed name for follow-on formula.

The Note to section 2.9.1—16 explains to readers that, under the labelling provisions in Standard 1.2.1 and section 1.2.2—2 of the Code, if a food has a prescribed name, that prescribed name must be used wherever the Code requires the name of that food to be stated or used.

Section 2.9.1—17: This section sets out the requirement for a measuring scoop in some packages of infant and follow-on formula in powdered form. This section is similar to current section 2.9.1—18.

Subsection 2.9.1—17(1) requires that a package of infant formula or follow-on formula in a powdered form must contain a scoop to enable the use of the formula in accordance with the directions contained in the label on the package.

Subsection 2.9.1—17(2) provides that subsection 2.9.1—17(1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

Section 2.9.1—18: This section requires that, for the Code's labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened. This section is similar to current section 2.9.1—22.

The Note to section 2.9.1—18 advises the reader that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—19: This section provides that, for the Code's labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula. The intention is that, while the name of the food may also appear elsewhere on the package, it must appear on the front of the package at least once. This is a new requirement.

In accordance with section 2.9.1—16, the name of the food is the prescribed name (for example, 'Infant formula' or 'Follow-on formula'.

The ordinary meaning of 'front of a package' will apply (for example, the surface that is displayed or visible to the purchaser under customary conditions of sale or use).

The Note to section 2.9.1—19 advises the reader that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—20: This section imposes requirements to state the source or sources of protein in infant formula and follow-on formula.

Subsection 2.9.1—20(1) provides that, for the Code's labelling provisions, the specific animal or plant source or sources of protein in the infant formula or follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19. Three

examples are provided to assist readers: ‘Infant formula based on cows’ milk’; ‘Follow-on formula based on goat’s milk’; and ‘Infant formula based on ‘soy protein’.

This subsection is similar to the current paragraph 2.9.1—23(1)(a) except it clarifies the source or sources of protein for declaration are animal or plant sources, but not partially hydrolysed protein. The subsection also clarifies the statement of protein source must always be included in the statement of the name of the food (the prescribed name) and imposes a new requirement for the statement of protein source and name of the food to appear together on the front of the package of infant formula or follow-on formula.

The Note to subsection 2.9.1—20(1) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—20(2) provides that, if a label of infant formula represents that the formula is partially hydrolysed, the words ‘partially hydrolysed’ must appear immediately adjacent to the statement of protein source required by subsection 2.9.1—20(1). An example is provided to assist readers: ‘Partially hydrolysed Infant formula based on cows’ milk’.

The effect of subsection 2.9.1—20(2) is to require the words ‘partially hydrolysed’ to appear together with the statement of protein source on the front of the package of infant formula. The requirement applies only if the label represents the infant formula is partially hydrolysed, and cannot apply to a follow-on formula.

Section 2.9.1—21: This section sets labelling requirements for infant formula that is represented as lactose free or low lactose.

Paragraph 2.9.1—21(1)(a) provides that, if a label represents that an infant formula is lactose free, the words ‘lactose free’ must be included in the statement of the name of the food required by section 2.9.1—19. An example is provided to assist readers: ‘Lactose free Infant formula from cows milk’.

The effect of the variation is that the words ‘lactose free’ are required to appear together with the name of the food on the front of the package of infant formula. The requirement applies only if the label represents the infant formula is lactose free, and cannot apply to a follow-on formula.

Paragraph 2.9.1—21(1)(b) provides that, if a label represents that an infant formula is low lactose free, the words ‘low lactose’ must be included in the statement of the name of the food required by section 2.9.1—19. An example is provided to assist readers: ‘Low lactose Infant formula from cows milk’.

The effect of the variation is that the words ‘low lactose’ are required to appear together with the name of the food on the front of the package of infant formula. The requirement applies only if the label represents the infant formula is low lactose, and cannot apply to a follow-on formula.

Paragraph 2.9.1—21(1)(c) provides that, if a label represents that an infant formula is lactose free or low lactose, the average quantity of lactose and galactose, expressed in grams, must also be included in the statement required by section 2.9.1—25 and in the same format as specified in the table to section S29—10 for those substances.

The Note to paragraph 2.9.1—21(1)(c) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(2) clarifies that the labelling requirements of Standard 2.9.1 (other than a requirement imposed by subsection 2.9.1—21(1)) also apply to infant formula that is represented as lactose free formula or low lactose formula.

The intent of subsection 2.9.1—21(2) is to clarify that infant formula represented as lactose free and low lactose must comply with general labelling requirements in Division 3 for infant formula, with the exception of specific labelling requirements in subsection 2.9.1—21(1).

Section 2.9.1—22: This section sets out the warning statements and directions required for infant formula and follow-on formula.

Paragraph 2.9.1—22(1)(a) provides that, for the Code's labelling provisions, the following warning statement is required for infant formula and follow-on formula: 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.' This warning statement is similar to the warning statement required by current section 2.9.1—19. However the warning statement is no longer required to include "Do not change proportions of powder except on medical advice". This part of the statement is now to be included in the required directions on preparation and use, as set out in subsection 2.9.1—22(5).

Paragraph 2.9.1—22(1)(b) provides that, for the Code's labelling provisions, the following is also required for infant formula and follow-on formula: 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'. This restates the warning statement currently required by paragraph 2.9.1—19(1)(d) of the Code.

The Note to subsection 2.9.1—22(1) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—22(2) provides that, for the Code labelling provisions, the required statements for infant formula and follow-on formula are ones indicating that:

(a) for infant formula—the infant formula may be used from birth;
(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and
(c) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.

These required statements on use are similar to the required statements listed in current subsection 2.9.1—19(4).

The Note to subsection 2.9.1—22(2) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—22(3) provides that the statements required by paragraphs 2.9.1—22(2)(a) and (b) must appear on the front of the package of the product. This is a new requirement.

Subsection 2.9.1—22(4) makes it clear that a statement required by subsection 2.9.1—22(2) may appear more than once on the label. This is a new clarification.

Subsection 2.9.1—22(5) sets out, for the Code labelling provisions, the directions on preparation and use that are required for infant formula and follow-on formula.

The required directions are directions which instruct in words and pictures that:

- each bottle must be prepared individually; and (paragraph 2.9.1—22(5)(a))
- if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and (paragraph 2.9.1—22(5)(b))
- previously boiled and cooled potable water must be used; and (paragraph 2.9.1—22(5)(c))
- if a package contains a measuring scoop—only the enclosed scoop must be used; and (paragraph 2.9.1—22(5)(d))
- for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice; and (paragraph 2.9.1—22(5)(e))
- for ready-to-drink formula—do not dilute or add other food except on medical advice; and (paragraph 2.9.1—22(5)(f))
- formula left in the bottle after a feed must be discarded within 2 hours (paragraph 2.9.1—22(5)(g)).

These directions are similar to the directions currently required by subsection 2.9.1—19(3) of the Code with the following exceptions. The word ‘must’ has replaced the word ‘should’ in paragraphs 2.9.1—22(5)(a), (c) and (d) to convey the importance of following these directions. The word ‘prepared’ has replaced the words ‘made up’ in paragraph 2.9.1—22(5)(b) for consistency with other labelling requirements for infant formula and follow-on formula. Paragraph 2.9.1—22(5)(c) includes the word ‘cooled’ as information about the temperature of the water to be used to reconstitute formula. Subsection 2.9.1—22(5)(g) includes the words ‘within 2 hours’ as information about when to discard unfinished formula after a feed.

The directions required at paragraph 2.9.1—22(5)(e) and (f) are similar to the warning statements currently required by paragraphs 2.9.1—19(1)(a), (b) and (c) of the Code.

Subsection 2.9.1—22(6) provides that paragraphs 2.9.1—22(5)(a), (b) and (c) do not apply to ready-to-drink formula.

Subsection 2.9.1—22(7) provides that paragraph 2.9.1—22(5)(d) does not apply to concentrated formula and to ready-to drink formula.

Subsection 2.9.1—22(8) provides that, for the Code’s labelling provisions, the proportion of powder or concentrate required to reconstitute the formula (in the case of infant formula or follow-on formula in powdered or concentrated form) and the weight of one scoop (in the case of powdered infant formula product) must be declared. This is similar to the requirement currently found in paragraph 2.9.1—21(1)(b) of the Code.

Section 2.9.1—23: This section prescribes print size for the statements required by subsection 2.9.1—22(1). If the package of infant formula or follow-on formula has a net weight of more than 500 g, the statements must be in a size of type of at least 3 mm. If the package of infant formula or follow-on formula has a net weight of 500 g or less, the statements must be in a size of type of at least 1.5 mm. The phrase ‘size of type’ is defined by subsection 1.1.2—2(3) of the Code to mean the measurement from the base to the top of a letter or numeral. Section 2.9.1—23 is similar to the requirement currently contained at section 2.9.1—20 as to print size.

Section 2.9.1—24: This section provides an optional format to declare added vitamins and minerals in the statement of ingredients for infant formula and follow-on formula.

Subsection 2.9.1—24(1) provides an exception to section 1.2.4—5 of the Code. Section 1.2.4—5 requires a statement of ingredients to list each ingredient in descending order of ingoing weight. Subsection 2.9.1—24(1) provides that, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients not need list the added vitamins and minerals in descending order of ingoing weight, provided that that statement of ingredients lists all added vitamins together under the subheading 'Vitamins', and all added minerals together under the subheading 'Minerals'.

Subsection 2.9.1—24(2) clarifies that section 1.2.4—8 of the Code does not apply to a statement of ingredients referred in subsection 2.9.1—24(1).

Section 2.9.1—25: This section requires a statement of required nutrition information for infant formula and follow-on formula.

Subsection 2.9.1—25(1) provides that, for the Code's labelling provisions, a statement containing the following nutrition information is required for infant formula and follow-on formula.

- The unit quantity of the food expressed in per 100mL (paragraph 2.9.1—25(1)(a)). The term 'unit quantity' is defined in subsection 1.1.2—2(3).
- The average energy content expressed in kilojoules, rather than kJ/100mL (paragraph 2.9.1—25(1)(b)).
- The average quantity of protein, fat and carbohydrate expressed in grams, rather than g/100mL as currently required (paragraph 2.9.1—25(1)(c)). The term 'average quantity' is defined in subsection 1.1.2—2(3).
- The average quantity of each vitamin or mineral (including any naturally-occurring amount), expressed in micrograms or milligrams, rather than in weight/100mL as currently required (paragraph 2.9.1—25(1)(d)).
- For infant formula only—the average quantity of choline, inositol and L-carnitine expressed in milligrams (including any naturally-occurring amount) (paragraph 2.9.1—25(1)(e)).
- The average quantity, if added, of any substance used as a nutritive substance, inulin-type fructans, galacto-oligosaccharides, or a combination of inulin-type fructans and galacto-oligosaccharides (paragraph 2.9.1—25(1)(f)). These are to be expressed in micrograms or milligrams, rather than the weight/100 mL as currently required by paragraph 2.9.1—21(1)(a) of the Code.

The Note to subsection 2.9.1—25(1) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—25(2) provides that, if docosahexaenoic acid, eicosapentaenoic acid, arachidonic acid, whey and/or casein is present in infant formula or follow-on formula, the statement required by section 2.9.1—25(1) may include the average quantity of that substance (including any naturally-occurring amount) expressed in milligrams or grams. This is a new requirement. Subsection 2.9.1—25(2) is intended to clarify the declaration of these substances is voluntary.

Subsection 2.9.1—25(3) provides that, if the infant formula and follow-on formula is in a powdered or concentrated form, the information required by subsections 2.9.1—25(1) and (2)

must be expressed in terms of the product as reconstituted according to the directions on the package. This subsection is similar to current subsection 2.9.1—21(2).

Subsection 2.9.1—25(4) provides that, unless another provision of the Code expressly provides otherwise, the nutrition information statement required by section 2.9.1—25 must not contain any other information. This is a new provision to clarify the presence of nutrition information that is not expressly permitted or required in the nutrition information statement would constitute a prohibited representation (for example, a prohibited nutrition content claim).

Section 2.9.1—26: This section prescribes the format for the nutrition information statement required by section 2.9.1—25. This is a new requirement.

Subsection 2.9.1—26(1) provides that a reference to the table in section 2.9.1—26 is a reference to the table to section S29—10.

Subsection 2.9.1—26(2) sets the following requirements.

- The statement must be in the same format as specified in the table (paragraph 2.9.1—26(2)(a)).
- The statement must state the nutrition information in the order specified in the table (paragraph 2.9.1—26(2)(b));
- The statement must be titled ‘Nutrition Information’(paragraph 2.9.1—26(2)(c)).
- The statement must have the following subheadings Vitamins’, ‘Minerals’ and ‘Additional’. Infant formula must also have the subheading Other nutrients’. Each subheading must be printed in a size of type that is the same or larger than the nutrient names stated in the statement (paragraph 2.9.1—26(2)(d)).
- The statement must state nutrients and subgroup nutrients using the names and units of measurement that are specified in the table for that nutrient and subgroup (paragraph 2.9.1—26(2)(e)).
- The statement must not include a *unit quantity other than per 100 mL (paragraph 2.9.1—26(2)(f)).

The intent of subsection 2.9.1—26(2) is to ensure the format and grouping of nutrients and substances in the nutrition information statement is presented in a consistent manner.

Subsection 2.9.1—26(3) provides that, if the statement includes the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide, that average quantity must: be included in the statement under the subheading ‘Additional’; and be in the same format as specified in the table for that substance.

Subsection 2.9.1—26(4) applies if the average quantity of choline, inositol or L-carnitine is included in nutrition information statement. Paragraph 2.9.1—26(4)(a) provides that, for infant formula, the average quantity must be included in the statement under the subheading ‘Other Nutrients’ because the addition of these substances is mandated and so they are not considered to be nutritive substances. Paragraph 2.9.1—26(4)(b) provides that, for follow-on formula, the average quantity must be in the statement under the subheading ‘Additional’ because these substances are considered to be nutritive substances. Paragraph 2.9.1—26(4)(c) requires that, in each case, the average quantity must be included or stated in the statement in the same format that is specified in the table for the relevant substance.

Subsection 2.9.1—26(5) applies if the nutrition information statement includes the average quantity of a substance listed in subsection 2.9.1—25(2). The subsection requires that that average quantity be included in the statement in the same format as specified in the table for

relevant substance.

Section 2.9.1—27: This section provides that the method listed in paragraph 1.1.1—6(3)(c) must not be used to calculate the average quantity of a substance in infant formula or follow-on formula. This is an exception to section 1.1.1—6 of the Code, which lists the methods for how average quantity is to be calculated for Code purposes.

Section 2.9.1—28: This section provides for the use of stage numbers on a package of infant formula or follow-on formula. This is a new requirement.

Paragraph 2.9.1—28(1)(a) provides that the number '1' may be used on the label on a package of infant formula in order to identify for consumers that that product is infant formula.

Paragraph 2.9.1—28(1)(b) provides that the number '2' may be used on the label on a package of follow-on formula in order to identify for consumers that that product is follow-on formula.

Subsection 2.9.1—28(2) sets out where a number used in accordance with subsection 2.9.1—28(1) must appear on the package of the product. For infant formula, the number must appear on the front of the package of the product, immediately adjacent to the statement required by paragraph 2.9.1—22(2)(a) (see above). For follow-on formula, the number must appear on the front of the package of the product, immediately adjacent to the statement required by paragraph 2.9.1—22(2)(b) (see above).

Section 2.9.1—29: This section sets out what the label on a package of infant formula or follow-on formula must not contain**.**

Subsection 2.9.1—29(1) provides that the package of infant formula or follow-on formula must not contain any of the following:

- A picture of an infant (paragraph 2.9.1—29(1)(a)).
- A picture that idealises the use of infant formula or a follow-on formula (paragraph 2.9.1—29(1)(b)).
- Information relating to another product (paragraph 2.9.1—29(1)(c)).The following example is provided to assist readers: the label on a package of infant formula must not refer to, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.
- The word 'humanised' or 'maternalised' or any word or words having the same or similar effect (paragraph 2.9.1—29(1)(d)).
- The words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect (paragraph 2.9.1—29(1)(e)).
- The abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect (paragraph 2.9.1—29(1)(f)).
- Words claiming that the formula is suitable for all infants (paragraph 2.9.1—29(1)(g)).
- Information relating to the nutritional content of human milk (paragraph 2.9.1—29(1)(h)).
- Information relating to the presence of a substance listed in subsection 2.9.1—29(3). This prohibition does not apply to a reference to a such a substance in a statement of ingredients or in declaration or statement expressly permitted or required by this Code (Paragraphs 2.9.1—29(1)(i)).
- Information relating to ingredients. This prohibition does not apply to a reference to ingredients in a statement of ingredients or in declaration or statement expressly permitted or required by this Code (paragraph 2.9.1—29(1)(j)).

- Information relating to the animal or plant source or sources of protein in the formula. This prohibition does not apply to a reference to a source of protein in a statement of ingredients or where required by subsection 2.9.1—20(1) of the Code (paragraph 2.9.1—29(1)(k)).
- The words 'partially hydrolysed' or any word or words having the same or similar effect. This prohibition does not apply to the use of such words in a statement of ingredients or where required by subsection 2.9.1—20(2) of the Code (paragraph 2.9.1—29(1)(l)).
- The words 'lactose free' or 'low lactose'. This prohibition does not apply to a declaration or statement required by section 2.9.1—21 of the Code (paragraph 2.9.1—29(1)(m)).
- A number used to identify for consumers that the product is infant formula or follow-on formula, except where required by section 2.9.1—28 (paragraph 2.9.1—29(1)(n)).

Subsection 2.9.1—29(1) lists the prohibited representations that are not to be used to market infant formula and follow-on formula. Paragraph 2.9.1—29(1)(c) and paragraphs 2.9.1—29(1)(i) to (n) are new prohibited representations.

Subsection 2.9.1—29(2) provides that, for the purposes of subsection 2.9.1—29(1), the term 'information' includes a reference by means of a name, a number, a picture, an image, a word or words.

Subsection 2.9.1—29(3) provides a list of substances for the purposes of paragraph 2.9.1—29 (1)(i). The listed substances are: an inulin-type fructan; a galacto-oligosaccharide; a nutrient; and a substance used as a nutritive substance.

The Note to subsection 2.9.1—29(3) identifies and explains to the reader that subsection 2.9.1—25 expressly requires or permits the substances in subsection 2.9.1—29(3) to be declared or stated in the declaration of nutrition formation required by that section.

Division 4: Division 4 contains the compositional, labelling and packaging requirements for special medical purpose products for infants. Division 4 comprises sections 2.9.1—30 to 2.9.1—43.

Section 2.9.1—30: This section provides the certain provisions of the Code do not apply to special medical purpose products for infants. Paragraph 2.9.1—30(a) provides that paragraphs 1.1.1—10(6)(b) and 1.1.1—10(6)(f) do not apply to special medical purpose products for infants. Paragraph 2.9.1—30(a) provides that, subject to an apparent contrary intention in the Code, Part 1.2 of Chapter 1 of the Code and Division 3 of Standard 2.9.1 do not apply to special medical purpose products for infants.

This variation reflects the same provisions of subsection 2.9.5—3(a) and 2.9.5—3(b), which note that 1.1.1—10(6)(b) and 1.1.1—10(6)(f) do not apply to foods for special medical purpose. The intent of this variation is to ensure that imported medical products produced in accordance with international regulations, that have differing nutritive substance and novel food permission to the Code, are not stopped at the border.

Section 2.9.1—31: This section imposes restrictions on the sale of special medical purpose products for infants.

Subsection 2.9.1—31(1) provides that a special medical purpose product for infants must not be sold to a consumer, other than from or by: a medical practitioner or dietitian; a medical practice, pharmacy or responsible institution; or a majority seller of that special medical purpose product for infants.

Subsection 2.9.1—31(2) defines who is a medical practitioner or a majority seller for the purposes of subsection 2.9.1—31(1).

*A **medical practitioner*** is defined to mean a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

A majority seller of a special medical purpose product for infants is defined to mean a person who: during any 24 month period, sold that special medical purpose product for infants to any of the following: a medical practitioner; a dietitian; a medical practice; a pharmacy; a responsible institution, provided that these sales represented more than half of the total amount of that product sold by the person during that 24 month period.

Section 2.9.1—32: This section sets compositional requirements for special medical purpose products for infants.

Subsection 2.9.1—32(1) provides that a special medical purpose product for infants must contain each substance listed in the table to section S29—5 and in the minimum and maximum (if any) amounts specified in that table.

The Note to subsection 2.9.1—32 (1) identifies and explains for readers the operation of column 4 of the table to section S29—5. This Note explains that it is recommended that a special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of a special medical purpose product for infants or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—32(2) provides that a special medical purpose product for infants need not comply with 2.9.1—32(1) when required for a particular medical purpose or where compliance with that subsection would otherwise prevent the sale of the food.

The intent of subsection 2.9.1—32(2)(a) is to allow special medical purpose products to vary their specialized formulation based on the nutrient requirements of the specified medical disease, disorder or condition. This can include deviation from multiple composition parameter.

The intent of subsection 2.9.1—32(2)(b) is to allow special medical purpose products to vary from the prescribed infant formula composition where it would prevent the sale of the food. For example, if a special medical purpose product for infants is formulated in accordance with an international regulations base infant formula composition, then a lower substance level in line with the intentional regulation would not stop the sale of the food.

Section 2.9.1—33: This section provides that a food may only be represented as a special medical purpose product for infants if it complies with Division 4 of Standard 2.9.1.

The draft variation does not currently include a section numbered as 2.9.1— 34. This is a result of the drafting process.

Section 2.9.1—35: This section sets out what the label on a package of a special medical purpose product for infants must not contain. The section provides that that package must not contain any of the following:

- A picture of an infant (paragraph 2.9.1—35(a)).
- The word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect (paragraph 2.9.1—35(b)).
- The words ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ or any word or words having the same or similar effect (paragraph 2.9.1—35(c)).
- The abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect (paragraph 2.9.1—35(d)).
- Information relating to another food (paragraph 2.9.1—35(e)).

The Note to section 2.9.1—35 advises readers of other provisions of the Code that also prohibit certain content on a label of a package of a special medical purpose product for infants *S*tandard 1.2.7 of the Code prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products, including a special medical purpose product for infants. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about a special medical purpose product for infants - must not be therapeutic in nature.

Section 2.9.1—36: This section sets out labelling and related requirements for special medical purpose products for infants.

Subsection 2.9.1—36(1) explains that the requirements listed in section 2.9.1—36 apply to a special medical purpose product for infants.

Subsection 2.9.1—36(2) requires a special medical purpose product for infants that is in a package to bear a label that complies with section 2.9.1—37.

Subsection 2.9.1—36(3) requires a special medical purpose product for infants that is in an inner package to bear a label that complies with section 2.9.1—42. ‘Inner package’, in relation to special medical purpose food for infants, is defined in section 2.9.1—3. Subsection 2.9.1—36(3) also provides that no other labelling requirement in the Code for any other packaging applies to that product.

Subsection 2.9.1—36(4) applies to a special medical purpose product for infants that is in a transportation outer. ‘Transportation outer’ is defined in subsection 1.1.2—2(3). Subsection 2.9.1—36(4) requires that the transportation outer or package containing the special medical purpose product for infants to bear a label that complies with section 2.9.1—43. The subsection also provides that no other labelling requirement in the Code for any other packaging applies to that product.

Section 2.9.1—37: This section sets out the information that must be stated on the label for a special medical purpose product for infants.

Subsection 2.9.1—37(1) requires the following information to be stated on the label.

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2 (paragraph 2.9.1—37(1)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—37(1)(b)).
- Information relating to foods produced using gene technology, in accordance with section 1.5.2—4, provided that the sale of that product is a sale to which Divisions 2 to 4 of Standard 1.2.1 applies (subparagraph 2.9.1—37(1)(c)(i)).

- Information relating to irradiated food, in accordance with section 1.5.3—9, provided that the sale of that product is a sale to which Division 2 or Division 3 of Standard 1.2.1 applies (subparagraph 2.9.1—37(1)(c)(ii)).
- Required advisory statements, warning statements, other statements, and declarations, in accordance with section 2.9.1—38 (paragraph 2.9.1—37(1)(d)).
- Information relating to ingredients, in accordance with section 2.9.1—39 (paragraph 2.9.1—37(1)(e)).
- Date marking information, in accordance with section 2.9.1—40 (paragraph 2.9.1—37(1)(f)).
- Directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons (paragraph 2.9.1—37(1)(g))
- Nutrition information, in accordance with section 2.9.1—41 (paragraph 2.9.1—37(1)(h)).

Subsection 2.9.1—37(2) requires the label of a special medical purpose product for infants to comply with Division 6 of Standard 1.2.1. Division 6 of Standard 1.2.1 includes legibility requirements for food for sale.

Section 2.9.1—38: This section sets out the mandatory statements and declarations required for special medical purpose products for infants.

Subsection 2.9.1—38(1) provides that the following statements are required for the purposes of paragraph 2.9.1—37(1)(d).

- A statement to the effect that the food must be used under medical supervision (paragraph 2.9.1—38(1)(a)).
- A statement indicating, if applicable, any precautions and contraindications associated with consumption of the food (paragraph 2.9.1—38(1)(b)).
- A statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated (paragraph 2.9.1—38(1)(c)).
- A statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph 2.9.1—38(1)(c). (Paragraph 2.9.1—38(1)(d)).
- if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group (paragraph 2.9.1—38(1)(e)).
- A statement indicating whether or not the food is suitable for use as a sole source of nutrition (paragraph 2.9.1—38(1)(f)).
- If the food is represented as being suitable for use as a sole source of nutrition, a statement to the effect that the food is not for parenteral use (paragraph 2.9.1—38(1)(g)). If that food has been modified in accordance with subsection 2.9.1—32(2), then the following statements are also required for that food.
    - A statement indicating the nutrient or nutrients which have been modified.
    - A statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate. This statement is not required if such a statement is provided in other documentation about the food.

Subsection 2.9.1—38(2) provides that, for the purposes of paragraph 2.9.1—37(1)(d), the required advisory statements and declarations are any that are required by the following provisions of the Code:

- items 1, 4, 6 or 9 of the table to section S9—2; or

- subsection 1.2.3—2(2); or
- section 1.2.3—4.

Subsection 2.9.1—38(3) provides that, for the purposes of paragraph 2.9.1—37(1)(d), the warning statement referred to in section 1.2.3—3, if applicable, is required.

Section 2.9.1—39: This section sets out the information relating to ingredients that must be stated on the label of a special medical purpose product for infants in accordance with paragraph 2.9.1—37(1)(e). That information is:

- a statement of ingredients; or
- information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4. That is, section 101.4 of Title 21 of the United States Code of Federal Regulations.

The intent of section 2.9.1—39 is to require the label on a package of a special medical purpose product for infants to comply with either Standard 1.2.4, the relevant Directive of the European Parliament and Council, or the relevant provision in the United States Code of Federal Regulations.

Section 2.9.1—40: This section sets out the date marking information that must be stated on the label of a special medical purpose product for infants in accordance with paragraph 2.9.1—37(1)(f).

Subsection 2.9.1—40(1) provides that the required date marking information is date marking information in accordance with Standard 1.2.5.

Subsection 2.9.1—40(2) provides that, for the purposes of subparagraph 1.2.5—5(2)(a)(ii), the words ‘Expiry Date’, or similar words, may be used on the label.

The intent is subsection 2.9.1—40 is to require the label on a package of a special medical purpose product for infants to comply with either Standard 1.2.5 or the words ‘Expiry Date’.

Section 2.9.1—41: This section sets out the nutrition information that must be stated on the label of a special medical purpose product for infants in accordance with paragraph 2.9.1—37(1)(h).

Subsection 2.9.1—41(1) requires the following nutrition information, expressed per given amount of the food:

- The minimum or *average energy content; and
- The minimum amount or *average quantity of: protein, fat and carbohydrate;
- The minimum amount or *average quantity of any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and
- The minimum amount or *average quantity of any other substance used as a nutritive substance in that product; and added to that product to achieve that product’s intended medical purpose as described in the statement required by paragraph 2.9.1—38(1)(c).

The intent of subsection 2.9.1—41(1) is to require the presence of energy and certain substances to be declared while providing flexibility for variations in the nutrition information.

Subsection 2.9.1—41(2) provides that the label that is required for a special medical purpose product for infants may state information relating to the source or sources of protein in that product.

Section 2.9.1—42: This section sets out the information that must be stated on the label on an *inner package that contains a special medical purpose product for infants.

Subsection 2.9.1—42(1) requires the following information to be stated:

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2 (paragraph 2.9.1—42(1)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—42(1)(b))
- Any declaration that is required by section 1.2.3—4 (paragraph 2.9.1—42(1)(c))
- Date marking information, in accordance with section 2.9.1—40 (paragraph 2.9.1—42(1)(d))

Subsection 2.9.1—42 requires the label on an *inner package that contains a special medical purpose product for infants to comply with Division 6 of Standard 1.2.1.

Subsection 2.9.1—42(3) provides that section 2.9.1—42 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.

Section 2.9.1—43: This section sets out the labelling requirement for a special medical purpose product for infants in transportation outer.

Subsection 2.9.1—43(1) provides that, if packages of a special medical purpose product for infants are contained in a transportation outer, the information specified in subsection 2.9.1—43(2) must be: contained in a label on the transportation outer; or contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

Subsection 2.9.1—43(2) makes it clear that the transportation outer is not required to have a label if the information specified is clearly discernible through the transportation outer on the labels on the packages inside.

Subsection 2.9.1—43(2) specifies the following information:

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2) (paragraph 2.9.1—43(2)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—43(2)(b)).
- The name and address of the supplier, in accordance with section 1.2.2—4 (paragraph 2.9.1—43(2)(c)). This information is not required to be contained in the label if it is provided in accompanying documentation.

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1028 to revise and clarify standards relating to infant formula products comprising category definitions, composition, labelling and representation of products. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared two draft variations – the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

This Explanatory Statement relates to the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation* (the draft variation)

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part

of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the draft variation amending Schedule 29 and other Standards in the Code as a consequence of proposed amendments to Standard 2.9.1 of the Code in the *Food Standards (Proposal P1028 – Infant Formula) Variation*. The purpose of all of the proposed amendments are to revise and clarify the Code as it relates to infant formula products comprising category definitions, composition, labelling and representation of products.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1028 includes two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

Given the broad scope of Proposal P1028, the Authority released a number of consultation papers prior to the first call for public comment, each focused on key aspects of infant formula regulation. The first call for submissions was held between 4 April – 17 June 2022. The second call for submissions (including the draft variation) will be open for a 10-week period.

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a formal Consultation Regulation Impact Statement (CRIS) in relation to the regulatory change proposed. A CRIS is not required because the function of the CRIS has been achieved by an appropriate alternative mechanism. This includes the statutory consultation under the FSANZ Act for the first call for submissions as well as this second call for submissions.

A Decision Regulation Impact Statement (DRIS) will be prepared by the Authority following the second call for submissions.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation.*

Clause 2 provides that the Code is amended by the Schedules to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the amendments made by the draft variation. See subclause 4(1).

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a five year transition period commencing on the date of gazettal, an infant formula product may be sold if the product complies with either the Code as in force without the amendments made by the draft variation and the *Food Standards (Proposal P1028 – Infant Formula) Variation*; or the Code as amended by those two instruments.

Schedule 1

Schedule 1 of the draft variation amends Schedule 29 of the Code.

Item [1] of Schedule 1 repeals sections S29—2 to S29—10; and substitutes them with new sections S29—2 to S29—10.

New section S29—2: this provision deals with the calculation of the energy content of infant formula products for the purposes of paragraph 2.9.1—4(2)(a).

Paragraph 2.9.1—4(2)(a) requires that, in Standard 2.9.1, energy must be calculated in accordance with new section S29—2.

New subsection S29—2(1) provides that the energy content of an infant formula product must be calculated using all of the following:

(a) the energy contributions of the following components only:

(i) fat; and
(ii) protein; and
(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

New subsection S29—2(2) provides that the energy content of an infant formula product must be expressed in kilojoules.

New section S29—2A: this provision sets out how the protein content of infant formula products must be calculated for the purposes of paragraph 2.9.1—4(2)(b).

Paragraph 2.9.1—4(2)(b) requires that, in Standard 2.9.1, protein content must be calculated in accordance with new section S29—2A.

New section S29—2A provides that the protein content of an infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen to protein conversion factor of 6.25.

New section S29—2B: this provision sets out how the vitamin A content of infant formula and follow on formula must be calculated for the purposes of paragraph 2.9.1—4(2)(c).

Paragraph 2.9.1—4(2)(c) requires that, in Standard 2.9.1, vitamin A content for infant formula and follow-on formula must be calculated in accordance with new section S29—2B.

New section S29—2B provides that the vitamin A content of infant formula and follow on

formula must be calculated using only the retinol forms of vitamin A prescribed in column 1 of the table to new S29—23 (see **item 2** below).

New section S29—3: this provision deals with the L-amino acids that must be present in infant formula and follow-on formula for the purposes of subsection 2.9.1—6(4).

Subsection 2.9.1—6(4) provides that the L-amino acids listed in the table to new section S29—3 must be present in infant formula and follow-on formula at a level no less than the corresponding minimum level specified in the table.

The table to new section S29—3 lists the L-amino acids that must be present in infant formula and follow-on formula; and their corresponding minimum amounts per 100 kJ of the respective infant formula / follow on formula.

New section S29—4: this provision deals with limits on fatty acids that may be present in infant formula and follow-on formula for the purposes of paragraph 2.9.1—7(1)(f).

Paragraph 2.9.1—7(1)(f) lists requirements for certain fatty acids present in infant formula and follow-on formula. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in infant formula or follow-on formula, that formula must contain not more than the maximum amount (if any) specified in Column 3 of the table for that fatty acid.

The table to new section S29—4 sets out the fatty acids that may be present in infant formula and follow-on formula; and their corresponding limits. The table has three Columns. Column 1 lists the fatty acids; and for each fatty acid:

- Column 2 sets out *any* maximum amount per 100 kJ;
- Column 3 sets out *any* 'Guidance upper level per 100 kJ'.

The Note to section S29—4 identifies and explains for readers the operation of column 3 of the table to that section. This Note explains that it is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table to section S29—4 in an amount that is not more than the amount (if any) specified for that substance in column 3. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 3 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

In summary:

- it is optional (i.e. not mandatory) for an infant formula or follow-on formula to contain a fatty acid listed in Column 1 of the table to new section S29—4;
- if an infant formula or follow-on formula contains a fatty acid listed in Column 1 of the table, the infant formula or follow-on formula must comply with the corresponding maximum limits for that fatty acid which are set out in the table;
- Recommended Guidance Upper Levels are listed for fatty acids where no maximum limit is set.

New section S29—5: this provision deals with the vitamins, minerals, electrolytes and other substances which infant formula must contain for the purposes of subsection 2.9.1—8(1) and section 2.9.1—32.

Subsection 2.9.1—8(1) deals with the nutritive substances that infant formula must contain. This provision requires infant formula to contain each substance listed in Column 1 of the table to new section S29—5 in an amount that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

Section 2.9.1—32 deals with compositional requirements for special medical purpose products for infants. This provision requires that, subject to subsection 2.9.1—32(2), a special medical purpose product for infants must contain each substance listed in Column 1 of the table to new section S29—5 in an amount that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

The table to new section S29—5 sets out the vitamins, minerals, electrolytes and other substances that infant formula and special medical purpose products for infants must contain; and their corresponding limits. The table has four Columns. Column 1 lists the vitamins, minerals, electrolytes, and other substances; and for each substance:

- Column 2 sets out the minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ' (this term is explained in the Note to new section S29—5 below).

The Note to section S29—5 identifies and explains for readers the operation of column 4 of the table to that section. This Note explains that it is recommended that infant formula and special medical purpose products for infants contain a vitamin, mineral, electrolyte or other substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and special medical purpose products for infants or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

New section S29—6: this provision deals with vitamins, minerals and electrolytes which follow-on formula must contain for the purposes of subsection 2.9.1—8(2).

Subsection 2.9.1—8(2) requires follow-on formula to contain each substance listed in Column 1 of the table to new section S29—6 in an amount that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

The table to new section S29—6 sets out the vitamins, minerals and electrolytes that follow-on formula must contain; and their corresponding limits. The table has four Columns. Column 1 lists the vitamins, minerals and electrolytes; and for each substance:

- Column 2 sets out the minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ'.

The Note to section S29—6 identifies and explains for readers the operation of column 4 of the table to that section. This Note explains that it is recommended that follow-on formula contain a vitamin, mineral, electrolyte or other substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

New section S29—7: this provision deals with nutritive substances which infant formula may contain for the purposes of subsection 2.9.1—9(1) i.e. the addition of these substances in infant formula would be optional.

Subsection 2.9.1—9(1) permits infant formula to contain nutritive substances listed in the table to section S29—7 provided that the amount of the substance in the formula (including any naturally-occurring amount) complies with their corresponding limits in the table.

The table to new section S29—7 sets out the nutritive substances that infant formula may contain; and their corresponding limits (this includes any naturally-occurring amount of the substance). The table has three Columns. Column 1 lists the nutritive substances; and for each substance:

- Column 2 sets out *any* minimum amount per 100 kJ;
- Column 3 sets out the maximum amount per 100 kJ

In summary:

- it is optional (i.e. not mandatory) for infant formula to contain a nutritive substance listed in Column 1 of the table to new section S29—7;
- if an infant formula contains a nutritive substance listed in Column 1 of the table, the infant formula must comply with corresponding minimum and / or maximum limits for that substance which are set out in the table;
- the amount of the nutritive substance in the infant formula includes any naturally-occurring amount of the substance).

New section S29—8: this provision deals with nutritive substances which follow-on formula may contain for the purposes of subsection 2.9.1—9(2) i.e. the addition of these substances in follow-on formula would be optional.

Subsection 2.9.1—9(2) permits follow-on formula to contain nutritive substances listed in the table to new section S29—8 provided that their amount of the substance in the formula (including any naturally-occurring amount) complies with the corresponding limits in the table.

The Note to subsection 2.9.1—9(2) explains that is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 3 of that table.

The table to new section S29—8 sets out the nutritive substances that follow-on formula may contain; and their corresponding limits. The table has four Columns. Column 1 lists the nutritive substances; and for each substance:

- Column 2 sets out *any* minimum amount per 100 kJ;

- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ' (this term is explained in the Note to new section S29—8 below).

The Note to section S29—8 identifies and explains for readers the operation of column 4 of the table to that section. This Note explains that it is recommended that follow-on formula contain a nutritive substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only. It is recommended that the amounts specified in column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

In summary:

- it is optional (i.e. not mandatory) for follow-on formula to contain a nutritive substance listed in Column 1 of the table to new section S29—8;
- if a follow-on formula contains a nutritive substance listed in Column 1 of the table, the follow-on formula must comply with any corresponding minimum and / or maximum limits for that substance which are set out in the table;
- the amount of the nutritive substance in the follow-on formula includes any naturally-occurring amount of the substance).

New section S29—9: this provision deals with permitted forms of nutritive substances in infant formula and follow-on formula for the purposes of paragraph 2.9.1—10(b).

Paragraph 2.9.1—10(b) requires that a nutritive substance in infant formula or follow-on formula, which is not a vitamin, mineral or electrolyte, must be in the permitted form listed in the table to section S29—9.

The table to new section S29—9 sets out the permitted forms of nutritive substances in infant formula and follow-on formula. The table has two Columns. Column 1 lists the nutritive substances and Column 2 lists the corresponding permitted form / forms for each substance.

The Note to section S29—9 explains that new section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products (for the purposes of paragraph 2.9.1—10(a)).

New section S29—10: this provision deals with the required format for a nutrition information statement for the purposes of Standard 2.9.1 as follows.

Paragraph 2.9.1—21(1)(c) provides that for the labelling provisions (as set out in Standard 1.2.1), if a label represents that an infant formula is lactose free or low lactose, the average quantity of lactose and galactose, expressed in grams, must be included in the statement required by section 2.9.1—25 and be in the same format as specified in the table to new section S29—10 for those substances.

Section 2.9.1—26 provides that the *Statement of nutrition information* required by section 2.9.1—25 for infant formula and follow-on formula (the Statement) must be in the same format specified in the table to new section S29—10, and state the nutrition information in the order specified in the table. Also, specific information contained in the Statement must be in the format specified in the table.

The table to new section S29—10 sets out the required format for the Statement.

The table has two Columns. Column 1 lists the nutrients and / or subgroup nutrients for the purposes of requirements in section 2.9.1—25. Column 2 sets out the corresponding average quantity per 100 mL of prepared formula for each nutrient / subgroup nutrient.

The Note to section S29—10 explains that:

- Where an asterisk (*) is placed next to a nutrient or subgroup nutrient in the table, it refers the reader to the related explanation provided in this Note.

- Entries and amounts for the following only need to be included when stated in accordance with subsection 2.9.1—25(2):

  - whey;
  - casein;
  - long chain polyunsaturated fatty acids;
  - docosahexaenoic acid;
  - eicosapentaenoic acid;
  - arachidonic acid.

- Entries and amounts for lactose and galactose only need be included when stated in accordance with subparagraph 2.9.1—21(1)(c).

- The heading ‘Other nutrients’ only need be included when required by subsection 2.9.1—26(2)(d)(ii).

- Entries and amounts for choline, inositol and L-carnitine are included under the heading ‘Other nutrients’ when required by paragraph 2.9.1—26(4)(a) and under the heading ‘Additional’ when required by paragraph 2.9.1—26(4)(b).

7.2 Item [2] of Schedule 1 of the draft variation would insert new section S29—23 after existing section S29—22.

New section S29—23: this provision deals with permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes, for the purposes of the following provisions in Standard 2.9.1:

section 2.9.1—10(a)	This provision requires a nutritive substance in infant formula or follow-on formula, which is a vitamin, mineral or electrolyte, must be in the permitted form listed in the table to new section S29—23.
section 2.9.2—4	This provision deals with additional compositional requirements for cereals for infants (from the age of 6 months) and permits such food to contain added iron; as well as thiamin, niacin, vitamin B6, vitamin C, folate, magnesium; in forms permitted in the table to new section S29—23.

section 2.9.2—5	This provision deals with additional compositional requirements for cereal-based food for infants from the age of 4 months and permits such food to contain added iron; and vitamin C to a maximum amount of 90 mg/100 g on a moisture free basis, both in forms permitted in the table to new section S29—23.
section 2.9.2—6	This provision deals with additional compositional requirements for non-cereal-based food for infants and permits fruit-based food to contain vitamin C or folate or both in the permitted forms set out in the table to new section S29—23.
section 2.9.3—3(2)(c)(iii)	This provision deals with compositional requirements for formulated meal replacements and permits vitamin K to be used as a nutritive substance in a formulated meal replacement if the vitamin is in a permitted form specified in the table to new section S29—23.
2.9.5—6	This provision deals with substances that may be added to food for special medical purposes; and permits substances that are both listed in Column 1 of the table to new section S29—23; and in a corresponding form listed in Column 2 of that table.

The table to new section S29—23 sets out the relevant vitamins, minerals and electrolytes; and their permitted form(s).

Schedule 2

Schedule 2 of the draft variation amends Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5, Schedules 8, 15, 19 and 25 of the Code.

Item [1] amends subsection 1.1.2—2(3) by inserting a definition of 'inner package' in relation to special medical purpose products for infants. The definition provides that 'inner package', in relation to special medical purpose products for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and
(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

An example is included as a note at the end of the definition. The example provided 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.

Item [2] amends subsection 1.1.2—2(3) by repealing the definition of 'protein substitute'.

This intent of this variation is to enable infant formula or follow on formula that uses a protein substitute (existing Standard 2.9.1—10) to meet the new Standard 2.9.1—6 which provides

that infant formula and follow-on formula must be only derived from one or more of the proteins listed in that subsection. This change reflects the amendments to Division 4, where the subsection 2.9.1–15 'Products for specific dietary use based on a protein substitute' has been repealed and replaced with requirements for special medical purpose products for infants.

Item [2A] amends subsection 1.1.2—2(3) by repealing the definition of 'medium chain triglycerides'.

The intent of this variation is to remove a definition that is self-explanatory and not needed.

Item [3] amends subsection 1.1.2—2(3) by repealing and replacing paragraph (c) of the definition of 'warning statement' . The new paragraph refers to 'subsection 2.9.1—22(1) (warning statements for infant formula product)'.

Item [4] amends subsection 1.1.2—3(2) by inserting a definition of 'special medical purpose product for infants'. The definition provides that 'special medical purpose product for infants' is a food that meets each of the following criteria.

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as being specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food).
- It is represented as being suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product.
- It is represented as being for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and
- It is intended to be used under medical supervision; and
- It is not suitable for general use.

The intent of this variation is to differentiate those specialised products that are intended for infants with a disease, disorder or medical condition from infant formula and follow on formula intended for healthy infants. The definition is intended to ensure that 'special medical purpose product for infants' are captured as an 'infant formula product' but for public health and safety reasons, are appropriately separated from products intended for healthy infants.

The definition is also intended to remove current ambiguity in Division 4 of Standard 2.9.1 which categorises both high risk and low risk infant formula products under three subsections.

The definition is intended to accurately capture infant formula products formulated for a disease, disorder or medical condition that are used as sole source of nutrition, and exclude other foods designed for infants that are not represented as sole source of nutrition and act as a supplementary or modular formulation.

Item [5] amends subsection 1.1.2—3(2) by repealing the definition of 'follow-on formula' and substituting a new definition. The new definition provides that 'follow-on formula' is a food that meets each of the following criteria:

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as either a breast milk substitute or replacement for infant formula,
- It is represented as being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

The intent of this variation is to ensure products that represent themselves as 'follow-on formula' are correctly directed to be regulated under Standard 2.9.1.

Item [6] amends subsection 1.1.2—3(2) by repealing the definition of 'infant formula' and substituting a new definition. The new definition provides that 'infant formula' is a food that meets each of the following criteria:

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as being a breast milk substitute for infants.
- It is represented as satisfying by itself the nutritional requirements of infants under the age of 4 to 6 months.

The intent of this variation is to ensure products that represent themselves as 'infant formula' are correctly directed to be regulated under Standard 2.9.1.

Item [7] amends subsection 1.1.2—3(2) by repealing the definition of 'infant formula product' and substituting a new definition. The new definition provides that 'infant formula product' means a food that meets each of the following criteria.

- It is a product based on milk or other edible food constituents of animal or plant origin.
- It is represented as being nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

Item [8] amends subsection 1.1.2—3(2) by repealing the definition of 'pre-term formula'.

This change reflects the amendments in Division 4, as there is no longer a subsection for 'pre-term formula' the definition is no longer needed.

Item [9] repeals and replaces paragraph 1.2.3—6(4)(b). The new paragraph refers to 'a special medical purpose product for infants.'

Item [10] repeals and replaces Note 2 to subsection 1.2.3—6(4). The new Note 2 states that Division 4 of Standard 2.9.1 applies to special medical purpose products for infants and sets out compositional and labelling requirements for such food.

Item [11] amends subsection 1.3.1—3(2) by inserting '(other than an infant formula product)' after 'any food'. The change is to ensure that the carry-over of food additives noted in subsection 2 does not apply to infant formula products.

Item [12] repeals and replaces paragraph 1.3.1—4(6)(k) with new paragraphs 1.3.1—4(6)(k) and 1.3.1—4(6)(l). Paragraph 1.3.1—4(6)(k) remains unchanged and states that 'rosemary extract is calculated as the sum of carnosic acid and carnosol'. Paragraph 1.3.1—4(6)(k) is a new provision and provides that 'phosphoric acid and phosphates are calculated as phosphorus'.

Item [13] repeals and replaces section 1.5.1—3 and the Note to that section. The current section 1.5.1—3 permits a food for retail to sale to consist of, or contain as an ingredient, any novel food listed in the table to section S25—2, provided that any conditions of use specified in that table for that novel food are complied with.

The new section 1.5.1—3 comprises subsections 1.5.1—3(1) and (2) and a Note to subsection 1.5.1—3(1).

The new subsection 1.5.1—3(1) restates the current section 1.5.1—3 with one change. The

change is that the subsection states that it and the permission that that subsection provides do not apply to an infant formula product.

The Note to subsection 1.5.1—3(1) restates the current Note to section 1.5.1—3.
New subsection 1.5.1—3(2) sets out when an infant formula product may consist of, or have as an ingredient, a novel food. The subsection provides that this shall be permitted only when and if each of the following criteria is met.

- The novel food is listed in the table to section S25—2.
- The table to section S25—2 expressly permits the presence of that novel food in that infant formula product (i.e., the table contains an express permission).
- Any conditions of use specified for that novel food in the table to section S25—2 are complied with.

The intent of this variation is to clarify existing requirements that novel foods must be assessed through a pre-market approval process before use in infant formula products and to unambiguously set out novel food permissions in S25—2.

Item [14] amends section 2.9.2—4 by omitting 'section S29—7' wherever occurring in section 2.9.2—4, and substituting 'section S29—23'.

Item [15] amends section 2.9.2—5 by omitting 'section S29—7' wherever occurring in section 2.9.2—5, and substituting 'section S29—23'.

Item [16] amends subsection 2.9.2—6(3) by omitting 'section S29—7' and substituting 'section S29—23'.

Item [17] amends subparagraph 2.9.2—3(2)(c)(iii) by omitting 'section S29—7' and substituting 'section S29—23'.

Item [18] amends paragraph 2.9.5—6(1)(b) by omitting 'section S29—7' and substituting 'section S29—23'.

Item [19] amends the table to section S8—2 (food additive names—alphabetical listing) by inserting two new entries into that table. The two new entries are:

Potassium hydroxide	525
Sodium hydroxide	524

Item [20] amends the table to section S8—2 (food additive names—numerical listing). by inserting two new entries into that table. The two new entries are:

524 Sodium hydroxide

525 Potassium hydroxide

Item [21] amends the table to section S15—5 by:

- repealing the food classes 13.1 (Infant formula products), 13.1.1 (Soy-based infant formula), 13.1.2 (Liquid infant formula products), and 13.1.3 (Infant formula products for specific dietary use based on a protein substitute); and

- replacing these with new food classes 13.1 (Infant formula products) and 13.1.1 (Special medical purpose products for infants).

The new table of food additive permissions now only has two food classes (categories), with the higher class of infant formula products which includes follow-on formula, and the sub-class of special medical purpose products for infants. The table includes new food additive permissions, especially for special medical purpose products for infants as an outcome of the safety assessment conducted and aligning with international regulations. Detailed condition statements have also been added as required.

Item [22] inserts a new entry into the table to section S19—4 (Maximum levels of metal contaminants). The entry is:

Aluminium	Infant formula and follow-on formula	0.5
	Special medical purpose products for infants formulated for pre-term infants	0.2

This amendment has removed the contaminant limits for aluminium from Standard 2.9.1 and added it to the contaminants schedule, Schedule 19 with other metals. It has also provided a single contaminant level for infant formula and follow on formula by removing the entry for soy-based formula which was at twice the level. The change has been made so all contaminant levels are in the relevant Schedule of the Code and also for public health and safety reasons.

Item [23] inserts a new entry into the table to section S19—4 (items dealing with 'Lead'). The entry is:

Infant formula products	0.01

The entry for the contaminant level for lead in infant formula products has been reduced from 0.02 to 0.01 mg/kg for public health and safety reasons.

Item [24] amends subsection S25—2 by repealing and replacing the permission and condition of use for the novel food 'Oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695)'. The effect of the amendment is to change the condition of use to 'May only be added to infant formula products'.

Item [25] amends subsection S25—2 by repealing and replacing the permission and condition of use for the novel food 'Isomalto-oligosaccharide'. The effect of the amendment is to change the conditions of use to provide that isomalto-oligosaccharide must not be added to food for infants and to formulated supplementary food for young children. The amendment reflects that new subsection 1.5.1—3(2) will now prohibit the addition of novel foods - such as isomalto-oligosaccharide - to infant formula products unless expressly permitted. The condition for 'Isomalto-oligosaccharide' for foods for infants (Standard 2.9.2) and for formulated supplementary food for young children (Standard 2.9.3) is retained as it is out of scope for P1028.

Item [26] amends subsection S25—2 by repealing and replacing the condition of use for the novel food 'Rapeseed protein isolate'. The effect of the amendment is to change the condition of use to provide that that novel food must not be added to food for infants. The amendment reflects that new subsection 1.5.1—3(2) will now prohibit the addition of novel foods to infant formula products unless expressly permitted.

As above, removing the clause for ‘Rapeseed protein isolate’ for food for infants (Standard 2.9.2) is out of scope for P1028.

Item [27] amends subsection S25—2 by repealing and replacing the permission and condition of use for the novel food ‘trehalose’. The effect of the amendment is to change the condition of use to provide an express permission for the purposes of new subsection 1.5.1—3(2) for that novel food’s addition to, and presence in infant formula products. The new condition of use provides that trehalose may only be added to infant formula products as a cryo-preservative for L(+) lactic acid producing microorganisms.