4 April 2022

Call for submissions –Proposal P1028

Infant Formula

FSANZ has assessed a proposal to revise and clarify standards for the composition, labelling, category definitions and representation of infant formula products. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

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. Electronic submissions can be made through the FSANZ website via the link how to make a submission. You can also 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) 10 June 2022

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:

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Supporting documents
The following attached documents informed the assessment of this Proposal:

SD1 Safety and food technology
SD2 Nutrient composition for infant formula products
SD3 Provision of information
SD4 Special medical purpose formula for infants
SD5 Consideration of costs and benefits
SD6 Assessment against Ministerial Policy Guidelines

Abbreviations and glossary

Abbreviation or Term	Meaning
ACNF	Advisory Committee on Novel Foods
ARA	Arachidonic acid
Breast milk	A general term for human milk provided from a mother's breast (described as mature milk to distinguish it from colostrum).
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CFS	Call for submissions
Codex	Refers to Codex Alimentarius
Codex Draft Standard for FuFOI	Refers to the Proposed Draft Revised Standard for Follow-up Formula, Section A: Follow-up Formula for Older Infants (see 22REP/NFSDU Appendix III)
Codex CXS 72-1981	Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
CP	Consultation paper
CRIS	Consultation Regulation Impact Statement
DHA	Docosahexaenoic acid
EPA	Eicosapentaenoic acid
EU	European Union
EU 2016/127	European regulation on compositional and information requirements for infant formula and follow-on formula
Follow-on formula (FOF)	An infant formula product that is represented as either a breast milk substitute or replacement for infant formula and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months, as defined in Standard 1.1.1 of the Code.
Follow-up formula (FUF)	Under CODEX CXS 156-1987, this is a food intended for use as a liquid part of the weaning diet for older infants (age 6-12 months) and for young children (age 12 -36 months).
FSANZ Act	*Food Standards Australia New Zealand Act 1991*
FSFYC	Formulated supplementary food for young children
FSMP	Food for special medical purposes
IFPSDU	Infant formula products for special dietary use
Infant	A person under the age of 12 months, as defined in Standard 2.9.1
Infant formula (IF)	An infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months, as defined in Standard 1.1.1 of the Code

Abbreviation or Term	Meaning
Infant formula products (IFP)	Products based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants; as defined in Standard 1.1.1 of the Code
Infant formula products for special dietary use (IFPSDU)	An infant formula product listed in Division 4 of Standard 2.9.1
Infant formula products for special medical purpose (IFPSMP)	Category of IFSPDU under the regulatory framework proposed in FSANZ 2021 CP3
INC	Infant Nutrition Council
MAIF Agreement	The Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement
ML	Maximum Level
MPL	Maximum Permitted Level
Ministerial Policy Guideline	The policy guideline on infant formula products
NIS	Nutrition information statement
OBPR	Office of Best Practice Regulation
SD	Supporting document
SMPPi	Special medical purpose products for infants
The Code	Australia New Zealand Food Standards Code
WHO	World Health Organization
WHO Marketing Code	WHO International Code of Marketing of Breast-milk Substitutes
WTO	World Trade Organization

Executive summary

Proposal P1028 Infant Formula reviews the regulatory requirements for infant formula products. We have sought to clarify or revise standards for 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 1st Call for Submissions (CFS) summarises the assessment for P1028. Each individual requirement of the standard has been considered and in most cases a preferred option presented. Requirements were reviewed through scientific risk assessment, analysis of international regulations and consultation with key stakeholders. Given the broad scope of this proposal, FSANZ released a number of consultation papers prior to this CFS, each focused on key aspects of infant formula regulation. Submitter input to these consultation papers was an important source of information for the assessment.

Key conclusions and preferred options are summarised on the following page. FSANZ now calls for stakeholder comments on these options. Submissions received will inform FSANZ's decision on whether to prepare a draft variation to amend the Code and, if so, on the nature of those amendments. Further public consultation will occur if, after consideration of submissions received in response to this 1st CFS, FSANZ prepares a draft variation.

1st CFS P1028 – Summary of key conclusions and preferred options for regulatory changes

SD1 - Safety and food technology

- Classifications for FA permissions: 13.1.1 IFP & 13.1.2 SMPPi.
- Carry over permission to be removed.
- Harmonisation of FA permissions (MPL and conditions) to align with EU and Codex as much as possible.
- Noting many SMPPi are manufactured in EU, consistency with EU regulations is important.
- Contaminants: amended MLs proposed for aluminium and lead; all others either no ML or no change from status quo.
- L(+) lactic acid permission to be amended "for acidification purposes".
- Changes to safety-related labelling requirements include revising two directions and a warning statement, proposing a new direction and clarifying the protein source statement.

SD3 – Provision of information

- Prescribe format of NIS in accordance with recommended format in the existing guideline in Schedule 29.
- Prescribe wording in the NIS for macronutrients.
- Only permit ingredient information in the statement of ingredients (except for ingredients like nutritive substances that must be declared in the NIS).
- Seeking comments on (1) format of the NIS (2) stage labelling and proxy advertising related only to IFP, and (3) specific labelling of partially hydrolysed formula as a modified IFP.

CFS

- The regulatory framework has been revised into two separate categories (See Figure 2). IFP serves by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant (infant formula and follow-on formula). High risk specialised infant formula products will form their own category to be known as SMPPi.
- Name of Standard 2.9.1 and definitions for IFP, IF, FOF, and SMPPi to be amended or introduced to reflect these categories.
- Definitions for protein substitutes, soy-based IF, pre-term formula and MCTs are proposed to be removed.
- Human milk fortifiers and pre-term supplementary products proposed to be included in SMPPi category.
- Pre-market assessment requirements for novel foods and nutritive substances to be considered as part of the broader review of these substances for all food categories (P1024).
- Clarify pre-market assessment requirements by amending novel food definition to reflect the intended consumer population for these foods.
- Schedule 25 proposed to be amended to restrict certain novel foods that were not assessed for the infant population from being used in IFP. The restriction will not be applied to FSFYC.
- The costs of this proposal are likely to be outweighed by the benefits. Benefits include IFP & SMPPi remaining safe and suitable for their intended purpose, regulatory clarity, greater international alignment and minimised trade barriers.
- Due regard has been given to all relevant principles of the Ministerial Policy Guidelines.
- FSANZ's review of infant formula regulations included developing a new guideline for application requirements that would reflect the Ministerial Policy Guideline. This was completed in 2013.

SD2 – Nutrient composition

- Protein sources prescribed as cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate (section 2.1.2).
- Modified formulas, including partially-hydrolysed & low-lactose/lactose-free, categorised as IFP.
- LC-PUFA's (specifically DHA), nucleotides, taurine and lutein to retain voluntary permission within Standard 2.9.1 (sections 2.1.2, 2.5.2, 4.4).
- Nutritive substances including choline, L-carnitine and inositol to be listed as mandatory substances within infant formula (section 2.5.2).
- FOF composition deviates from IF for calcium, L-carnitine, choline and myo-inositol (section 3).

SD4 – SMPPi

- SMPPi are to align with the infant formula nutrition composition (detailed in SD2), except where required to address the specific disease, disorder or medical condition the product is intended for (see section 2).
- Labelling incorporates several measures from Standards 2.9.1 and 2.9.5 where appropriate to address the products' special medial purpose (see section 3).

Abbreviations: IFP = infant formula products, IF = infant formula, FOF = follow-on formula, IFPSDU = infant formula for special dietary use, SMPPi = special medical propose product for infants, FA = food additive, MPL = maximum permitted level, ML = maximum level, FSFYC = formulated supplementary foods for young children, MCT = medium chain triglycerides, NIS = nutrition information statement

1 Introduction

1.1 The Proposal

Breastfeeding is the recommended way to feed a baby. Infant formula and follow-on formula (FOF) are the only safe and nutritious substitute for breast milk for infants who are not breastfed. 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 contain 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 food additives, contaminants, labelling 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 ensures that infant formula products remain safe and suitable, account for market developments and reflect changes in the international regulatory context.

The outcome of the proposal 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*
- align with relevant international and overseas regulations, as appropriate in the Australian and New Zealand context.

1.3 Scope

This paper summarises FSANZ's assessment for the proposal in accordance with the FSANZ Act. The assessment included all aspects of Standard 2.9.1 and Schedule 29, and covered the infant formula products listed in Table 1.2. It also includes revision of standards related to infant formula products in the Code, and any consequential amendments.

Proposal P1028 does not include:

- Products marketed as toddler milks, which are designed for children aged one to three years. 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). New permissions for forms of nutrients and food additives may be considered in future if permitted in relevant overseas or international regulations.
- Review of nutrient definitions (such as trans-fatty acids, carbohydrates).
- Code requirements, such as significant figures or definitions.

Initially Proposal P1028 was intended to include only infant formula and not infant formula products for special dietary use (IFPSDU) or FOF (FSANZ 2016). This decision was taken to limit the size of the project and, for FOF, 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 (see section 1.4). Many stakeholders supported inclusion of FOF and specialised infant formulas in P1028. 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 P1028.

Additionally the review of the Codex Standard for Follow-up Formula (CODEX CXS 156-1987) has 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 FOF (6 - 12 months) and the European Union (EU) regulation for FOF (EU 2016/127). FSANZ notes the Proposed Draft Revised Standard for Follow-up Formula: Section A: Follow-up Formula for Older Infants[1] (Codex Draft Standard for FuFOI), incorporating provisions for composition and labelling, is now at Step 7,the final step prior to being submitted to the Codex Alimentarius Commission for adoption.

The scope of Proposal P1028 now includes the topics of specialised infant formulas and follow-on formula (Table 1.2).

Table 1.3 Products included in the scope of P1028

Infant formula products	
Infant formula	Infant formula based on mammalian sources of milk (e.g. cow milk, goat milk)
	Infant formula based on edible constituents of plant origin (e.g. soy)
Follow-on formula	Infant formula based on mammalian sources of milk (e.g. cow milk, goat milk)
	Infant formula based on edible constituents of plant origin (e.g. soy)
IFPSDU	Lactose free formula and low lactose infant formula
	For premature or low birth weight infants
	For metabolic, immunological, renal, hepatic and malabsorptive conditions
	For specific dietary use based upon protein substitutes
	Hydrolysed (partially or extensively) infant formula

[1] 22REP/NFSDU Appendix III, Section A: Follow-up Formula for Older Infants

1.4 Procedure for assessment

This proposal is being assessed under the Major Procedure requirements of the FSANZ Act, which require two rounds of public consultation. Any draft variation of the Code will be provided for comment at the next round of public consultation. Following this, FSANZ will consider a final draft variation of the Code, and if approved, provide the variation to the Food Ministers' Meeting for consideration.

1.5 Previous public consultation for P1028

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 requirements 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. Generally, specific stakeholder comments have not been directly addressed in this call for submissions report (CFS) but are noted and responded to specifically as needed.

Details of previous consultation undertaken for P1028 are listed in Table 1.4. As applicable, reference to these papers are cited throughout this CFS including Supporting Documents (SD). The CPs and submissions are available on the FSANZ website.[2]

Table 1.5 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 2016a)	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 products for special dietary use (FSANZ 2017)	August 2017	I**nfant formula for special dietary use:** regulatory framework, organisation of products subcategories, definitions, product 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, 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 IFP, definitions for IFP, regulatory framework and detailed approach to regulation of IFPSDU, labelling considerations for IFPSDU.

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

1.6 The current regulatory environment

Standard 2.9.1[3] was finalised in 2002 after 10 years of development (ANZFA, 2002). The standard specifically regulates the compositional and labelling requirements for infant formula products and applies to all infant formula products whether in powder, liquid concentrate or 'ready-to-drink' forms. Standard 2.9.1/Schedule 29 is the most prescriptive of all standards in the Code that regulate a food category. The intent of Standard 2.9.1/Schedule 29 includes the following key aspects:

- mandatory composition for infant formula and follow-on formula
- restrictions on the addition of substances (vitamins, minerals, food additives and other substances) unless expressly permitted
- labelling requirements for safe preparation and use and informed choice (specifically prohibits some types of representations on product labels).

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 Standard 2.9.1/Schedule 29 were considered through the assessment for P1028 and are noted in this CFS and SDs.

Additional general background information was provided in the 2016 CP (FSANZ, 2016). This included the history of the regulation of infant formula products, international regulations, infant feeding guidance and the Australian and New Zealand market place. Specific background information to individual topics is covered where relevant in this CFS and SDs.

We note several new permissions and changes to current compositional requirements have been made to Standard 2.9.1/Schedule 29 through the application process since the start of this proposal (Table 1.5). No substantive changes to the mandatory composition, definitional or labelling requirements have been made since the gazettal of the standard in 2002.

Table 1.6 New permissions or changes to standards for infant formula products since 2002

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

[3] The proposal P1025 Code Revision (completed in 2016) changed the structure of Standard 2.9.1 so that groups of prescribed requirements are listed in Schedule 29.

Since 2011 when a review of infant formula regulations was proposed, FSANZ has completed two additional projects that were separate to Proposal P1028:

(1) Amendments to the Application Handbook. Part 3 of the *Application Handbook* contains guideline requirements made under section 23 of the FSANZ Act. Guidelines specify the form or kinds or information that must be included in applications to amend the Code. Following notification to FSANZ of the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (in May 2011), a new guideline specific to infant formula products for inclusion in the *Application Handbook* was developed. The new guideline reflects the data requirements for applications that are needed to satisfy the Ministerial Policy Guideline. The *Application Handbook* containing the new guideline came into effect in August 2013.

(2) Proposal P1039 - Micro criteria for infant formula. This proposal reviewed microbiological limits set by Standard 1.6.1 and Schedule 27 to ensure infant formula microbiological limits reflect recent scientific knowledge and approaches to food safety. The proposal was completed in March 2016.

1.7 Risk assessment and consideration of the evidence

Risk assessments were completed across a number of topics. Reports for the assessments were published with previous CPs in 2016, 2017 and 2021. Conclusions from risk assessments are considered and cited in this CFS and SDs where applicable. The risk assessments that have been completed are:

- Nutrition assessment (FSANZ 2016a)
- 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).

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

- Microbiological safety of powdered infant formula: Effect of water temperature on risk (Attachment to SD1)
- Consumer research on infant formula labelling (Attachment to SD3).

2 Regulatory framework

Standard 2.9.1 regulates various types of infant formula products including:

- infant formula for 0 - 12 months
- follow-on formula for 6 - 12 months, and
- infant formula for special dietary use (several subcategories).

During the development of Standard 2.9.1, FSANZ's predecessor (ANZFA) noted that although specialised infant formula was captured in the regulation of infant formula products (as IFPSDU), there was some overlap with the features of Food for Special Medical Purposes (FSMP). At the time, it was suggested that highly specialised infant formula products could later be transferred to a standard for FSMP once it was developed. However,

during Proposal P242 – Foods for Special Medical Purposes[4], FSANZ proposed instead to consider infant formula for special medical purposes in a forthcoming review of Standard 2.9.1.

In the 2016 and 2017 consultations for this proposal, retaining the provisions for specialised infant formula products in Standard 2.9.1 was considered to be the appropriate approach. This was mainly because if requirements for IFPSDU were to be removed from Standard 2.9.1 and placed into Standard 2.9.5 – Food for Special Medical Purposes, all composition and safety requirements relevant to infant formula products would also have to be incorporated into Standard 2.9.5. Stakeholders did not support this option.

2.1 Current regulations

2.1.1 Australia and New Zealand

Standard 2.9.1 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.

Schedule 29 prescribes information for Standard 2.9.1 covering calculations, permitted nutritive substances, amino acid minimums, required amounts and permitted forms of vitamins, minerals, and electrolytes, fatty acid limits, and guidelines.

Figure 1 presents an overview of the current regulatory framework for products covered under Standard 2.9.1.

2.1.2 International

Codex Alimentarius

Codex Alimentarius, through the Codex Committee for Nutrition and Special Dietary Uses (CCNFSDU), updated its infant formula standard in 2007 to include new provisions in Section B for formula for special medical purposes intended for infants. Section B sets out the composition, quality, labelling and safety requirements by referencing the requirements for infant formula in Section A, where appropriate. It also draws on the Codex provisions for labelling of FSMP (Codex CXS 180-1991).

European Union

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

[4] which led to the development of Standard 2.9.5

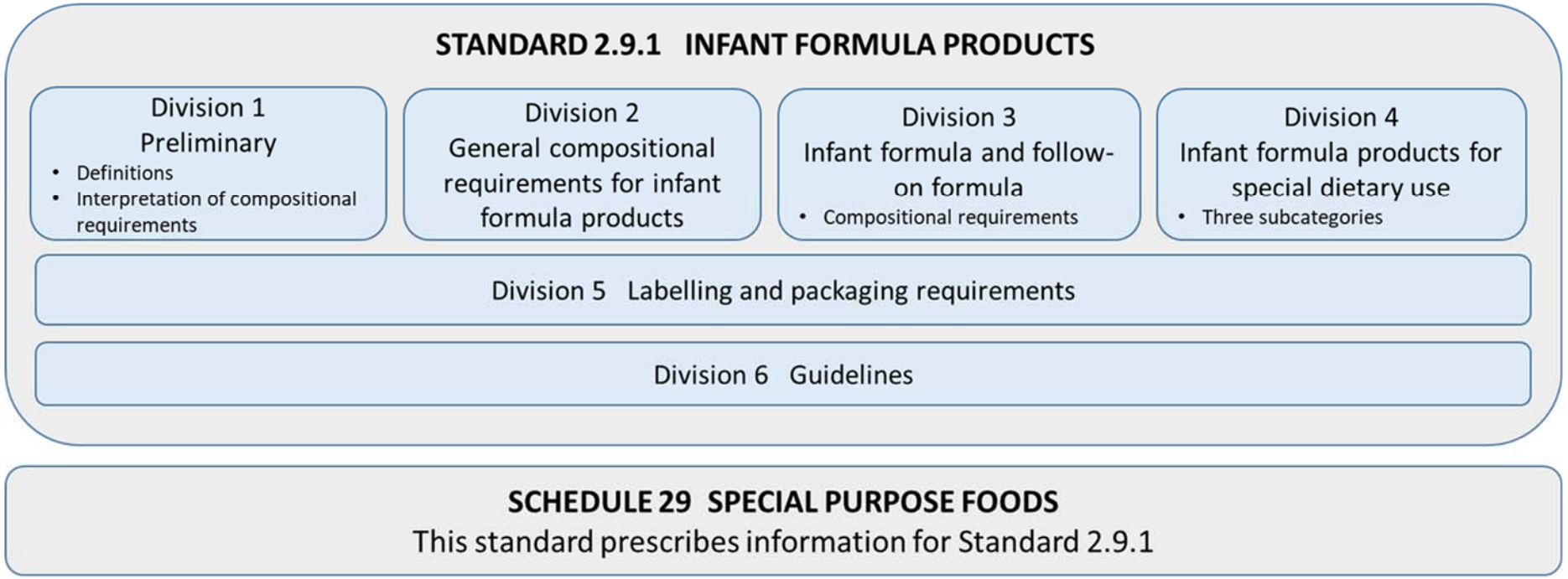

Figure 1 Code requirements for infant formula products

Note: Standard 2.9.1 applies only to infant formula products. Formulated supplementary food for young children (also referred to as 'toddler milks') are not infant formula products and are regulated by Standard 2.9.3.

2.2 Previous consultations on the regulatory framework

FSANZ has undertaken extensive consultation on the regulatory framework, focused mainly on specialised infant formula products currently covered under Division 4. This has included multiple rounds of public consultation and targeted consultation on specific issues and potential options to inform this proposal. The main issues or problems to be addressed, as identified in these papers, were:

- There are areas of regulatory uncertainty related to the broad nature of the current subcategories, the range of products in each category and related definitions. It is not always clear which category products fall into and what their requirements are.
- The range of available products may pose different risks depending on their specialised nature. Some IFPSDU are not safe for use by healthy infants, while others can be consumed with little risk of harm.
- Categorisation by condition is not useful as many can be used for multiple conditions. No consistent approach is used internationally. There is a need to more clearly include supplementary or modular products that can be used in combination to meet an individual infant's special requirements.
- The current approach is not well harmonised with the EU, which is the source of most products.
- Potential increased regulation for products for transient gastrointestinal conditions such as: restricted sale in relation to protein modified and lactose free/low infant formula products; level of evidence to support product on market; labelling requirements to ensure caregivers are not misled.

Developing the most appropriate approach to address these issues/problems has been a significant challenge in P1028. This is because many of the specialised infant formula products are only manufactured overseas and therefore consistency with international regulations is critical to ensure products are available for the infants that need them.

In 2017 and 2021, FSANZ proposed two potential regulatory frameworks for specialised infant formula products. The first approach was opposed by all stakeholders with numerous alternative options proposed by submitters. These were summarised in the FSANZ 2021 CP3 (FSANZ 2017).

A second approach was subsequently proposed in 2021 (FSANZ 2021c), incorporating a set of distinct principles to underpin and guide a proposed framework for regulating the composition, use of and access to specialised infant formula products.

These consolidated principles are that specialised infant formula products:

- serve as a sole or principal source of nourishment
- serve as a substitute for human milk, and replacement for infant formula and follow-on formula
- are formulated for infants with a specific disease, disorder or medical condition
- are intended to meet an infant's nutritional requirements to support growth and development
- are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose
- have a nutrient composition that reflects that of IF or follow-on formula except where necessary to meet the intended purpose
- are intended for use under medical supervision to manage risk to unhealthy infants
- used in infancy and beyond should be accommodated in regulation
- are subject to a restriction on sale.

These principles were not intended to be set in regulation. Nor do they replace the requirements of the FSANZ Act and the assessment criteria prescribed by that Act, but are important to underpin and guide the framework of the regulation of specialised infant formula products.

The key element of the proposed framework was that it would regulate specialised infant formula products under a single category with risk management approaches that were based on the risks associated with the highest risk products i.e. those that were formulated for infants with serious, potentially life threatening diseases or conditions.

Table 2.2 summarises the key elements of the current regulatory framework for Standard 2.9.1 and each of the proposed approaches from 2017 and 2021.

Table 2.2 Key elements of regulatory requirements for IFPSDU considered in P1028

Element	Current Code requirements	Proposed in 2017	Proposed in 2021
Framework	IFPSDU requirements listed in Division 4 - Infant formula products for special dietary use.	IFPSDU to include four subcategories: • products for special dietary use based on a protein substitute • products for transient gastroenterological conditions • products for premature or low birthweight infants • products for special medical purposes.	IFPSDU to become one category that includes both low and high risk specialised infant formula product.
Definitional elements	No defined term for IFPSDU. Three subcategories - products for: • pre-term and low birthweight infants • metabolic, immunological, renal, hepatic and malabsorptive conditions • specific dietary use based on a protein substitute.	**Retain** the name and category IFPSDU **New definition** – IFPSDU means an IFP that is specifically formulated: (a) for an infant with a specific disorder, disease or medical condition; (b) to satisfy, either partially or fully, the special nutritional requirements of that infant; and (c) to be used under medical supervision. **New subcategory** Infant formula products for special medical purpose (IFPSMP) **New definition** for IFPSMP means an IFPSDU: (a) for an infant who has: i. medically determined nutrient requirements ii. limited or impaired capacity to take digest, absorb, metabolise or excrete food, including another type of infant formula products.	• Serves as substitute for human milk, and replacement of Infant formula and follow-on formula • Formulated on basis of scientific evidence • Is for infants who have special medically determined nutrient requirements • Limited or impaired capacity to take digest, absorb etc. • Whose dietary management cannot be managed without use of the special infant formula product • for use under medical supervision.
Compositional elements	Compositional requirements are detailed in Division 4 and differ based on the three subcategories noted above.	FSANZ did not propose compositional requirements in 2017 and instead sought input from stakeholders.	Deviation from general composition extended to all IFPSMP. Current provisions for energy range, maximum protein, minimum fat, PRSL in protein substitutes and the guideline level for manganese were proposed to be removed. Nutrient composition of all IFPSMP proposed to reflect that of infant formula or follow-on formula except where necessary to meet the intended purpose of the product.

Evidence of purpose	Not specified within Standard 2.9.1.	FSANZ did not consider this element within the FSANZ 2017 CP.	Scientific evidence to support the categorisation of products as IFPSMP to be enshrined in regulation.
Extension of use beyond infancy	Not specified within Standard 2.9.1.	FSANZ did not consider this element within the FSANZ 2017 CP.	Extension of use for IFPSMP beyond infancy may be appropriate in some circumstances.
Distribution and access	Not specified within Standard 2.9.1.	Considered issues around accessibility of pre-term infant formula through general sale.	Access to IFPSMP to be restricted to medical practitioners, responsible institutions, or permitted sellers.
Labelling[1]	A prescribed name and warning statement for pre-term infants. Mandatory labelling statements for products for metabolic, immunological, renal, hepatic and malabsorptive conditions. Food name and nutrition information statements for lactose free or low lactose products.	Sought stakeholder views about: • the need for prescribed names for IFPSDU and subcategories • the utility of the FSMP labelling statement about using the product under medical supervision in place of the warning statement for pre-term formula. Preliminary views that two existing exemptions for IFPSDU from Division 5 labelling requirements should remain.	Apply the provisions as follows to IFPSMP: • FSMP labelling statements in paragraphs 2.9.5—19(1)(a) to (f) and approaches consistent with FSMP provisions for ingredient and date marking information • directions for preparation and use in subsection 2.9.1—19(3). Not apply to, or exempt IFPSMP from: • 'Breast milk is best' warning statement • statements about offering other foods in addition to infant formula products and that the infant formula products may be used from birth Maintain existing labelling requirements for lactose free and low lactose formula.
Human milk fortifiers[2] **and pre-term supplementary products**	Not clearly captured by any subcategory in Division 4 of Standard 2.9.1 or by Standard 2.9.5 when related to infants.	FSANZ did not propose requirements for these products in 2017 and instead sought input from stakeholders.	FSANZ proposed to potentially regulate these products in Standard 2.9.5 and give further consideration to this approach at a later stage of the proposal.

[1] See also section 5.7 of FSANZ 2021 CP3 (FSANZ 2021c) where the assessment of this topic is addressed specifically.

[2] These refer specifically to bovine-derived (or other sourced) fortifiers to be added as supplementary nutritional ingredients to human milk. It does not refer to human milk-derived fortifiers which are human-tissue based substances that are not regulated under the Code and are out of scope for P1028.

2.3 Stakeholder views

Comments to the 2021 CP were provided by industry and government stakeholders. In line with previous consultations, all submitters confirmed that specialised infant formula products are best regulated under Standard 2.9.1 and not Standard 2.9.5.

2.3.1 Principles for purpose, composition, use and sale of specialised infant formula products

In general, submitters agreed with most of the aspects of the principles intended to underpin a regulatory framework for specialised infant formula products. However, some principles were difficult to reconcile with the feasibility of a proposed regulatory framework that would cover both high and low risk specialised infant formula products as a single category. For example, allowing flexibility in composition for those high risk products intended for seriously ill infants and, at the same time, requiring pre-market assessment for any new substances added to low risk infant formula products that can be consumed safely by healthy infants.

The principle related to the restriction of was strongly opposed by industry stakeholders. Additional summarised comments and FSANZ's responses are listed in Table 2.3.1.

Table 2.3.1 Stakeholder views regarding the regulatory framework principles

Stakeholder views	FSANZ response
Principles need further examination as some apply to all infant formula products, and some specifically to specialised infant formula	FSANZ recognises that some principles apply across both high and low risk specialised infant formula products and may not be meaningful or useful and has taken this into account in the proposed regulatory framework.
Unnecessary to repeat principles that are already part of the definition of infant formula products.	FSANZ agrees but notes that principles were not intended to replace definitions prescribed in the Code.
Composition requirements for specialised infant formula products need to be flexible & adaptable to advances in science and enable imported products meeting EU, CODEX or US regulations to be sold without amendment to the Code. These are products used under medical supervision.	FSANZ agrees and has taken this into account in the proposed regulatory framework for this CFS paper.
Do not support 'efficacy' being included in the principle for formulation based on scientific evidence. Considers alignment with the Ministerial Policy Guideline is more appropriate.	Noted. Comment is difficult to address when differentiation between low and high risk products needs to be considered. That is, formulation of low risk products (that can be consumed safely by healthy infants) should support normal growth and development but formulation for a high risk products needs to support the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition. It is difficult to consider efficacy in both contexts. FSANZ agrees that regard for the Ministerial Policy Guideline for low risk products is appropriate.
General agreement that the continued use of specialised infant formula products beyond infancy may be appropriate under the supervision of healthcare professional.	In line with submitter comments, FSANZ agrees that there may be need for healthcare professionals to determine the medical need to use a specialised infant formula product (i.e. high risk) and it would be unreasonable to regulate this within Standard 2.9.1.

Proposal of an additional principle that notes the regulation should incorporate protections regarding labelling, presentation, advertising, and promotional and commercial practices, with adjustments for necessary labelling relating to the intended purpose of the product.	FSANZ agrees and has taken this into account in the proposed regulatory framework for this CFS.

2.3.2 Regulatory framework

In relation to the regulatory framework proposed in the 2021 CP, the main comment from industry submitters was that the framework abrogated a risk-based categorisation by combining those IFPSDU products which are safe for consumption by healthy infants (i.e. low risk) with medical purpose products which are unsafe if consumed by a healthy infant (i.e. high risk). Thus, industry submitters opposed the proposed framework and suggested a two-tiered approach that separates low risk products (that are for the dietary management for a transient condition) from high risk products (that are for use under medical supervision for the dietary management of infants with a diagnosed disease, disorder, or condition).

Government submitters supported the proposed approach (a single category for all FSMP), however noted additional risk management would be needed to cover the potential increase in products that would fall under the single category. That is, subcategories would be needed to enable appropriate characterisation of purpose and ensure regulatory clarity.

Stakeholder views on the proposed regulatory framework in FSANZ 2021 CP3 (FSANZ 2021c) are summarised in Table 2.3.2.

Table 2.3.2 Stakeholder views regarding the regulatory framework proposed in FSANZ 2021 CP3

Summary of the issue	FSANZ response
Oppose categorising IFPSDU as IFPSMP as will lead to new products which mislead caregivers.	As discussed in section 2.4, FSANZ is now proposing a new regulatory framework which addresses this issue.
Oppose exemptions to the WHO International Code of Marketing of Breast-milk Substitutes labelling requirements for any infant formula product.	Noted. As discussed in section 2.4, FSANZ is now proposing that only high risk IFPSDU are Special Medical Purpose Products for infants (SMPPi). SMPPi are proposed to be exempt from certain provisions, noting these products are for use under medical supervision. See section 3 of SD4.
Regulatory gaps in IFPSMP regulations: use beyond 12 months, no reference to introduction of solid foods, and compositional requirements.	As discussed in section 2.4, FSANZ is now proposing that only high risk IFPSDU are SMPPi for use under medical supervision. See section 3 of SD4 for proposed labelling requirements .
Support the proposed approach for the single FSMP category with subcategories to be allowed if specific regulation beyond IFPSMP standard and provided there are sufficient risk management strategies put in place to manage the broadening of regulations to allow products for potentially any condition.	As discussed in section 2.4, the new proposed regulatory framework is accompanied by comprehensive risk management strategies, which include specific labelling requirements, use under medical supervision and restricted sale.
Concerned that marketing for the management of transient gastrointestinal conditions, including health claims, will be made about low risk IFPSMP.	As discussed in section 2.4, FSANZ is now proposing low risk IFPSMP are regulated as modified IFP and they are subject to the same labelling requirements (and prohibitions) as standard IFP. Labelling specific to 'lactose free' and 'low lactose' IFP and partially hydrolysed products is discussed in section 5 of SD3

2.4 Discussion

2.4.1 Infant formula products

The regulatory framework for infant formula products intended for healthy infants is proposed to be retained. The requirements in Standard 2.9.1 and Schedule 29 are intended to ensure that infant formula products are safe and suitable for consumption by an infant under the age of 12 months. This includes when products are consumed as a sole source of nutrition by an infant aged up to 4 to 6 months and as part of a progressively diversified diet, from 6 to 12 months.

Definitions of infant formula products and other terms are discussed in section 3.1.

2.4.2 Modified infant formula products

Given stakeholder views to separate low risk products (that are for the dietary management of a transient condition) from high risk products (that are for use under medical supervision for the dietary management of infants with a diagnosed disease, disorder, or condition), the proposed approach is to include a subcategory that deviates from the baseline infant formula or follow-on formula composition by only having modified protein and/or lactose free/low lactose content.

FSANZ is not proposing to define the proposed subcategory for modified infant formula products but the characteristics of these products 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.

The definition for protein substitute is proposed to be removed (see section 3.3). The conditions for lactose free/low lactose will be retained to provide regulatory certainty for these products in the Code (see section 4.4 of SD2). Any other infant formula product that deviates from the baseline infant formula or follow-on protein composition (such as use of an alternative protein source) would require pre-market approval (see section 2.1.2 and 4.4 of SD2).

Specific compositional requirements for hydrolysed protein and lactose free/low lactose infant formula products is covered in SD2 Nutrient composition.

Specific labelling requirements for these modified infant formula products are discussed in Section 5 of SD3.

2.4.3 Special Medical Purpose Products for infants (SMPPi)

Given the views of stakeholders in 2012, 2016, 2017 and 2021 and the widespread support for consistency with relevant Codex Standards and EU legislation, the proposed approach is to remove the category of IFPSDU within Standard 2.9.1 and the current specific subcategories contained within Division 4. Instead it is proposed a new category will be included for *Special Medical Purpose Products for infants* (SMPPi).

This proposed approach more clearly aligns with international regulations and with the intended purpose of specialised products for infants. It also retains these specialised medical purpose products for infants within Standard 2.9.1 as supported by stakeholders.

The proposed new approach allows for the inclusion of specialised supplementary or modular products specifically suitable and formulated for use in infants within Standard 2.9.1. These include bovine derived human milk fortifiers for pre-term infants and formula products which may not serve as the sole or principal source of nourishment. It is noted that these products do not fit the current definition of an infant formula product which is proposed to be retained - see section 3.1.

It is anticipated that this new approach will provide regulatory clarity with respect to SMPPi that are currently captured within Division 4 of Standard 2.9.1 and more clearly differentiate these products from those that sit outside of this Division. It also differentiates those FSMP that are not specifically formulated for use in infants (such as formulated enteral feeds), and which are regulated by Standard 2.9.5 – Food for Special Medical Purposes (FSMP).

To assist with regulatory clarity, it is proposed that any special medical purpose product specifically formulated to be suitable for infants <12 months of age be regulated by Standard 2.9.1, noting that some of these specialised products may also be suitable and consumed up to three years of age or older. FSMP that are formulated for those one year and older (and not be to consumed by those < 12 months of age) will continue to be regulated by Standard 2.9.5.

The 2021 CP3 included 'principles' that were developed to underpin the category of specialised infant formula products. Based on stakeholder feedback to the 2021 paper, many of these support the basis for the SMPPi category. Principles for SMPPi include:

- SMPPi are specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition.
- SMPPi are for use under medical supervision.
- SMPPi must be safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data.
- For those SMPPi that may be the sole source of nutrition, the composition is to be based on infant formula and follow-on formula in order to take into account the specific nutritional requirements of infants, and modified as appropriate to satisfy the particular disease, disorder or medical condition.
- SMPPi may form the sole source of nutrition, or not.

Translation of these principles to the definition for SMPPi is provided in section 3.2.

2.4.4 Human milk fortifiers and pre-term supplementary products

Human milk fortifiers (HMF) and modular products such as sources of carbohydrate or fat provide flexible feeding options in supplementing human milk for pre-term and low birthweight infants. It is currently unclear whether modular products and other specialised supplementary products for infants are covered by Standard 2.9.5 or Standard 2.9.1.

Modular products are used for dietary management in infants with medical conditions such as malabsorptive disorders and in-born errors of metabolism. Medical professionals use such products to alter the quality of the various nutrients normally fed to infants as well as concentrations of those nutrients. Infants who cannot tolerate existing proprietary formulas may require/benefit from a modular formula and in this regard, such products are considered to 'partially satisfy' the medically determined nutritional requirements of these infants. Specialised supplementary products for infants would include bovine derived human milk fortifiers, noting that breast milk derived human milk fortifiers are not currently regulated within the Code.

Previous consideration

In 2021 CP3, we reported that products used as human milk fortifiers and pre-term supplementary products are not clearly captured by any subcategory in Division 4 of Standard 2.9.1 or by Standard 2.9.5 when related to infants. We proposed that these products be regulated under Standard 2.9.5.

Stakeholder views

Eleven stakeholders commented to the 2021 CP3 with mixed views on the proposed option at that time to regulate infant products that serve a supplementary role under Standard 2.9.5. Concerns were raised that this would mean that infant-specific permissions/restrictions for food additives, processing aids, novel foods, contaminants, nutritive substances and some labelling elements will need to be addressed to ensure regulatory certainty and protection of infant health and safety. It was also raised that if these products were regulated under Standard 2.9.5, then they would fall outside the Ministerial Policy Guideline.

Discussion

Comments provided to the 2021 CP3 were in the context of the proposed regulatory framework in that paper, which categorised all specialised infant formula products under one sub-category of infant formula products. As such, it meant that modular products such as human milk fortifiers and pre-term supplementary products could not be included as they are nutritionally incomplete and not intended to provide the sole source of nutrition for an infant.

Under the proposed regulatory framework in this CFS, modular products such as human milk fortifiers and pre-term supplementary products would be included in the SMPPi category. This will enable SMPPi permissions and restrictions to be applied to products without need for duplication in Standard 2.9.5.

2.5 Preferred option

Infant formula products are 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.

Special medical purpose products for infants are 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.

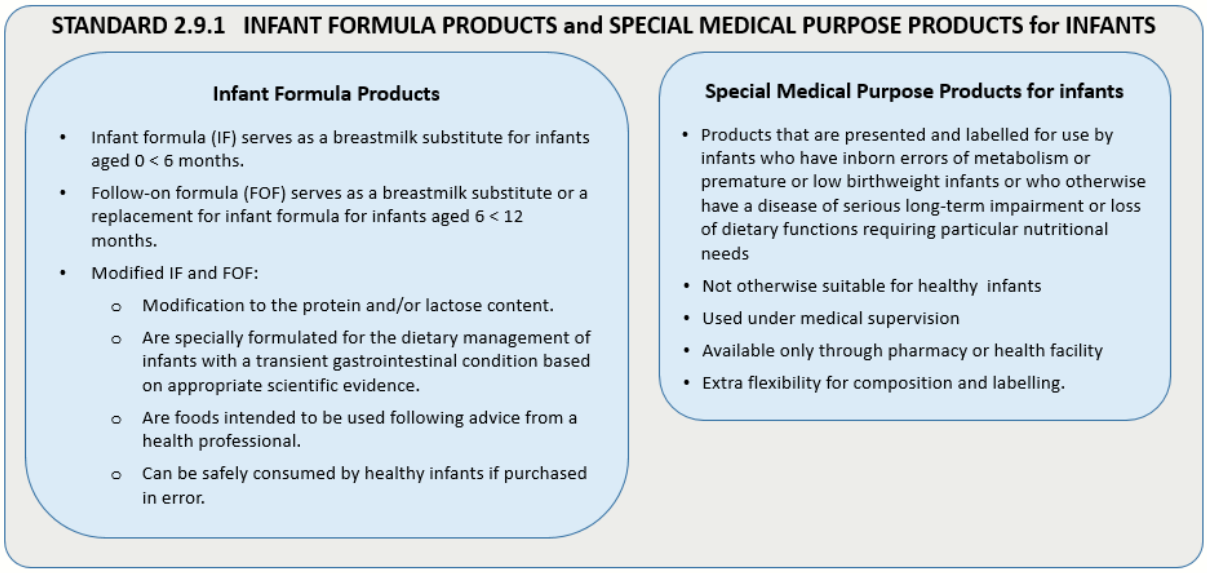

Figure 2: Proposed categories for Standard 2.9.1

To implement the revised regulatory framework, the following changes to Standard 2.9.1 are envisaged:[5]

- remove the Infant Formula Products for Special Dietary Purposes categorisation and the current associated sub-categories
- create a new category and definition in Standard 2.9.1 for Special Medical Purposes Products for infants
- rename Standard 2.9.1 – "Infant Formula Products and Special Medical Purpose Products for infants"
- remove definition of 'protein substitute' with requirements for hydrolysed protein used in infant formula products to be included in Standard 2.9.1

A consequence of the proposed framework is that food additive permissions may apply differently across the infant formula products and SMPPi categories. For infant formula products (including the modified products in this category), food additives will be permitted only at the lower Maximum Permitted Level (MPL) (see SD1).

3 Definitions

3.1 Definitions for infant formula products

3.1.1 Previous consideration

Definitions for infant formula product and infant formula were considered in the 2021 CP3, with numerous amendments discussed. At that time the view was that infant formula (and follow-on formula) and specialised infant formulas would be retained as products that fall within the single category of infant formula products. As such, the following definitions were proposed:

[5] These changes are noted here for explanatory reasons. Proposed drafting for Standard 2.9.1, Schedule 29 and related standards will be covered in the 2nd CFS.

Infant formula product means a product that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age of the infant.

Infant formula is 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.

3.1.2 Stakeholder views

Nine submissions to the 2021 CP3 included comments on proposed definitions (Table 3.1.2). Comments on specialised infant formula products are addressed in section 3.2.

Table 3.1.2 Stakeholder views

Summary of the issue	FSANZ response
Definition should cover base ingredients to ensure suitable ingredients with a history of safe use in these products are used.	The proposed 2021 definition removed the reference to base ingredients so that it would encompass all specialised infant formula products (i.e. as a subcategory of infant formula products). This is no longer the case with the proposed regulatory framework. See section 2.4.
Suggests infant formula products does not need its own definition (as is the case with the Codex CXS 72-1981) and instead it would just refer to a list of products.	The definition for infant formula products is needed to clarify that infant formula and follow-on formula are included in this definition, and to prescribe age ranges for both products. FSANZ notes that the lack of a definition for infant formula products in Codex CXS 72-1981 may be due to the difference in structure between the Code and Codex, where requirements for Codex follow-up formula (FuF) (6-12 months) are set in a different standard to infant formula.
The definition of infant formula products should be amended to include supplementary infant products and retain wording about the base ingredient requirements.	The proposed regulatory framework now explicitly recognises modular products such as human milk fortifiers and pre-term supplementary products as SMPPi as they are for use under medical supervision. See section 2.4
In line with Codex, EU regulations, and the Ministerial Policy Guideline does not support including ages in definition of infant formula products or infant formula. Suggests that removing age prescription allows consideration of developing science on measures to address allergies and of ANZ policy guidance to health professionals.	Whilst definitions for infant formula and follow-up formula under Codex and the Codex Draft Standard for FuFOI do not include age ranges, the terms “infant” and “older infant” are defined so in effect, age ranges for these products are prescribed in Codex. The Code aligns with Codex on these age ranges.

3.1.3 Discussion

FSANZ notes as a result of the new regulatory framework proposed in this CFS many of the issues raised by submitters in response to the 2021 CP3 have been addressed. However responses to other stakeholder views are provided in Table 3.1.2. The following discussion presents broader considerations around definitions.

In section 2.4, FSANZ concluded that the preferred option for high risk specialised infant formula products is to segregate these products into their own category (SMPPi) that will

have separate compositional and labelling requirements. This removes the necessity for the definition of infant formula products to include all specialised infant formula products (which was the case in the 2021 CP3). As a result, the definition for infant formula products reverts to the existing definition. There was general support for this definition in submissions to the 2021 CP3.

Follow-on formula was not considered specifically in 2021 because at that time, follow-on formula was not included in the scope of Proposal P1028. As follow-on formula is now in scope (see CFS, section 1.2), it is proposed the current definition under Standard 1.1.2—3 is retained.

3.1.4 Preferred option

The preferred option is to retain the proposed definition from the 2021 CP3 for infant formula and to include the existing definitions in the Code for infant formula products and follow-on formula. The preferred options for the definitions of infant formula product, infant formula and follow-on formula 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.

3.2 Definition for SMPPi

3.2.1 Current regulations

No defined term exists in the Code for products that could be classified as *'infant formula products for special medical purposes'* or the now proposed category of *'special medical purpose products for infants'* (SMPPi) (See section 2). Definitions related to this category from the Code and from overseas are given in Table 3.2.1. All definitions have common elements, many of which were highlighted in stakeholder submissions.

From these definitions, the key elements refer to products that:

- are for use under medical supervision
- may be a substitute for human milk, infant formula or follow-on formula
- are for sole or partial feeding
- are specially formulated
- are intended for the dietary management of infants with a diagnosed disorder, disease or condition.

Table 3.2.1 Related definitions for SMPPi

Regulation	Definition
ANZ Standard 2.9.5 definition of food for special medical purposes	A food that is (a) specially formulated for the dietary management of individuals (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; or (ii) for the dietary management of a disease, disorder or medical condition
Codex infant formula standard (Part B)	Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2 - Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX CXS 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.
Regulation (EU) No 609/2013	There is no specific definition for 'Food(s) for special medical purposes for infants'. However more generally, 'Food for Special Medical Purposes' means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.
US Infant formula Act	Exempt formula: An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labelled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

3.2.2 Stakeholder views

Both industry and government stakeholders provided feedback to the 2021 CP3. All agreed on the approach to create a definition for special medical purpose formulas around the elements of a food for special medical purpose. All also agreed that the definition needs to delineate those formulas that are needed for a medically determined disease, disorder, or condition from those that are used for less serious and/or transient conditions.

A number of definitions for the special medical purpose category of infant formula were proposed by submitters with various differences. All generally included key definitional points that are aligned with the principles listed in section 2.4.3.

3.2.3 Discussion

Given previous stakeholder support, FSANZ drafted a new definition for *infant formula products for special medical purposes* in 2021 proposed to sit under the broader category of *infant formula product for special dietary use*. FSANZ is now of the view that based on stakeholder comments, the broader category of *infant formula product for special dietary use* is no longer needed and that it be replaced with a new category and definition of SMPPi.

Introducing a new definition for SMPPi should provide regulatory clarity, differentiate SMPPi from products for healthy infants and reduce the ambiguity surrounding the classification of some products.

FSANZ considers this category should include products for all situations where breast milk or infant formula products are not suitable to meet the nutrition requirements of infants with a disease, disorder or medical condition. The nutrient composition of SMPPi should mimic the requirements of infant formula products however may deviate where required to address the special medical purpose of the product. Further, they may have a nutrient adapted formulation, and may or may not constitute the sole source of nourishment for the infant.

Some submitters noted that current Code definitions do not reflect the diversity of SMPPi and as such can lead to ambiguity at the enforcement level. Such products:

- can be based on milk protein or synthetic amino acids not derived from plant or animal origin
- can be for sole source but, in the case of metabolic disorders, they may not necessarily be sole source depending on the patient's condition
- are often required to replace breast milk completely in conditions or disorders where breast milk has to be restricted or is not suitable
- do not necessarily serve as a principal source of nutrition and may serve as a secondary source of nourishment depending on the patient's condition.

It is thought that a definition of SMPPi would provide for highly specialised products including those that may pose a risk to healthy infants. As such, these products are for use under medical supervision. FSANZ considered relevant definitions in international regulations (Table 3.2.1) and considered that, for consistency, the Code's definition of FSMP could form a suitable basis for SMPPi. As modular or supplementary products do not serve as a sole or principal source of nourishment but should be regulated as SMPPi, FSANZ has given consideration as to where such products should sit within the Code and recommends they be specifically included within Standard 2.9.1 (see the proposed regulatory approach above).

The important elements for a definition of SMPPi include where:

- a food is specially formulated for exclusive or partial feeding of an infant of any age who has a disordered capacity to take, digest, absorb, metabolise or excrete nutrients or metabolites or has medically determined nutrient requirements
- an infant's dietary management cannot be completely achieved without using the product
- use is under medical supervision
- the product is represented as being a food for special medical purposes or for the dietary management of infants with a disease, disorder or medical condition.

3.2.4 Preferred option

The preferred option is a new definition for *Special Medical Purpose Products for infants* (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.

3.3 Definition for protein substitute

3.3.1 Current regulation

The Code (section 1.1.2—2) defines protein substitute as follows:

> ***protein substitute*** means:
>
> (a) L-amino acids; or
>
> (b) the hydrolysate of one or more of the proteins on which infant formula product is normally based; or
>
> (c) a combination of L-amino acids and the hydrolysate of one or more of the proteins on which infant formula product is normally based.

There is no comparable definition under Codex 72-1981 or EU regulations.

3.3.2 Previous consideration

In light of the proposed framework in the 2021 Consultation paper, where all current Division 4 infant formula categories would fall under the proposed IFPSMP category, it was considered that the definition for protein substitute would be removed. This would permit the nutrient composition of all IFPSMP to reflect that of infant formula or follow-on formula except where necessary to meet the intended purpose of the product. However, we also asked for stakeholder views on the types and characterisation of partially hydrolysed infant formula products that were currently on the market and whether these were efficacious in the dietary management of allergy.

3.3.3 Stakeholder views

All submitters agreed that a definition for protein substitute was not needed. Stakeholders also commented that:

- Partially hydrolysed formulas on the market in Australia and New Zealand are based on whey proteins and, in other countries, may be based on casein or a whey:casein mix.
- Information on the level of protein denaturation in partially hydrolysed formulas is generally not available. Industry submitters indicated this can be provided if needed.
- Partially hydrolysed infants formulas are not recommended for dietary management or treatment of allergy and are considered ineffective to prevent or reduce the risk of allergy and related conditions.
- Partially hydrolysed infant formulas are not placed on the market for management or prevention of allergy.

- Extensively hydrolysed or amino acid based infant formulas may be recommended for infants with diagnosed allergy. These would be used under medical supervision and/or listed on the Pharmaceutical Benefits Scheme.
- There is some differentiation between partially and extensively hydrolysed infant formulas (Vandenplas et al. 2019) where partial hydrolysates typically contain peptides of average molecular weight <5 kDa, and extensive hydrolysates contain peptides (> 90%) with a molecular weight <3kDa. However, there would be considerable overlap in these cut-offs as well as differences resulting from methodology, protein source and manufacturing processes.

3.3.4 Discussion and preferred option

Based on stakeholder views, and in line with the proposed regulatory framework, the definition for "protein substitute" is proposed to be removed. Those products intended for the dietary management of a diagnosed condition, disorder or disease (such as allergy) will 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 those based on extensively hydrolysed protein or L-amino acids.

Compositional requirements for protein in infant formula products, including those based on partially hydrolysed protein, is discussed in SD2 and their specific labelling in SD3.

3.4 Other definitions

In the 2021 CP3 (FSANZ 2021c), FSANZ discussed other relevant definitions (Table 3.3) and proposed that these definitions be retained. Specific questions to submitters were posed on other definitions.

Table 3.4 Other definitions in Standard 2.9.1

Subject	Use	Definition in Standard 2.9.1—3
Soy-based infant formula	For a limit on aluminium Subclass of food additives for infant formula in Schedule 15.	An infant formula product in which soy protein is the sole source of protein.
Pre-term formula	For a limit on aluminium Subcategory of Division 4 Standard 2.9.1 including labelling requirements.	An infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.
Medium chain triglycerides (MCT)	Permitted for use in protein substitute subcategory in Division 4.[6]	Triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

3.4.1 Soy-based infant formula

In the 2021 CP3, FSANZ asked

> *Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.*

[6] As discussed in the 2021 Consultation paper 2, section 2.9.1—11 permits MCT to be present only as a natural constituent of a milk-based ingredient of that formula; or as a component of a processing aid in the preparation of a permitted fat-soluble vitamin. Consultation paper 2 proposed to retain this restriction. The definition would be retained in Standard 2.9.1 for these purposes.

Most submitters agreed that soy-based formula was self-explanatory and a definition was not needed. In relation to aluminium limits, FSANZ's preferred option is to set one aluminium limit for all products (see SD1, section 5.2.3). If this option is adopted, it also removes the need for a definition for soy-based infant formula. Codex CXS 72-1981 does not define soy-based infant formula.

Preferred option

The preferred option is to remove the definition for "soy-based infant formula" from Standard 2.9.1.

3.4.2 Pre-term formula

In the 2021 CP3, FSANZ asked

> *Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.*

Previous consideration

In CP3, FSANZ proposed to retain the definition of pre-term formula, particularly because it might be needed for further differentiation from human milk fortifiers. We also considered that this definition may be needed for the purposes of the food additive and/or aluminium requirements. There is no equivalent definition under Codex or the EU regulation.

Stakeholder views

Nine submitters commented on the definition for "pre-term". Several suggested additional definitional elements such as defining an age for "pre-term", its use as a breast milk substitute, or to provide guidance about transitioning from pre-term formula to standard infant formula. Other submitters considered a definition was not needed as the term was self-explanatory or covered by current medical definitions, and that individual classes of products should not need to be specifically defined if sufficient risk management strategies are in place.

Discussion

Consistent with the NHMRC Infant Feeding Guidelines and the Healthy Eating Guidelines for New Zealand Babies and Toddlers (NHMRC 2012, MoH 2021), FSANZ considers guidance about infant feeding of pre-term and underweight infants should be obtained from medical professionals. It is outside the scope of P1028 to provide a medical definition for "pre-term" or "premature".

The existing definition provides regulatory clarity about pre-term infant formulas, as it is currently classed as an "infant formula product". The proposed regulatory framework would shift pre-term infant formulas to SMPPi.

For these reasons, FSANZ considers that the definition for pre-term is not needed.

Current and proposed changes to risk management approaches (i.e. warning statements) for pre-term infant formulas is addressed in section 3.3.2 of SD4.

Preferred option

The preferred option is to remove the definition for "pre-term" from Standard 2.9.1.

3.4.3 Medium chain triglycerides (MTC)

Most submitters to the 2021 CP3 agreed that the MCT definition is not needed. One industry submitter supported maintaining the definition if the restrictions are retained, however changing the term to 'MCT oil". FSANZ has proposed to include a permission for the addition MCT within SMPPi however specific compositional limits will not be set and are to be determined based on the products special medical purpose, supported by generally accepted scientific data. As the current restrictions will be removed, FSANZ retains its view from 2021 CP3 that within the context of the standard, MCT is self-explanatory and a definition is not needed.

Preferred option

The preferred option is to remove the definition for "medium chain triglycerides" from Standard 2.9.1.

3.4.4 New definitions

In the 2021 CP3, FSANZ asked

> *Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.? (Section 4.3)*

Stakeholder views

Eleven submitters responded to this question with mixed views.

- Industry organisations (4) considered that new definitions were not needed on the basis that the terms are not defined in EU regulations and are generally understood.

- One heath professional organisation was also of the view that given the complexity and range of the specialised formula available and the range of severity of these conditions such definitions need not be included in food standards.

- Health professional organisations (3) identified definitions were needed for food additives used in infant formula, and better understanding of terms such as 'gastrointestinal disorders' is needed as these may relate to specific allergy diagnoses.

- One public health organisation was of the view that authoritative medical definitions of these conditions are necessary and would 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.

- Government submitters (2) were of the view that special purpose infant formula must be required to state the condition that they have been formulated to manage.

Preferred option

The preferred option is to not introduce new definitions on terms such as gastrointestinal reflux, gastrointestinal disorders or impairment of the gastrointestinal tract, inborn errors of metabolism or related. 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.

The use of mandatory statements in relation to the purpose of SMPPi is addressed in section 3.2.1 of SD4.

4 Novel foods and nutritive substances

4.1 Pre-market assessment requirements

4.1.1 Previous consideration

Consideration of pre-market assessment requirements for infant formula products related to whether a review of the provisions for novel foods and nutritive substances should be included in the scope for P1028. In 2016, FSANZ proposed that a review of these provisions should be included in P1028 to address issues around definitions for nutritive substances and novel foods, category overlap between novel foods and nutritive substances, and nutritive substances that are naturally present in an ingredient. The 2021 CP3 (FSANZ 2021c) proposed that this review was 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).

4.1.2 Stakeholder views

There were 13 submissions (nine industry, four government) on the 2021 proposed approach to remove the review of pre-market assessment requirements for novel foods and nutritive substances from the scope of P1028. Comments are summarised in Table 4.1.2.

Table 4.1.2 Stakeholder views on pre-market assessment of novel foods and nutritive substances in infant formula products

Summary of issue	FSANZ response
Supports principle of risk-based, 'graduated' consideration of new foods, where pre-assessment is required.	FSANZ will review this issue in relation to infant formula products under Proposal P1024 when it resumes, and within the context of any relevant policy guidelines.
Supports adopting and adapting international reviews for some new foods or food substances.	Not in scope for P1028.
Supports pre-market assessment for products classified under 2.9.1—14 (Products for metabolic, immunological, renal, hepatic and malabsorptive conditions).	The requirements and regulatory framework for special infant formula categories have been revised. See section 2 of this report.
Supports pre-market assessment for novel ingredients added to infant formula.	This is already the case. Under section 1.1.2—12, substances that are concentrated, refined or

	synthesised and are not normal foods or ingredients are subject to pre-market assessment.
Substances such as alpha-lactalbumin, that are naturally present in milk (whey) protein ingredients, and therefore are not added without permission and support protein and amino acid requirements.	Section 1.1.2—12 defines *used as a nutritive substance* as any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food. Section 1.1.1—10(6)(b) prohibits any substance *used as a nutritive substance* unless expressly permitted by the Code. FSANZ's understanding is that a substance such as alpha-lactalbumin that is isolated and purified from a 'natural source' has been manipulated from that natural source. It cannot be automatically assumed that it is safe when added back to an infant formula product. Clause 1.1.2—12 would apply to any macronutrient.
Submitter notes that some substances have been reviewed by the Advisory Committee on Novel Foods (ACNF) who concluded that there were no safety concerns identified, or no concerns regarding composition.	ACNF views are not binding and relate to whether a substance is novel or not. The ACNF view does not constitute a safety assessment. The ACNF no longer considers questions about substances to be added to infant formula products as such substances are subject to pre-market assessment.
Use of the term 'optional ingredients', as used in Codex, is preferred instead of 'may be used as a nutritive substance'. Recommends that this is reconsidered as part of the future review.	FSANZ agrees that such a change would have broader implications than just Standard 2.9.1 and would need to be included in the P1024 review.
The novel food definition is unclear about the intended consumer population; suggests an interim measure to reduce the ambiguity that emphasises novel food for the intended population.	FSANZ agrees that this will clarify requirements for pre-market assessment. We propose that text be added to section 1.1.2—8 so that a novel food is defined as a non-traditional food for the intended consumer population.
Opposes the removal of novel foods and nutritive substances from scope of P1028 on basis that infants are vulnerable population & greater level of risk assessment needs to be applied to infant formula products.	FSANZ is proposing to review the regulatory framework for novel foods and nutritive substances in infant formula products with P1024 so that requirements for infant formula products are considered **in parallel** with other food categories. This is to prevent inconsistency in the Code and regulatory ambiguity. It is not proposed that infant formula products will be assessed as part of one food category. Assessment under P1024 will still include assessment of infant formula products commensurate with the level of risk for this population and in consideration of the Ministerial Policy Guideline.
Related to above, deferring consideration of the pre-market assessment requirements of nutritive substances and novel foods for infant formula and combining with Proposal P1024 would undermine P1028 and introduce regulatory ambiguity into the Standard.	FSANZ disagrees that regulatory ambiguity will be introduced by deferring review of pre-market requirements, noting existing stringent regulations include: (1) general prohibition unless pre-market assessment (Standard 1.1.2) (2) pre-market assessment of novel foods and nutritive substances for infant formula products must include application of the Ministerial Policy Guideline (3) application of the Ministerial Policy Guideline is enshrined in Application Handbook Guidelines (which are statutory requirements)

	(4) definition of protein sources (see section 2.1.2 of SD2). (5) changes in definitions 1.1.2 implemented through P1025 and proposed changes in this CFS.
Several comments related to differing interpretations in the Code on whether substances that are naturally present in an ingredient of infant formula products require pre-market assessment.	As noted in comment above, FSANZ's understanding is that under section 1.1.2—12, substances that are concentrated, refined or synthesised and are not normal foods or ingredients are subject to pre-market assessment. As such, a single substance that is purified from a commonly used ingredient would require pre-market assessment.
Several comments relating to the policy guideline, i.e. substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children.	The Ministerial Policy Guideline is applied to pre-market assessments of new substances added to infant formula products. This has been the case for recent assessments of applications to amend Standard 2.9.1. See: Human milk oligosaccharides (2'-FL and LnNT): A1155, A1190 (gazetted), A1233 (current) sc-FOS: A1055 (gazetted)
Concerns raised about novel sources for protein include legumes, grains and so-called pseudo grains, and potato.	FSANZ is proposing to amend the definitions so that a novel food is defined as a non-traditional food for the intended consumer population. As concentrated forms and as primary source of nourishment, the protein sources named by the submitter are not traditional foods for the intended population (i.e. infants) and thus would require pre-market assessment. FSANZ is also proposing to specify protein source in Standard 2.9.1. This is discussed in section 2.1.2 of SD2.
Concerns raised that FSANZ would be ignoring policy directives in considering regulatory approaches that could range from 'all-encompassing prohibition to open permission, or involve a graduated approach commensurate with the risk posed by a substance to infant health'	As addressed above, the current assessment process includes consideration of the Ministerial Policy Guideline in applications to add nutritive substances or novel foods to infant formula products. The quoted text is from the 2016 paper which was intended only to provide background. There is no intention to remove the pre-market assessment requirement for adding new nutritive substances or novel foods to infant formula products.
Submitter commented that the regulatory framework for nutritive substances and novel foods for general foods cannot be applied to infant formula products. A nutritive substance that may be considered low risk in the general food supply and able to be added without pre-market assessment, would not necessarily be considered low risk for infant formula.	As with novel food definition, the definition for 'used as a nutritive substance" in section 1.1.2-2 can be amended to indicate 'for the intended population' as a safeguard that the nutritive purpose must be appropriate, safe & beneficial for the infant population. Currently any new substance added to infant formula products must be assessed through the application process which includes a safety assessment against Application Handbook guidelines. The guidelines requires evidence to be provided to support safety and normal growth and development of infants.
It is unlikely that clarifying the regulatory approach for permissions of substances for infant formula will introduce inconsistencies for the general food supply.	See discussion. The regulatory approach for pre-market assessment has been clarified in P1028 and in P1026 Code revision. Any further changes in the regulatory approach that is undertaken in isolation of P1024 risk introducing inconsistencies or regulatory uncertainty. A regulatory framework for infant formula products (a food) that is separate from that for other foods is not consistent with the way the Code works. What is being suggested by

	FSANZ is that any fundamental change to how the Code handles permissions for novel foods and nutritive substances should be reviewed for general foods in conjunction with infant formula products. Circumstances around vulnerable populations such as infants would not be ignored.
Safe and suitable provisions are inadequate for infant formula and do not incorporate the range of regulatory elements set out in the Ministerial Policy Guideline	Assessment to permit new substances to be added to infant formula includes consideration of benefit in line with the Ministerial Policy Guideline. This is enshrined in the Application Handbook guidelines (statutory requirements) and has been demonstrated in recent applications to amend the Code for infant formula products (see above).
FSANZ should acknowledge the clear advice of the Ministerial Policy Guideline for pre-market safety assessment for these substances. How will P1024 account for unique elements of the Ministerial Policy Guideline including: (1) demonstration of a 'substantiated beneficial role', (2) establishment of expert panel, and (3) clarification of the levels of evidence for a 'substantiated beneficial role'	FSANZ notes elements (1) – (3): (1) Is already part of FSANZ process. See applications for 2'-FL. (2) Is also part of the process where needed. An expert panel was established for the review of A1155. (3) Review of the Application Handbook is the best place to specify the levels of evidence that will be required. Such a review has been in progress but delayed due to resourcing. FSANZ notes that guidelines in the Handbook are legislated requirements and therefore changes would be subject to public consultation process and consideration of stakeholder views.
Submitters acknowledged that amendments to definition under P1025 provided necessary clarity on some of the milk protein fractions added to infant formula. But also P1028 should provide additional regulatory identity of such substances when added to standard infant formulas**.**	FSANZ notes the 2nd CFS for P1025 (FSANZ 2014, page 20) where clarity on definition of 'used as a nutritive substance' was discussed. At the time, it was proposed that the issue will be considered in Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods. Stakeholders supported this approach at that time.

4.1.3 Discussion

Overall, industry supported the proposed approach to exclude the consideration of novel foods and nutritive substances from the scope of this proposal. Government submitters did not support this approach.

The Code establishes a general prohibition on the addition of novel foods or nutritive substances to foods unless these are expressly permitted through an application or proposal to amend the Code. The reason for removing a larger review of novel foods and nutritive substances requirements from P1028 is that more fundamental changes or a new overarching approach in the Code can be considered in the context of all foods. An advantage of this approach would be the ability to consider regulations for novel foods and new nutritive substances as applied to any vulnerable population group.

The 2021 CP3 indicated that the reason to remove novel foods and nutritive substances from the scope of P1028 was to ensure that inconsistencies and regulatory ambiguity are not introduced into the Code. Setting novel foods and nutritive substances requirements for infant formula products would effectively treat these products differently to all other food categories, potentially diminishing the regulatory clarity P1028 seeks to achieve.

Nevertheless, in this CFS, several changes have been proposed that improves regulatory clarity for the regulation of novel food and nutritive substances in infant formula products. These are in addition to changes already implemented through P1025 *Code Revision* (gazetted in 2016). The proposed changes in conjunction with existing stringent requirements

for pre-market assessment should allay concerns until the review around the broader regulatory framework for nutritive substances and novel foods resumes.

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.

4.1.4 Preferred option

The preferred option is to retain the proposed approach from 2021 CP3, i.e. 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.

4.2 Novel foods – Schedule 25

4.2.1 Previous consideration

FSANZ 2021 CP3 (FSANZ, 2021c) reviewed the current permissions for novel foods listed in Schedule S25 – Permitted Novel Foods. The schedule indicates the conditions of use for the novel food. For some novel foods (e.g. isomalto-oligosaccharide) the conditions restrict the use of the novel food in infant formula products, infant foods and formulated supplementary food for young children (FSFYC) aged 1 to 3 years, as the assessment for the novel food did not include a safety assessment for this population group.

The other novel foods in Schedule 25 are silent in this respect and as such, could be construed as being permitted in infant formula products, infant foods and FSFYC. We reviewed previous risk assessments of novel foods for which no conditions are set in Schedule 25 in relation to infants or young children. We found that the suitability of these novel foods for this cohort was either not assessed prior to listing in Schedule 25 or was assessed as safe for consumption. FSANZ considered permissions or prohibitions of novel substances in infant formula products, infant food and FSFYC should be clarified according to their original assessments.

FSANZ proposed to add the conditions to novel foods listed in Schedule 25 to reflect the original intention of the assessments for these novel foods and to restrict them from use in infant formula, infant foods, and FSFYC (unless explicitly assessed for these population groups). The proposed conditions are listed in Table 4.2.1.

Table 4.2.1 Proposed conditions for novel foods in relation to infants and young children

Permitted novel food (S25)	Proposed conditions
α-cyclodextrin	Must not be added to: (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children.
γ-cyclodextrin	
Diacylglycerol oil (DAG oil)	
Isomaltulose	
D-tagatose	
Trehalose	
Dried marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA)	No conditions set.

Oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA)	No conditions set.
Oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexanoic acid (DHA)	No conditions set.

4.2.2 Stakeholder views

There were eight submissions (five industry, three government) on the 2021 proposed approach to clarify the conditions for novel foods listed in Schedule 25. Comments are summarised in Table 4.2.2.

Table 4.2.2 Stakeholder views

Summary of the issue	FSANZ response
Supports conditions imposed for novel foods for infant formula and follow-on formula, where not assessed for this population group.	FSANZ notes that all submitters essentially supported the proposed approach to amend novel food conditions so that they are restricted for the infant population (i.e. infant formula and follow-on formula).
Generally opposes retrospective application of conditions to existing novel food permissions but considers restrictions appropriate for the most vulnerable groups of infants who consume infant formula and follow-on formula.	As noted in FSANZ 2021 CP3 the status of these novel substances as either clearly permitted or prohibited needs to be clarified according to their original assessments.
Does not support conditions imposed for FSFYC as this is not in scope for P1028 and suggests there are other mechanisms for making such amendments outside of P1028.	FSFYC, which are regulated under Standard 2.9.3, are not in scope for P1028. Therefore, we agree with the submitter and do not propose to impose conditions in Schedule 25 for FSFYC.

In addition the following question was asked in FSANZ 2021 CP3:

> *To manufacturers, please provide information on whether the substances (novel foods) listed in Table 5 (reproduced in Table 4.2.1, above) are used in infant formula products, food for infants and formulated supplementary food for young children.*

Four industry submitters responded that the substances listed in Table 4.2.1 are not used in infant formula products for the Australian or New Zealand markets.

4.2.3 Discussion

The proposed changes clarify existing novel food permissions and do not represent new regulatory controls for novel food substances in infant formula products. This view is supported by the majority of submitters.

4.2.4 Preferred option

The preferred option is 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 (i.e. infant formula and follow-on formula). The conditions will not be applied to FSFYC.

5 Safety and food technology (SD1)

Safety and food technology covers aspects related to the safety of infant formula products – from manufacture of the product to preparation by caregivers. The topics include:

- food additives
- contaminants
- processing aids
- L(+) lactic acid producing microorganisms used in the manufacture of IFP
- labelling for safe preparation and use (see section 7.1 of this CFS).

The 2016 Consultation paper gathered preliminary stakeholder views on these topics which were summarised and addressed in FSANZ 2021 CP1 (FSANZ 2021a). SD1 to this CFS summarises the entirety of the P1028 assessment for safety and technology, and concludes with proposed options for Standard 2.9.1/Schedule 29 and other relevant standards. The options are provided below.

5.1 Food additives

FSANZ has proposed only two food categories in the Code for food additive permissions, being 13.1.1 Infant formula products and 13.1.2 SMPPi.

FSANZ's earlier proposal to remove carry-over permissions for food additives, to be consistent with Codex and the European regulations, is maintained. To ensure this does not cause problems for products manufactured overseas, permissions for certain food additives used in nutritive preparations (as identified by the industry) are included in the relevant food additive permissions to ensure consistency with European regulations. FSANZ has further sought to ensure consistency of food additive permissions with Codex and European regulations.

FSANZ has developed three principles to guide consideration of the risk management approach for food additives. These are:

1. the protection of infant health and safety
2. the number of food additives used in infant formula products should be the least number necessary to achieve the required technological functions; and
3. consideration of harmonisation with international standards.

The third principle is of particular relevance to SMPPi, noting these products are generally not produced in Australia and New Zealand, but mainly imported from Europe. Consistency with European regulations is therefore very important. Following continued assessment using these principles and consideration of submission comments to FSANZ 2021 CP1, the following permissions for food additives, Maximum Permitted Level (MPL) and any additional conditions are proposed for the two categories (Table 5.1 below).

Table 5.1 Proposed MPL for infant formula products and SMPPi

Food additive	FSANZ proposed MPL (mg/L)	
	Infant Formula Products	SMPPi
Calcium carbonates (INS 170)	NP	GMP (aligns with EU) (13.1.5.1)
Calcium citrates (INS 333)	NP	GMP (aligns with EU) (13.1.5.1)
	Permit as carrier in nutrient preparations, consistent with EU MPL and with condition statement.	
Calcium hydroxide (INS 526)	2000 (aligns with Codex and EU), limits for sodium, potassium and calcium.	
Sodium carbonates (INS 500)	2000 (aligns with Codex) limits for sodium, potassium and calcium.	
Sodium hydroxide (INS 524)	2000 (aligns with Codex), limits for sodium, potassium and calcium. Consequential addition also needed to Schedule 8.	

Potassium carbonates (INS 501)	2000 (align Codex) limits for potassium.	
Potassium hydroxide (INS 525)	2000 (aligns with Codex), limits for potassium. Consequential addition also needed to Schedule 8.	
Phosphoric acid (INS 338)	450 (as phosphorus), (aligns with EU). Additional condition statements on ions.	450 (as phosphorus), (aligns with EU). Only for pH adjustment.
Calcium phosphates (INS 341)	Consistent with EU: Specific permission for tricalcium phosphate (INS 341(iii)) in nutrient preparations added to products (MPL in nutrient preparation 70 mg/L as phosphate).	
Sodium phosphates (INS 339) Potassium phosphates (INS 340)	450 (as phosphorus), (aligns with Codex). Additional condition statements relating to calcium/phosphorous ratio.	
Citric and fatty acid esters of glycerol (CITREM) (INS 472c)	9000 for liquid products, and 7500 for powdered products, (aligns with Codex and EU).	
Starch sodium octenylsuccinate (INS 1450)	NP	20,000 for extensively hydrolysed protein formulas (aligns with Codex and EU), with condition statement.
Locust bean (carob bean) gum (INS 410)	1000, maintain current permission, align Codex.	5000 for gastro-oesophageal forumlas (aligns with EU), with condition statement.
Pectins (INS 440)	NP	2000 for extensively hydrolysed protein liquid formulas (aligns with Codex), with condition statement.
		5000 mg/L for gastro-intestinal disorder formulas, (aligns with EU) with condition statement.
Xanthan gum (INS 415)	NP	1000 for extensively hydrolysed protein formulas (aligns with Codex), with condition statement
		1200 for gastrointestinal, protein mal-adsorption, or inborn errors of metabolism formulas (align with EU), with condition statement.
Guar gum (INS 412)	1000 (aligns with the Code, Codex and EU), with condition statement	10,000 for extensively hydrolysed protein formulas (aligns with EU), with condition statement.
Sodium alginate (INS 401)	NP	1000 for metabolic disorders and for general tube-feeding (aligns EU) with condition statement.
Sodium carboxymethylcellulose (INS 466)	Not proposing to permit use of sodium carboxymethylcellulose in any infant formula product. Seeking any information from stakeholders on current use and levels to inform a final decision	
Sucrose esters of fatty acids (INS 473)	NP	120 for extensively hydrolysed protein formulas (aligns with EU) with condition statement.
Diacyltartaric and fatty acid esters of glycerol (INS 472e)	Remove the permission in the Code (aligns Codex and EU).	

NP= Not Permitted

Some minor clarifications to the Code relating to food additive permissions as noted in FSANZ 2021 CP1 were supported in submissions and will be made. Submissions supported not making amendments to the food additive names and Code numbers (INS numbers) of food additives, and this is agreed.

5.2 Contaminants

Sixteen submissions were received in response to FSANZ 2021 CP1 relating to issues of chemical contaminants. FSANZ considered the responses from each submission alongside the various contaminants developing in coming up with its preferred approach. The summary of FSANZ's preferred approach to the regulation of the 13 chemicals or chemical group contaminants is provided in Table 5.2 below. No changes are proposed to the current Maximum Levels (ML) for three contaminants, no MLs are proposed for eight contaminants, and changes for aluminium and lead are proposed consistent with FSANZ 2021 CP1.

Table 5.2 Proposed ML for infant formula products and SMPPi

Contaminant	FSANZ preferred approach
Acrylonitrile	No change to the ML of 0.02 mg/L 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 0.05 mg/100mL for aluminium for IFP including soy-based.
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/L to 0.01 mg/L in IFP and apply to infant formula on a ready-to-feed basis.
Melamine	No ML to be established.
Tin & inorganic tin	No change to the ML of 250 mg/L.
Vinyl chloride	No change to the ML of 0.01 mg/L.
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.

Submissions were received and considered on two other matters from the FSANZ 2021 CP1. They were:

- MLs for infant formula products expressed in either dry powder form, or as consumed
- definition of contaminant.

Four industry submissions preferred the MLs to be in the dry powder form as this would be more practical for implementation, though they could accept it 'as consumed' to align with Codex if there were strong opposing views. FSANZ's proposed approach in the FSANZ 2021 CP1 was 'as consumed' for reasons explained in that document, which was supported by two submitters. After considering submissions and earlier assessment FSANZ's preferred option for MLs is 'as consumed' form in mg/kg.

In relation to a contaminant definition, FSANZ's preferred option is to proceed with the FSANZ 2021 CP1 approach. This is to not change the definition of analytes which are common to both infant formula and other foods, but rather address this issue as part of a possible future review of Standard 1.4.1 (potentially aligning with Codex).

5.3 Processing aids

No changes to the Code related to processing aids is required, similar to what was noted in the FSANZ 2021 CP1.

5.4 L(+) lactic acid producing microorganisms

FSANZ assessed the risk to the health and safety of infants — healthy, as well as preterm, low birth weight and immunocompromised — from the addition to infant formula products of any L(+) lactic acid producing microorganisms (FSANZ 2021b). FSANZ concluded that the use of non-toxigenic L(+) lactic acid producing bacteria in the production of fermented infant formula, where no viable bacteria are present in the final product, does not present a risk to public health and safety. On this basis and taking into consideration information provided by stakeholders (noted in section 6 of SD1) FSANZ's preferred option is to retain the existing permission, however clarify that L(+) lactic acid producing microorganisms may only be added *for acidification purposes*. FSANZ also proposes to clarify the permission that only non-pathogenic or non-toxigenic microorganisms may be used.

FSANZ also notes that microorganisms added to infant formula products for a probiotic purpose require pre-market assessment as a novel food prior to use.

The use of L(+) lactic acid producing microorganisms for acidification in SMPPi should only be used if supported by generally accepted scientific data.

6 Nutrient Composition (SD2)

Nutrient composition reviewed in FSANZ 2016 CP was only for infant formula (i.e. for infants 0 - 12 months) to gather preliminary stakeholder views. FSANZ 2021 CP2 provided stakeholders with FSANZ's proposed approach and gathered further evidence on outstanding issues. Within these consultations many stakeholders considered the inclusion of follow-on formula in Proposal P1028 to be advantageous. It was considered that overlap in requirements for these infant formula products would overly complicate the standard if the categories were not included in P1028. FSANZ has now introduced follow-on formula into the scope of the proposal.

FSANZ has considered scientific assessments, stakeholder views and international regulations and outlined preferred regulatory approaches for the composition of macronutrients, micronutrients, optional substances, equivalents, conversion factors and ratios prescribed for infant formula products. FSANZ has also given consideration to the revision of the Codex Standard for Follow up Formula (CXS 156-1987), specifically the Codex Draft Standard for FuFOI (See section 1.2).

The following sections summarise FSANZ's preferred regulatory approaches for the nutrient composition of infant formula products. The detailed summary of the assessment is provided at SD2.

6.1 Infant formula

The majority of FSANZ's proposed regulatory decisions for the composition of infant formula align with the *Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex CXS 72-1981). Proposed composition requirements that do not align with Codex CXS 72-1981 are where Standard 2.9.1 or Schedule 29 values were

retained[7] or where the European regulation on compositional requirements for infant formula (EU 2016/127) was proposed[8] as the most appropriate level to ensure infant health and safety within Australia and New Zealand.

6.2 Follow-on formula

FSANZ considered that the nutrient composition for follow-on formula should only deviate from infant formula where there is substantiated science to support the differences in requirements between the age groups. FSANZ's preferred regulatory approaches for the composition of follow-on formula were to align with the proposed composition for infant formula, except where the Codex Draft Standard for FuFOI level differed and was more appropriate within the Australian and New Zealand context. The Codex Draft Standard for FuFOI maximum for calcium was adopted for follow-on formula due to the increased calcium requirements for infants aged 6 – 12 months. FSANZ proposed, in alignment with the Codex Draft Standard for FuFOI, that no minimum level was preferred for choline and myo-inositol.

6.3 Infant formula products

Spanning across both sub-categories, FSANZ has considered permitted forms, vitamin and mineral supplementation guidance, measuring scoop requirements and formula modifications such as low lactose/lactose free and partially hydrolysed proteins. FSANZ has proposed to:

- adopt permitted forms present within CXS 72-1981 where appropriate
- remove the guideline on advice regarding additional vitamin and mineral supplementation
- not prescribe a standardised measuring scoop or ratio, and
- accommodate partially hydrolysed proteins and low lactose/lactose free formulas within the infant formula product category.

FSANZ's proposed nutrient composition for infant formula and follow-on formula are summarised below in Table 6.3.

Table 6.3 Proposed nutrient composition for infant and follow-on formula

Nutrient	Unit	Infant formula		Follow-on formula	
		Min	Max	Min	Max
Energy	kJ/L	2500	2950	2500	2950
Protein (cow)	g/100 kJ	0.43	0.7	0.43	0.7
Protein (soy)	g/100 kJ	0.54	0.7	0.54	0.7
Carbohydrates	g/100 kJ	NS	NS	NS	NS
Total fat	g/100 kJ	1.05	1.4	1.05	1.4
Linoleic acid (LA)	mg/100 kJ	90	330*	90	330*
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1
Docosahexaenoic acid (DHA)^	mg/100kJ	NS	7.2	NS	7.2
Arachidonic acid^	% total FA	NS	1	NS	1
Trans fatty acid^	% total FA	NS	4	NS	4
Phospholipids^	g/L	NS	2	NS	2
Vitamin A	µg RE/100 kJ	14	43	14	43
Vitamin B6	µg /100 kJ	8.5	45*	8.5	45*
Vitamin B12	µg /100 kJ	0.025	0.36*	0.025	0.36*
Niacin	µg /100 kJ	70	360*	70	360*
Riboflavin	µg /100 kJ	14.3	119*	14.3	119*
Vitamin C	mg/100 kJ	1.7	17*	1.7	17*
Vitamin D	µg /100 kJ	0.25	0.63	0.25	0.63
Vitamin E	mg α-TE/100 kJ	0.12	1.2*	0.12	1.2*
Vitamin K	µg /100 kJ	0.24	6.5*	0.24	6.5*

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

Phosphorus	mg/100 kJ	6	24*	6	24*
Calcium	mg/100 kJ	12	35*	12	43*
Magnesium	mg/100 kJ	1.2	3.6*	1.2	3.6*
Iron	mg/100 kJ	0.2	0.5	0.2	0.5
Folic acid	µg /100 kJ	2.5	12*	2.5	12*
Sodium	mg/100 kJ	5	14	5	14
Chloride	mg/100 kJ	12	38	12	38
Potassium	mg/100 kJ	14	43	14	43
Pantothenic acid	µg /100 kJ	96	478*	96	478*
Manganese	µg /100 kJ	0.25	24*	0.25	24*
Zinc	mg/100 kJ	0.12	0.36*	0.12	0.36*
Thiamin	µg /100 kJ	10	72*	10	72*
Biotin	µg /100 kJ	0.24	2.4*	0.24	2.4*
Copper	µg /100 kJ	8.5	29*	8.5	29*
Iodine	µg /100 kJ	2.5	14*	2.5	14*
Selenium	µg /100 kJ	0.48	2.2*	0.48	2.2*
Taurine^	mg/100 kJ	0.8	3	NS	3
Choline	mg/100 kJ	1.7	12*	NS	12*^
Myo-inositol	mg/100 kJ	1.0	9.5*	NS	9.5*^
L-Carnitine	mg/100 kJ	0.3	0.8	0.3^	NS^
Adenosine-5′-monophosphate^	mg / 100 kJ	NS	0.38	NS	0.38
Cytidine-5′-monophosphate^	mg / 100 kJ	NS	0.6	NS	0.6
Guanosine-5′-monophosphate^	mg / 100 kJ	NS	0.12	NS	0.12
Inosine-5′-monophosphate^	mg / 100 kJ	NS	0.24	NS	0.24
Uridine-5′-monophosphate^	mg / 100 kJ	NS	0.42	NS	0.42
Total free nucleotide 5'-monophosphates^	mg / 100 kJ	NS	3.8	NS	3.8
Fluoride	µg /100 kJ	NS	24	NS	24
2′-O-fucosyllactose	mg / 100 kJ	NS	96[1]	NS	96[1]
LA:ALA	ratio	5:1	15:1	5:1	15:1
Ca:P	ratio	1:1	2:1	1:1	2:1
Vitamin E : fatty acids	ratio	0.5mg : 1g	NS	0.5mg : 1g	NS
Eicosapentaenoic acid	ratio	NS	≤ DHA	NS	≤ DHA

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

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

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

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

7 Labelling

7.1 Safety and technology (SD1)

FSANZ consulted stakeholders through FSANZ 2016 CP and FSANZ 2021 CP1 on specific labelling requirements for directions for preparation and use, date marking, warning statements, prescribed names, certain age-related statements and protein source information that reside in Division 5 of Standard 2.9.1. Following stakeholder views to FSANZ 2021 CP1, FSANZ undertook an additional microbiological safety assessment to inform its assessment of the proposed changes to two specific directions for preparation and use.

Based on stakeholder views, consumer evidence and Australian and New Zealand infant feeding guidelines, FSANZ is not proposing changes to most safety-related labelling requirements. These include directions to:

- prepare bottles individually
- instruct that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours, and
- instruct that, where a package contains a measuring scoop, only the enclosed scoop should be used.

FSANZ is also proposing to maintain:

- the current approach not to prescribe the exact wording or pictures to be used for the required directions for preparation and use
- existing requirements for date marking and storage instructions
- legibility requirements for generic or specific warning statements
- the existing 'breast milk is best' warning statement
- prescribed names 'Infant formula' and 'Follow-on formula'
- age-related statements, and
- the requirement for the co-location of the protein source statement with the name of the food.

For the remaining safety-related labelling requirements, FSANZ's preferred options were also informed (in some cases) by findings of additional microbiological safety assessment. The proposed changes include:

- revised direction for water used to reconstitute powdered infant formula to include the word 'cooled' and for the discard unfinished formula direction to include the text 'within 2 hours'
- for ready-to-drink formula, to not apply directions that each bottle be prepared individually, that made up formula is refrigerated and used within 24 hours prior to use, to use potable, previously boiled water
- for concentrated and ready-to-drink formula, to not apply the direction to only use the enclosed scoop.

Other changes being proposed include consolidating the warning statements for powdered, concentrated and ready-to-drink infant formula products into a single prescribed warning statement applicable to all product types. FSANZ is also proposing to clarify the source of protein statement to ensure the origin of the protein is declared and that this statement needs to appear in a prominent position just once on the label.

7.2 Provision of information (SD3)

In considering labelling requirements for provision of information (ingredient and nutrition labelling, labelling of modified products, overall representation), FSANZ has had regard to the current policy and regulatory environment, requirements in the Code, international and overseas regulations, consumer evidence (Attachment 1 to SD3) and stakeholder views received in response to earlier consultations in 2012 and 2016.

FSANZ is proposing to maintain existing requirements for the following labelling elements:

- for labelling of ingredients: generic requirements for a statement of ingredients, allergen declarations and genetically modified foods
- to not align the declaration of ingredient names in the statement of ingredients and nutrient names in the nutrition information statement (i.e. the status quo)
- existing specific labelling requirements for lactose free and low lactose infant formula products.

FSANZ is also proposing to maintain the current non-regulatory approach for the notification of changes to product formulations.

In regard to other labelling elements, FSANZ's preferred options are based on optimising information to enable caregivers of formula-fed infants to make informed choices and to assist health professionals when providing infant feeding advice. Proposed changes include a permission for the optional grouping of added vitamins and minerals in the statement of ingredients under the subheadings 'Vitamins' and 'Minerals'.

For nutrition information, FSANZ is proposing a prescribed format for the nutrition information statement (NIS) to:

- permit additional subheadings ‘Vitamins’, ‘Minerals’ to group the micronutrients and ‘Additional’ to group optional substances
- only permit the base unit of expression (per 100 mL as reconstituted) require nutrition information (excepting energy) to be expressed as the ‘average quantity’ and clarify the calculation methods for average quantity that will not apply to infant formula products
- clarify declarations for the weight of one scoop (if a powdered product), and
- permit with prescribed wording and format the voluntary listing in the NIS of ‘Whey’, ‘Casein’, ‘Docosahexaenoic acid’, ‘Eicosapentaenoic acid’ and ‘Arachidonic acid’ as indicated in Section 3 of SD3.

FSANZ proposes the proportion of powder or concentrate required to reconstitute the formula according to directions must not be located in the NIS.

FSANZ has also considered the issue of ingredient claims and is proposing to only permit information about ingredients in the statement of ingredients (except for ingredients (e.g. nutritive substances) that are required to be declared in the NIS).

In addition, FSANZ is specifically seeking evidence and stakeholder comment to inform consideration on the format of the NIS, stage labelling and proxy advertising related only to infant formula products, and labelling of partially hydrolysed formula as a modified infant formula product.

8 Special Medical Purpose Products for infants (SD4)

8.1 Composition

FSANZ has proposed that Special Medical Purpose Products for infants (SMPPi) composition should meet the composition prescribed for infant formula products, except where deviation is required to address the specific disease, disorder or medical condition the product is intended for, and in doing so any deviation that meets international regulations, such as the EU, Codex or US.

FSANZ has also proposed other compositional requirements as follows:

- Removal of the manganese guideline maximum for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.
- Permission for the addition of MCT to SMPPi, where required to address the products special medical purpose. Specific compositional limits have not been set and are to be determined based on the specific disease, disorder or medical condition, supported by generally accepted scientific data.
- Permission for the addition of molybdenum and chromium to SMPPi, where required to address the products special medical purpose. Specific compositional limits have not been set and are to be determined based on the specific disease, disorder or medical condition, supported by generally accepted scientific data.
- Exemption from the measuring scoop requirements prescribed in Standard 2.9.1, where required to address the clinical nature and special medical purpose of the product.

8.2 Labelling

FSANZ has considered the applicability of labelling requirements in Standard 2.9.5 – Foods for Special Medical Purposes (FSMP) to SMPPi, and whether any specific labelling

requirements for infant formula products in Standard 2.9.1 and other generic requirements in Chapter 1 of the Code should also apply. FSANZ has also had regard to stakeholder comments provided in response to FSANZ 2021 CP3.

Based on the assessment made, FSANZ is proposing to apply the following labelling requirements to SMPPi:

- to label food as 'genetically modified'
- FSMP labelling requirements for inner packages, transportation outers, mandatory labelling information, mandatory statements and declarations, nutrition information requirements (subparagraphs 2.9.5—13(b)(i) and (ii)), and
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

FSANZ is proposing labelling requirements that would not apply to SMPPi, or where SMPPi are exempt are:

- the name of business address
- characterising ingredients and components
- prescribed names 'Infant formula' and 'Follow-on formula', a prescribed name for SMPPi, warning statements, directions for preparation and use, age-related statements, a protein source statement, prohibited representations, and
- FSMP labelling requirements for nutrition information (subparagraphs 2.9.5—13(b)(iii) or (iv)), requirements for claims in relation to lactose and gluten content (sections 2.9.5—14 and 15) and existing conditions for 'lactose free' and 'low lactose' for infant formula products (as discussed in Section 5.1 of SD3).

9 FSANZ Act assessment requirements

When assessing this proposal, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

9.1 Section 59

9.1.1 Consideration of costs and benefits

Paragraph 59(2)(a) requires FSANZ to have regard to whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure.

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Consultation Regulation Impact Statement (CRIS) for this proposal (OBPR correspondence dated 14 October 2021, OBPR ID: 25089). This exemption was provided as the OBPR agreed that a separate CRIS process is not expected to yield new information on costs and benefits. The OBPR noted the extensive consultation that has already taken place and the two legislated six-week consultations planned for 2022.

FSANZ, however, has given consideration to the costs and benefits of its preferred options for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the direct and indirect benefits to the community, government or industry that would arise from the development or variation of the proposed changes to standards.

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.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered, particularly benefits, cannot easily be assigned a dollar value.

Submitters are welcome to provide further evidence on costs and benefits during this consultation. Additional information from this CFS will inform FSANZ's decision on whether to amend the Code and how, and may enable FSANZ to refine the analysis and consideration of costs and benefits.

More details are included in SD5, including how numbers of infants, products lines (stock keeping units (SKU)) and some costs were estimated.

9.1.2 Costs and benefits

Consumers

Overall, infants that are fed infant formula products may benefit from improved composition according to current science. The major compositional changes, including to food additives, contaminants and purity of fat sources will likely further ensure that infant formula products remain safe and suitable for infants into the foreseeable future. It is not possible to quantify safety outcomes.

Improved product labelling would also assist with safe use and help parents and caregivers to select appropriate products for their infants. That may reduce harm to infants caused by unsafe preparation or selection. The numbers of parents that might improve preparation or selection because of improved product labelling is, however, unknown.

Infants who are particularly vulnerable and depend on SMPPi will benefit from greater certainty of continued access to special formula through greater alignment with international regulations. Benefits to the health of such infants will lead to well-being benefits for caregivers and other family members.

Every year, around 168,000 Australian and 24,000 New Zealand infants are likely fed infant formula by age six months. This may increase to approximately 245,000 Australian and 48,000 New Zealand infants 6 – 12 months and toddlers aged 12 months and above. That amounts to almost 3 million infants per decade in Australia and New Zealand. Hence, there are likely to be large (albeit unquantifiable) public health benefits from ensuring continued safety and suitability of products covered in this proposal. Some of the health benefits may stay with infants for the rest of their lives. Public health benefits of the proposal are therefore assumed to outweigh the short-term costs described below.

On the cost side, in the short-run, some (mainly domestic) product manufacturers may pass-on some of the increased costs of meeting new domestic standards to parents and caregivers through higher prices of infant formula products. In the longer-run, greater alignment with international regulations will likely reduce production costs and consumers may then benefit from price reductions.

Industry

There will be production costs during the transition period to comply with the preferred options, if approved. The three most significant costs are likely to be:

1. one-off product reformulation to meet new domestic standards at an estimated general range of AU $80,000 to AU $200,000 per affected product line, depending on

circumstances of each product. There is insufficient information to-date on how many product lines may need to reformulate or whether multinational producers may experience markedly lower reformulation costs than domestic producers

2. processes to further reduce contaminant levels, including relevant carry-overs in fats, and
3. one-off product label changes to meet new standards at an estimated average AU $8,000 with a general variation of +/- 20% per affected product line, totalling AU $800,000 +/- 20% across industry. That assumes 100 product lines are sold in the Australia-New Zealand markets. Any staff and other resourcing needed for education and communication to healthcare professionals, customers, consumers and patients related to the label changes, would be additional to the AU $800,000 +/- 20%.

An adequate transition period to make the above changes would help reduce the above production costs.

FSANZ could also seek to further minimise costs to industry by permitting the carried-over additives in any product that meet the following criteria:

- are confirmed by a formal risk- assessment as being safe, and
- are present as a result of carryover only.

Throughout this consideration of costs and benefits and SD5, FSANZ expresses a “stock keeping unit” or SKU as a “product line”. In this context, a SKU is the same as a product line.

Further details on costs are provided in SD5.

Overall, it is expected that in the longer-term the above transitional costs would be outweighed by net-savings to production costs to industry from greater alignment with international regulations. Greater alignment will reduce duplication costs after requiring fewer differences in infant formula product compositions for the Australia-New Zealand market compared to overseas markets.

It is also expected that businesses would benefit from the greater regulatory certainty, including (but not limited to) greater certainty about:

- permitted additives and contaminants
- clarifications about conditions for permitted novel foods in Schedule 25
- definitions of Special Medical Purpose Products for infants vs other infant formula products, and
- other aspects of the proposal that improve regulatory certainty.

The standards are not expected to limit market access nor notably reduce market viability for infant and follow-on formula products. FSANZ expects that very few products would be unable to adapt to the new standards and that competition between manufacturers would not be significantly affected.

Government

Improved infant health outcomes and particularly reduced safety incidents may reduce burdens on health-care by an unquantifiable amount.

There may be small one-off costs to jurisdictions of adjusting monitoring enforcement systems to reflect updated standards for infant formula products.

Longer-term certainty of monitoring and enforcement is likely to improve, including (but not limited to) from greater certainty of:

- permitted food additives

- permitted protein sources
- contaminant levels
- what constitutes SMPPi, and
- other substances that are or are not permitted in infant formula products unless approved through pre-market assessment

That will lead to longer-term effectiveness and efficiency of monitoring and enforcement.

Conclusion

Based on consultation and engagement to-date, FSANZ currently concludes that the following benefits are likely to outweigh the costs of this proposal:

1. further ensuring that infant formula products and SMPPi remain safe and suitable into the foreseeable future for almost 3 million infants a decade
2. regulatory clarity for producers and enforcement agencies
3. greater international alignment and fewer trade barriers enabling longer-term production-cost savings, and improving sustainability of supply. Fewer trade barriers will particularly benefit the most vulnerable infants that depend on continued access to special formula products for high-risk health conditions.

However, FSANZ will take into account any extra feedback received during this CFS, noting the extensive consultations already undertaken.

Questions

1. To what extent do you agree with FSANZ's conclusion on benefits outweighing the costs?
2. Do you agree with FSANZ's summary of industry costs and that the main costs will be:
    a. one-off product reformulation to meet new domestic standards
    b. processes to further reduce contaminant levels, and
    c. one-off product label changes to meet new standards?
3. Do you agree with FSANZ's current estimates of relabelling costs in SD5 (pg.4 - 6)?
4. Do you agree with FSANZ's current estimates of reformulation costs in SD5 (pg. 3 – 4)?
5. Do you agree that reformulation costs would be lower for multinational companies than domestic companies, if there is an adequate transition period?
6. Do you have any further information on estimated numbers of products that:
    a. sell in Australia and New Zealand
    b. would need to reformulate?
7. Do you have any further information on the numbers of companies that would need to reformulate, or how many products your company would need to reformulate?
8. Do you have any other comments on costs and benefits as presented in this section or in SD5?

Please provide any relevant evidence to support your comments on any of the above questions.

9.1.3 Other measures

At this stage there are no other measures that would be more cost effective than the proposed options to be developed as food regulatory measures for this proposal. FSANZ seeks comments on this assessment to inform its decisions on preparation of a draft

variation (at the 2nd CFS) on Standard 2.9.1/Schedule 29 or other standards related to infant formula products.

9.1.4 Any relevant New Zealand standards

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

9.1.5 Any other relevant matters

Other relevant matters are considered below.

9.2 Subsection 18(1)

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

9.2.1 Protection of public health and safety

Infant formula products are a safe alternative to breastfeeding. Standard 2.9.1 and Schedule 29 (and some related standards) set specific compositional and labelling requirements to ensure these products are safe and suitable. This proposal aims 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 in section 1.6) underpin the proposed options in this CFS.

9.2.2 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 currently covered in Division 5 of Standard 2.9.1. The assessment for Proposal P1028 includes a review of these requirements which is covered in SD1, SD3 and SD4.

9.2.3 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 includes a review of these requirements which is covered in SD3.

9.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to assess this proposal. Mainly this has been reported in relation to food additives, nutrients, and other compositional requirements. Where evidence was lacking, particularly in the relation to consumer behaviour, FSANZ commissioned research reviews and utilised these reviews in the assessment (see Attachment 1 to SD3 of the CFS and SD4 to FSANZ 2021a).

- **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 options in this assessment, if adopted, will clarify and update to current standards, and align with international standards where possible. This supports efficiency and competitiveness in the food industry.

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

The standards regulating the infant formula industry have implications for domestically manufactured products for both the domestic and international markets, and internationally manufactured products for the domestic market. FSANZ has endeavoured to develop regulatory options that are safe but do not disadvantage any of these trade circumstances.

- **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 adequately addressed. Our assessment against the Ministerial Policy Guidelines is provided at SD6.

10 Risk communication

10.1 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 1.4 and comments summarised throughout this CFS.

The release of this 1st CFS will be supported by a media release, updated website information and public notification via Food Standards News and social media channels. Following the release of the 1st CFS, we will also hold webinars to further engage interested parties.

The statutory consultation process specified in the FSANZ Act for this proposal includes a 2nd CFS which will include draft variations to the Code.

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (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.

This issue will be fully considered at the next stage of the assessment. As explained above, FSANZ has yet to decide to prepare a proposed measure. Submissions received in response to this Call for Submissions will inform that decision. If FSANZ decides to prepare a proposed measure, public consultation must occur in relation to that measure, once prepared. If necessary, notification will be made at that point in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreements. This will enable other WTO members to comment on any proposed amendments.

11 References

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