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Consultation paper 3 – Regulatory framework and definitions

Proposal P1028 – Infant Formula

Executive summary

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

The protection of public health and safety is a primary objective for FSANZ. Infant formula must be safe for formula-fed infants to consume, and its nutrient composition must support normal growth and development when infant formula is used as the sole or principal source of nutrition up to 12 months of age.

Infant formula products are regulated in the Australia New Zealand Food Standards Code (the Code) under Standard 2.9.1 – Infant formula products and Schedule 29 – Special purpose foods. Other standards also contain provisions related to definitions, calculations and nutrition information, such as Standard 1.1.2 – Definitions used throughout the Code, Standard 1.2.8 – Nutrition information requirements and Schedule 11 – Calculation of values for nutrition information panel.

This paper is the third in a series of consultation papers that discusses regulatory options for Standard 2.9.1 and Schedule 29. Consultation paper 1 covered Safety and Food Technology and Consultation paper 2 Nutrient Composition. The consultation papers will inform FSANZ's assessment of this proposal which has yet to occur. This assessment and the proposed regulatory approach based on that assessment will be set out in the first Call for Submissions.

The focus of this paper is the regulatory framework particularly for special infant formulas or infant formula products for special dietary use (IFPSDU) under the current provision in the Code. This includes an analysis of FSANZ's approach, principles on which regulation is best established, definitions and proposed options for IFPSDU. The paper also covers novel foods and nutritive substances, as well as some aspects of labelling. This paper follows previous consultations undertaken in 2012, 2016 and 2017 which considered these topics. Proposed approaches are made with consideration to the objectives of the proposal, the requirements of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) and relevant risk management principles.

Based on the analysis to date, including consideration of stakeholder views from previous consultations, FSANZ proposes the following regulatory and risk management approaches for Standard 2.9.1 and relevant schedules.

1) Deferring consideration of requirements to permit new novel foods and nutritive substances in infant formula products to the broader review of the Code's provisions applicable to all foods.

2) Amending Schedule 25 Novel foods to include conditions for existing permissions for novel foods to restrict them from use in infant formula products, infant foods, and formulated supplementary food for young children (FSFYC).

3) Regulating special infant formulas that are sole or principal sources of nutrition as infant formula products. Supplementary infant products such as human milk fortifiers are proposed to be regulated by Standard 2.9.5.

4) Amending definitions for infant formula products, infant formula, and IFPSDU (including subcategories of IFPSDU).

5) Renaming specialised infant formulas as 'infant formula products for special medical purposes' (IFPSMP) which introduces consistency with Standard 2.9.5. Along with this change, new or amended provisions are proposed for compositional requirements and defining the purpose of products categorised as IFPSMP, extension of use beyond infancy, restriction of sale and labelling considerations.

We are seeking stakeholder comment on key issues and proposed approaches. Specific questions for stakeholders have been included and a summary list is provided in the final section of the paper.

Contents

Glossary

Abbreviation or Term	Meaning
2012 Consultation paper	Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code: Consultation paper, 26 September 2012
2016 Consultation paper	Consultation Paper – Proposal P1028 Infant Formula, 23 February 2016
ASCIA	Australasian Society of Clinical Immunology and Allergy
ANZFA	Australia New Zealand Food Authority; the predecessor of FSANZ
APBS	Australian Pharmaceutical Benefits Scheme
Codex	Abbreviation for Codex Alimentarius
Complementary feeding	The gradual introduction of solid food and fluids along with the usual milk feed (breast milk or infant formula) to an infant's diet (Ministry of Health, 2008).
DAWE	Department of Agriculture, Water and the Environment
IEM	Inborn errors of metabolism
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FOF	Follow-on formula means 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.
FSMP	Refers to Code definition of Food for special medical purposes
FSANZ Act	Food Standards Australia New Zealand Act 1991.
Infant	A person under the age of 12 months, as defined in Standard 2.9.1
IF	Infant formula means 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.
IFP	Infant formula products are 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.
IFPSDU	Infant formula products for special dietary use

Abbreviation or Term	Meaning
IFPSMP	Infant formula products for special medical purposes
NHMRC	National Health and Medical Research Council (Australia)
NFA	National Food Authority; the predecessor of ANZFA
PRSL	Potential renal solute load
The Code	Australia New Zealand Food Standards Code
US	United States of America
US FDA	US Food and Drug Administration
WHO	Word Health Organization

1 Introduction

1.1 Proposal P1028

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

Although the standards in the Code that regulate infant formula are mostly working well, Proposal P1028 aims to ensure that these standards are appropriate, clear and function well now and into the future. The overarching goal of Proposal P1028 is to ensure that infant formula remains safe and suitable by taking account of current science, market developments and the international regulatory context. The proposal is considering issues raised by stakeholders relating to regulatory clarity, the application of Ministerial policy guidance and alignment with updated international regulations. This is a large and complex project prepared under section 113(6) of the *Food Standards Australia New Zealand Act 1991 (*the FSANZ Act) and assessed under the Major Procedure.

The scope includes all requirements for infant formula products (IFP) in Standard 2.9.1. The specific products under consideration in this paper are general infant formula (IF) and infant formula for special dietary use (IFPSDU). Specific requirements for follow-on formula (FOF) will be addressed in the 1st Call for Submissions (CFS).

1.2 The Proposal to date

This proposal is reviewing all aspects of regulation relating to IF and IFPSDU. Prior to 2021, FSANZ has released two consultation papers[1] on this proposal:

The **2016** P1028 Consultation paper focused on the regulation of infant formula. Infant formula products for special dietary uses and follow-on formula were excluded from scope.

The **2017** P1028 Consultation paper focused on IFPSDU. Many submissions to the 2016 paper requested IFPSDU be included in the Proposal's scope given requirements for IFPSDU are founded on those for IF.

FSANZ has also released two 2021 Consultation papers (CP): CP1 – Safety and Food Technology and CP2 – Nutrient Composition. CP1 considered the relevant matters in the context of the structure of IFPSDU. Any changes proposed in CP1 for IFPSDU will be integrated with the outcomes of this Consultation paper in the 1st CFS.

The entire consultation undertaken to date has enabled FSANZ to examine the available evidence and scope, regulatory issues, and to consider options to improve the current regulation. The reasons for preparing the Proposal and a description of the current standards for the regulations of infant formula were provided more fully in the 2016 Consultation paper[1].

1.3 Progressing the Proposal

This Consultation paper is the third in a series of consultation papers to inform development of the 1st CFS that will summarise the consideration of issues and options in line with FSANZ Act objectives. A basic cost/benefit analysis will accompany the 1st CFS.

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

1.4 Third Consultation paper 2021

The scope of this paper, which builds on previous public consultations and submissions, considers the following topics:

- pre-market assessment framework for IFP
- definitions for IFP
- regulatory framework and detailed approach to regulation of IFPSDU
- labelling considerations for IFPSDU.

1.5 Approach

Where FSANZ has previously consulted on an issue, we have outlined the proposed approach and discussed its rationale based on the preceding assessment by FSANZ and input from stakeholders. In some sections, we are proposing a very different approach to what was proposed in previous consultations. For these topics, we are presenting our preliminary views on the new approach.

Neither proposed approaches nor preliminary views are decisions about amendments to the Code. These will be made once the statutory assessment is completed and a summary is presented under section 59 of the FSANZ Act (i.e. in the 1st CFS).

For this Consultation paper, FSANZ is seeking input from stakeholders on our preliminary views and proposed approaches. In some sections, we have posed questions to stakeholders to further inform the 1st CFS. These are also listed at the end of this document.

1.6 Background

1.6.1 Regulatory approach to developing or varying food standards

Section 18 of the FSANZ Act sets out the three primary objectives, in descending order of priority, that FSANZ is required to consider in developing or varying a food standard. These are:

(a) the protection of public health and safety;
(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

(a) the need for standards to be based on risk analysis using the best available scientific evidence;
(b) the promotion of consistency between domestic and international food standards;
(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food; and
(e) any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council[2].

These objectives and principles are relevant for the revision and clarification of standards. The first objective is paramount given the vulnerability of formula-fed infants, particularly those for which IFPSDU provides the sole source of nutrition during the first months of life.

[2] Now known as the Food Ministers' Meeting; previously the Australia and New Zealand Ministerial Forum on Food Regulation

The Code

Provisions for IFP and its three categories: IF, FOF and IFPSDU are located in Standard 2.9.1 – Infant Formula Products and Schedule 29 – Special Purpose Foods. These are shown schematically in Figure 1.

Division 4 of Standard 2.9.1 allows IFPSDU to be specially formulated for a particular use, such as for pre-term infants or those with metabolic, immunological, renal, hepatic and malabsorptive conditions. The nutrient composition of these products is permitted to deviate from mandatory compositional requirements for IF or FOF consistent with the purpose of the product. In all other respects, it must comply with the provisions in Standard 2.9.1.

Other standards in the Code also contain specific provisions for IFP, including IFPSDU:

- Standard 1.3.1 – Food additives and Schedule 15 – Substances that may be used as food additives which regulate the use of food additives in the production and processing of food.
- Standard 1.4.1 – Contaminants and Natural Toxicants and Schedule 19 – Maximum levels of contaminants and natural toxicants which set out the maximum levels of specified metal and non-metal contaminants and natural toxicants in nominated foods.
- Standard 1.6.1 – Microbiological limits for food and Schedule 27 – Microbiological limits in food which list the maximum permissible levels of foodborne microorganisms that pose a risk to human health in nominated foods, or classes of foods.

1.6.2 International and overseas regulations

Requirements for IFPSDU in overseas markets vary although most standards are developed with reference to Codex Alimentarius (Codex). Given the extent of importation from overseas, Codex, European Union (EU) and United States (US) standards are particularly relevant to IFPSDU. The IFPSDU formulas are described in the various overseas regulations as infant formulas for special dietary use, foods or formulas for special medical purposes intended for infants, special purpose infant formulas, or exempt infant formulas.

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 foods for special medical purposes (FSMP) (Codex STAN 180-1991).

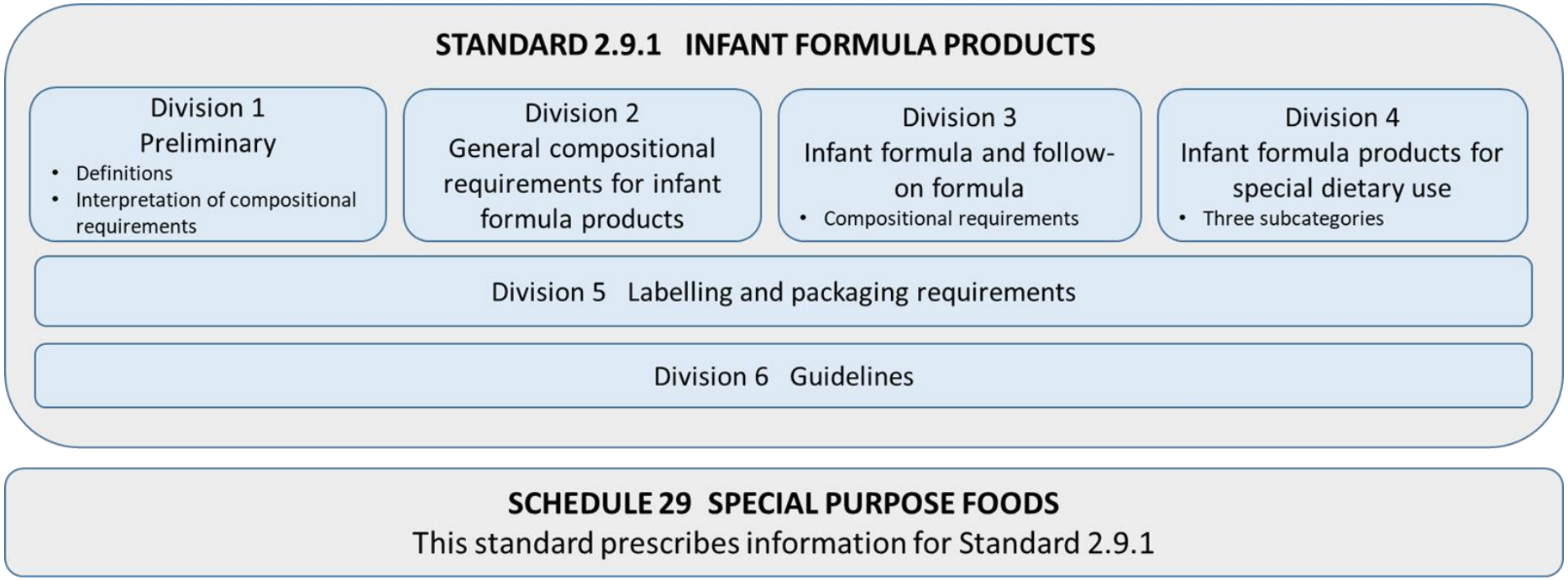

Figure 1: *The structure of the Code for requirements for infant formula products.*

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.

The relevant Codex standards for infant formula for special dietary use are:

- Codex STAN 180-1991 – Standard for the Labelling of and Claims for Foods for Special Medical Purposes
- Codex STAN 72-1981 – Standard for Infant Formula (Section A) and Formulas for Special Medical Purposes Intended for Infants (Section B)
- Codex STAN 193-1995 – General Standard for Contaminants and Toxins in Food and Feed; revised 2015
- Codex STAN 192-1995 – General Standard for Food Additives; revised 2016 (GFSA).
- Codex GL 10-1979 – Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children; revised 2008 (Codex Advisory list).

European Union

The EU regulates special purpose infant formulas as food for special medical purposes specifically designed for infants. EU regulations for this type of product are summarised in Table 1. 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.

Table 1: EU regulations for FSMP

Legislation/Regulation	Description	Note/Comment
Regulation (EU) No 609/2013 on food intended for infants and young children, FSMP, and total diet replacement for weight control	The overarching Regulation including the definition of FSMP	Repeals Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009)
Commission Delegated Regulation (EU) 2016/128	Outlines the specific compositional and information requirements for FSMP including for infants.	Adopted 25 September 2015; applied to FSMP infants from 22 February 2020
Commission Delegated Regulation (EU) 2016/127	Outlines the specific compositional and information requirements for infant formula and follow-on formula and requirements on information relating to infant and young child feeding.	Adopted 25 September 2015; applied from 22 February 2020
Regulation (EU) No 1169/2011 on the provision of food information to consumers, taking into account the specificities of the products	Outlines requirements on labelling, presentation and advertising of foodstuffs including the nutrition labelling for foodstuffs.	

United States

Infant formula is regulated under section 412 of the Federal Food, Drug and Cosmetic Act (FFDCA) and the US Food and Drug Administration's (FDA) implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR). Special purpose infant formulas are defined in section 412(f)(1) of the Infant Formula Act and are regulated by 21 CFR 107 subpart C.

The Infant Formula Act defines 'exempt infant formula'. The regulations specify that infant formulas that are represented and labelled for use by for an infant who has an inborn error of metabolism (IEM) or low birthweight or who otherwise has an unusual medical or dietary problem, are only exempt from the requirements of the Infant Formula Act if such formulas comply with regulations prescribed by the Secretary. Subpart C establishes the terms and conditions that a manufacturer must meet with respect to IEM. Medical foods may also include infant formulas used for IEM under section 412(h)(1) of the FFDCA; 21 CFR 107.50. Relevant parts of 21 CFR are:

- 106 – Infant formula requirements pertaining to current good manufacturing practice, quality control procedures, quality factors, records and reports, and notifications
- 107 – Infant formula
- 170 – Food additives.

According to by 21 CFR 107 subpart C, exempt infant formulas are divided into two general classifications:

1) Products available at the retail level, typically represented and labelled for use to provide dietary management of diseases or conditions that are not clinically serious or life threatening, even though such formulas may also be represented and labelled for use in clinically serious or life-threatening disorder..

2) Products not available at the retail level, typically prescribed by a physician and that must be requested from a pharmacist or directly distributed to institutions. These products generally represented and labelled solely to provide dietary management of specific diseases or conditions that are clinically serious or life threatening and generally are required for prolonged periods of time.

The US FDA reviews submitted information in relation to the composition and labelling of all such formulas prior to sale or charitable distribution.

1.6.3 Ministerial policy guidelines

FSANZ must have regard to Ministerial policy guidance in developing and varying standards in the Code. The relevant policy is the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (the Policy Guideline)[3].

In relation to IFPSDU, the Policy Guideline refers to products specifically formulated to meet the dietary needs of premature or low birthweight infants, or infants with metabolic, immunological, renal, hepatic and malabsorptive conditions. No reference is made to products based on a protein substitute.

The Policy Guideline includes a section devoted to *Specific Policy Principles* for *Infant Formula Products For Special Dietary Uses*. It contains three *Specific Policy Principles* for IFPSDU that relate to purpose, product composition and labelling as well as an explanation of which generic *Specific Policy Principles* for IFP do not (d)-(h) or may not (i)-(j) apply to IFPSDU. The Policy Guideline also refers to the regulation of infant formula "being consistent to the greatest extent possible" with relevant World Health Organization (WHO) and World Trade Organization (WTO) agreements and Codex standards.

The *Specific Policy Principles* relevant to IFPSDU are:

[3] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Infant%20Formula%20May%202011.pdf

o) Infant formula products for special dietary uses must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.

p) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.

q) The labelling and advertising of infant formula products should clearly specify the special dietary or medical uses for which the product is intended.

1.7 Submissions to 2016 and 2017 Consultation papers

The number of submitters to the previous P1028 consultation papers is provided at Table 2. A smaller subset of these submissions provided views on the specific issues presented in this paper (as indicated in relevant section). The regulatory principles and proposed approaches discussed in this paper draw heavily from the submissions to the 2016 and 2017 consultation papers.

Table 2: Number and breakdown of submitters to previous consultations by sector

Sector	Number of submitters	
	2016 Consultation paper (IF)	2017 Consultation paper (IFPSDU)
Government	7	9
Industry	24	8
Health professional	6	11
Consumer/consumer group	4	2
Total	41	30

2 Novel Foods and Nutritive Substances

2.1 Pre-market assessment requirements

Background

In preliminary planning for P1028, FSANZ was concerned with the uncertainty and ambiguity in the definition and regulation of novel foods and nutritive substances added to IFP (FSANZ 2012a).

In 2016, FSANZ outlined arguments supporting development of a regulatory framework for the addition of new substances to IFP (FSANZ 2016). This included considering the basis for requiring pre-market assessment of new substances for use in infant formula, and subsequently the procedure and information required to determine their safety and nutritive or health benefit. Specific issues considered were definitions for nutritive substances and novel foods (in the context of IFP), category overlap between novel foods and nutritive substances, and nutritive substances that are naturally present in an ingredient.

As a first step, we considered that the principles for the overarching regulatory approach for infant formula needed to be established. The regulatory approach could range from an all-encompassing prohibition to open permission, or involve a graduated approach commensurate with the risk posed by a substance to infant health. We sought information from stakeholders in 2016 that would guide a regulatory approach and allow for improved compliance with and enforcement of the Code.

At that time, the Proposal P1024 – *Revision of the Regulation of Nutritive Substances and Novel Foods*, was also being assessed. This proposal sought to develop an alternative framework for the regulation of nutritive substances and novel foods in the Code. It was considered that the approach implemented under P1024 for general foods could also apply to IFP, with additional concerns addressed under P1028 given the vulnerability of formula-fed infants.

Current regulation

Subsection 1.1.1—10(6) prohibits the use of novel foods and nutritive substances in IFP unless permitted by the Code. Novel foods are regulated by Standard 1.5.1 – Novel Foods and S25 – Permitted Novel Foods. A definition for 'used as a nutritive substance' is given in section 1.1.2—12. Permissions for the use of nutritive substances other than vitamins and minerals in IFP are listed in section S29—5.

Preliminary view

In 2016, FSANZ acknowledged that definitions of novel foods and 'used as a nutritive substance' are not completely clear and have caused manufacturers difficulty in determining whether a substance is permitted or not in the Code. Specific questions were asked about whether all or certain substances for use in infant formula should have a pre-market assessment and, if so, how these substances should be grouped or characterised.

Summary of submitter comments

Submitters agreed that novel foods and nutritive substances added to infant formula should undergo a pre-market assessment before inclusion in IFP. However, submitters disagreed on substances (for example, those derived from macronutrient ingredients) that this requirement should apply to and whether this question should be addressed as part of P1028 or P1024 (Table 3).

Table 3:Submitter comments on pre-market assessment requirements for novel foods and nutritive substances

Submitter	Comments
Industry	All manufacturers and industry bodies supported the inclusion of Standard 2.9.1 (and all relevant standards in the Code) as part of the Proposal P1024.
Health professionals	Considered that all substances proposed to be used in IFP should require pre-market assessment.
Government	Generally, government submitters supported the exclusion of Standard 2.9.1 from the scope of Proposal P1024 but acknowledged the potential regulatory gap or inconsistency in the Code that may arise if these are to remain separate. One submitter suggested that a review of the definitions of novel foods and 'used as a nutritive substance' relevant to IFP should await progression on Proposal P1024. Submitters also indicated that the current regulations are unclear whether new substances can be added to IFPSDU without pre-market approval. One submitter supported the specific exclusion of non-approved bioactive substances and nutritive substances from permission for special purpose formulas unless specifically needed for the intended condition.
Consumer	One academic submitter provided information about the technical attributes and role of lactoferrin, and increased ratio of α-lactalbumin to β-lactoglobulin in pasteurised RTF liquid formula.

Discussion

Since the initial planning stages for P1028, the Proposal P1025 Code Revision was completed (in effect March 2016). Amendments made under P1025 have added clarity around the definition of 'used a nutritive substance' and thus more certainty around substances that require pre-market assessment. Firstly, section 1.1.2—12 now focusses attention on the purpose of addition of the substance to a food i.e. to achieve a nutritional purpose. Secondly, substances that are subject to the clause are substances that are concentrated, refined or synthesised and are not normal foods or ingredients.

Circumstances have also changed around the progression of Proposal P1024. We previously argued that a review of the regulation of novel foods and 'used as a nutritive substance' in IFP would be best undertaken in P1028. As noted above, P1024 was being assessed concurrently. However, work on P1024 has now been deferred as stakeholder views varied significantly on key aspects of the approach presented following the assessment.

Whilst a separate review of nutritive substances and novel foods under P1028 may be important to ensure that it correctly addressed particular risks to infants, the concurrent assessment of the two proposals is also important to ensure that inconsistencies and regulatory ambiguity are not introduced into the Code. Therefore FSANZ has reconsidered the need to include a review of the regulation of novel foods and 'used as a nutritive substance' applicable to IFP in P1028.

To assess the extent of use of substances in the marketplace that might be regarded as novel foods or 'used as a nutritive substance' without a permission in the Code, FSANZ sampled the labelling of a total of 67 IF, FOF and IFPSDU products in 2021. Forty of these products were made in Australia or New Zealand. IFPSDU were classified as such if the label included advice to use under medical supervision.

Four substances were identified in a total of 11 products representing 16% of all surveyed products from five different manufacturers. Eight of the 11 products were made in Australia or New Zealand. Nearly all potential substances were present in general IF (Table 4).

Table 4: IFP on the market that include substances of interest

Substance	Total products	IFPSDU	General IF	Country of origin	
				Australia or New Zealand	Other/not specified
Alpha-lactalbumin	3	0	3	1	2
Beta casein (A2)	3	0	3	3	0
Lactoferrin – bovine	2	0	2	2	0
OPO fat – palm based oil enriched with palmitic acid in sn-2 (min 52%)	3	1	2	2	1
Total	11	1	10	8	3

Between 2016 and 2021, the Advisory Committee on Novel Foods[4] (ACNF) received only one request for advice about novel foods proposed to be added to IFP. ACNF enquiries

[4] See Regulation of novel foods at Regulation of novel foods (foodstandards.gov.au)

relating to IFP are not considered by the committee if the substance/ingredient clearly requires a pre-market assessment.

Industry continues to seek permissions to add new nutritive substances and novel foods to infant formula, such as recent applications for addition of human milk oligosaccharides and a microorganism functioning as a probiotic to IFP. Pre-market assessment is required for all nutritive substances and novel foods.

Proposed approach

The above arguments and the relatively small number of substances having uncertain regulatory status has persuaded FSANZ not to proceed with a separate review of novel foods and nutritive substances applicable to IFP under P1028. Future assessment of P1024 will consider the broader review of the Code's provisions for novel foods and nutritive substances applicable to all foods. The requirement that all food sold – including IFP – must be safe and suitable continues to apply in the interim. This proposed approach has relevance to the nutrition information statement for IFPSDU which was raised in the 2016 Consultation paper and will be discussed in the 1st CFS (to follow this consultation paper).

2.2 Novel Foods – Schedule 25

In recent times, Schedule S25 – Permitted Novel Foods has indicated the conditions of use for a novel food in relation to IFP, infant foods and formulated supplementary food for young children (FSFYC) aged 1 to < 4years. For example, oil derived from marine micro-algae (Schizochytrium sp. ATCC PTA 9695) is permitted for use only in IFP. In contrast isomalto-oligosaccharide must not be added to IFP, foods for infants, and FSFYC. The other novel foods in S25 (except phytosterols) are silent in this respect and as such, could be construed as being permitted in IFP, infant foods and FSFYC.

A review of previous risk assessments of novel foods for which no conditions are set in S25 in relation to infants or young children indicates that the suitability of these novel foods for this cohort was either not assessed prior to listing in S25 or was assessed as safe for consumption. FSANZ, therefore, considers that the status of these novel substances as either clearly permitted or prohibited in IFP, infant food and FSFYC should be clarified according to their original assessments.

Permitted novel foods in S25 for which conditions in IFP are unclear are listed in Table 5. The original risk assessments for these substances undertook dietary exposure assessments for the population aged 2 years and older and their conclusions imply that consumption posed no risk to health for the population aged 2 years and older. No comment was made in relation to infants or young children under 2 years other than for sources for DHA. Further, FSANZ is not aware of evidence that these substances (α-cyclodextrin, γ-cyclodextrin, Diacylglycerol oil, isomaltulose, D-tagatose and trehalose) are being added to IFP. On this basis, it is proposed to amend the conditions of use to prohibit the listed novel food from use in IFP, infant food and FSFYC where the assessment was silent in relation to safety for infants and children under 2 years.

Table 5 provides the proposed conditions based on original assessments (that is, based on the exposure assessment which did not include infants and young children < 2 years) of novel foods but only in relation to infants and young children. The existing conditions related to other matters for the novel foods shown in Table 5 and those not shown are out of scope of this consideration and will remain in Schedule 25.

Table 5: 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	Must not be added to (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children
Diacylglycerol oil (DAG oil)	Must not be added to (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children
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
Isomaltulose	Must not be added to (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children
D-tagatose	Must not be added to (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children
Trehalose	Must not be added to (a) infant formula products; and (b) food for infants; and (c) formulated supplementary food for young children

Proposed approach

FSANZ proposes to add the conditions listed in Table 5 to novel foods listed in Schedule 25. This will achieve the original intention of the assessments for these novel foods which is to restrict them from use in infant formula, infant foods, and FSFYC. However, to fully inform our assessment, FSANZ seeks the following information:

QUESTION

1) To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.

3 Specialised infant formula products

During the development of Standard 2.9.1, FSANZ's predecessor (ANZFA) noted that although specialised infant formula was captured in the regulation of general infant formula (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[5], FSANZ proposed instead to consider infant formula for special medical purposes in a forthcoming review of Standard 2.9.1.

3.1 Approach to regulation of IFPSDU

Preliminary view

In 2017 we proposed retaining the provisions for IFPSDU in Standard 2.9.1. This was based on submitter views from 2012 and 2016 Consultation papers that generally supported co-locating IFPSDU provisions with infant formula provisions. It was also noted that if IFPSDU were to be removed from Standard 2.9.1, all composition and safety requirements relevant to infant formula would also have to be incorporated into Standard 2.9.5 – Food for Special Medical Purposes.

Submitter views

Four submissions supported the preliminary approach. Submitters agreed that it is important to retain the requirement for these products to be based on the composition, safety and labelling requirements of infant formula. There was no support for the products to only be regulated by Standard 2.9.5 as that Standard does not specify relevant minimum composition requirements. Submitters also agreed that it would not be ideal to duplicate or cross-reference infant formula provisions in another standard. However, they supported that certain important elements of FSMP regulation should be brought into Standard 2.9.1 if required. One submitter noted the importance of maintaining a link to Standard 2.9.5 given that several of these products can also be used after 1 year of age.

Discussion

FSANZ has reviewed the approach to regulation taken by Codex, EU and US standards. Codex and US standards mostly retain the discrete concept of infant formulas for special medical purposes. In contrast in the EU, these formulas are integrated into a broader regulation of foods for special medical purposes for all ages.

In the overseas regulations and Standard 2.9.1, IFPSDU type products are permitted to deviate from the nutrient reference composition of IF or FOF to achieve their purpose but in all other respects must comply with the nutrient composition of IF. Standard 2.9.1 already has a reference nutrient composition for IF and FOF. In contrast Standard 2.9.5 does not set a reference composition except for micronutrients in standard S29–21 for FSMP that are a sole source of nutrition. Also, in Standard 2.9.5, the ingredient sources, age ranges and extent to which these products are nutritionally complete may extend far beyond the original concept of IF as a sole or principal source of nutrition. For these reasons, the regulation of IFPSDU should be retained in Standard 2.9.1.

[5] which led to the development of Standard 2.9.5

Proposed approach

It is proposed to retain the regulation of IFPSDU in Standard 2.9.1. Regulating IFPSDU in Standard 2.9.1 means it would be an IFP as defined. The classification of supplementary products for pre-term infants in Standard 2.9.1 or Standard 2.9.5 is discussed in greater detail in section 5.5.1 below.

3.2 Human milk fortifier 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. Fortifiers derived from cow's milk are added to human milk as a nutritional supplement to provide extra energy, minerals (such as calcium and phosphate) and vitamins. FSANZ understands that these products can vary in scope of composition and be used in combination with other nutrient supplements in the hospital setting.

Canadian regulations

Canada's Food and Drug Regulations have been recently amended to establish a framework for human milk fortifiers (HMF) to provide continued access to existing HMFs currently on the Canadian market and a clear regulatory pathway for new and innovative products. These amendments, including a definition for HMFs, were officially published in the Canada Gazette Part II[6].

Human milk fortifier has been defined to mean a food that:

(a) includes at least one added vitamin, mineral nutrient or amino acid, and

(b) is labelled or advertised as intended to be added to human milk to increase its nutritional value in order to meet the particular requirements of an infant in whom a physical or physiological condition exists as a result of a disease, disorder or abnormal physical state.

Information about HMF was provided by submitters to the 2017 consultation (Table 6).

Table 6: Submitters comments about HMF in 2017

Submitter	Comments
Industry	Human milk fortifiers are supplied from overseas by a very small number of manufacturers. They are used only to supplement pre-term breastfed babies in hospital and are appropriately regulated under Standard 2.9.5.
	HMF are designed to increase the nutritional content of breast milk to help pre-term infants achieve an optimal growth rate. The general composition of HMF provides additional energy from protein, carbohydrates and fat. It contains vitamins, minerals and trace elements to supplement breast milk. HMF are used primarily for infants who are both pre term (<37 weeks) and low birthweight. Industry does not support use for other indications. HMF are designed for use within the hospital setting for breastfed infants. HMF do not fit the definition of IFP. Certain labelling requirements and directions listed in Standard 2.9.1 would not be applicable to HMF and this would need to be taken into account; specifically, standard 2.9.1—19 is not appropriate. The trade and distribution access for HMF should be the same as for FSMP.

[6] https://www.canada.ca/en/health-canada/services/infant-care/infant-formula.html

Health professionals	It is appropriate that HMF are regulated under Standard 2.9.5. Understands that the particular use of HMF is not standardised routine practice in all NICU settings in terms of an infant's age, amount of HMF used, and length of time of usage. These products should be subject to some of the provisions in the Code relevant to IFP, such as microbiological limits.
	A HMF is used for pre-term and low birthweight infants to add protein, energy and micronutrients (especially bone minerals) to human milk to meet advisable nutrient intakes. The source of protein is usually cow's milk. The degree of hydrolysis in the various products in ANZ differs, depending on the brand. HMF are generally not suitable for use in term infants. There is currently some interest in the commercialisation of HMF using human milk but this is likely to cross several regulatory regimens. We are concerned that one HMF in ANZ has not had its formula adequately reviewed for many years despite updated nutrition guidelines. Companies also use different reference compositions for human milk. It would be beneficial for FSANZ to standardise the composition of pre-term human milk, according to Boyce et al (2016), to assist industry. We are concerned that the Code does not regulate microbiological limits and processing standards for modular products such as energy or protein supplements used as fortifiers.
Government	Modular products regulated under Standard 2.9.5 providing sources of one or more macro-nutrients may be used in conjunction with other sources of nourishment. One government considered that HMF are better regulated under Standard 2.9.5.

Discussion

Currently, human milk fortifiers (HMF) are not overtly captured by any subcategory in Division 4 of Standard 2.9.1 or by Standard 2.9.5. HMF and supplementary products for premature or low birthweight infants would not meet the current definition of IFP since they serve a supplementary role rather than as the sole or principal source of liquid nourishment for infants.

Most submitters who provided a response preferred HMF to be regulated by Standard 2.9.5. Some noted that, if regulated in Standard 2.9.1, the definition of IFP might need to expand to include them. Another submitter preferred a reference nutrient composition for pre-term human milk to be developed by FSANZ.

FSANZ considers that the supplementary products for premature and low birthweight infants such as HMF should be regulated under Standard 2.9.5. However, it is recognised that additional provisions relevant to IFP may be useful to insert into Standard 2.9.5 to clarify its scope. It will be important to review the differences in other parts of the Code between IFP and HMF and other supplementary products with respect to their need for a reference nutrient composition, the range of permitted forms of vitamins and minerals, food additives, contaminants and microbiological limits as well as labelling to determine the appropriate regulation.

As most HMF are imported, the microbiological risks are managed by the Department of Agriculture, Water and the Environment (DAWE), who manage food safety risks at the border. FSANZ's imported food risk assessments on human milk and human milk products, which were provided to DAWE, can be accessed on the FSANZ website[7].

Proposed approach

[7] See FSANZ advice on imported food (foodstandards.gov.au)

IFPSDU that are sole or principal sources of nutrition are proposed to be regulated as IFP, whereas other infant products that serve a supplementary role are proposed to be regulated by Standard 2.9.5. Subsequent consideration will be given to any particular provisions relevant to infant products that are needed in Standard 2.9.5 at a later stage.

4 Definitions

The overarching definition of Infant Formula Products (IFP) sets out the scope of the regulation in Standard 2.9.1 and the products that fall within that standard. By retaining Division 4 – Infant Formula Products for Special Dietary Use in Standard 2.9.1 rather than transferring it to Standard 2.9.5, the definition of IFP applies to infant formula (IF), follow-on formula (FOF) and IFPSDU.

4.1 Definition of infant formula product

The definition of IFP in the Code and also in the Ministerial Policy Guideline are shown in Table 7. Codex, EU and the US do not have definitions for IFP.

Table 7: Current definitions of infant formula product

Document	Definitions of Infant Formula Product
Standard 1.1.2 –Definitions used throughout the Code and noted in section 2.9.1—3	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.
Ministerial Policy Guideline	A manufactured product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

Preliminary view

The 2016 Consultation paper noted submissions to Proposal P1025 – Code Revision that generally supported clarification of the definition of IFP. Based on this support, FSANZ's preliminary view was that the definition of IFP should be retained. In the 2017 Consultation Paper the overarching definition was not specifically discussed although comment was received.

Submitters' views in 2016 and 2017

The 2016 Consultation paper sought comments on our preliminary approach to retain the definition as amended in 2015. Only one submission commented on the definition and supported the preliminary approach. However, submitters in 2017 noted the current definition of IFP would not capture important elements of several formulas used for medical conditions, leading to a lack of clarity and potential enforcement issues (Table 8).

Table 8: Submitter comments about the definition of infant formula products

Key issues
The IFPSDU definition should capture 'formula for special medical purposes' noting these products are evidence-based and their appropriate use is supported by access limitations and the need for management by medical professionals.

Key issues
A health professional group commented that “several infant formula for metabolic conditions are designed to be used in conjunction with breast feeding or standard infant formula to provide sufficient intake of the relevant nutrient/ metabolite e.g. phenylalanine in PKU. The specialised infant formula is nutritionally inadequate if used as a sole and sometimes principal liquid source of nourishment. The same is true for several products used for preterm infants e.g. human milk fortifier, which should be captured”. Also “whilst IFPSDU best fit under Standard 2.9.1, it is important to maintain a link to Standard 2.9.5 given that several of these products are used after 1 year of age”.
A health professional organisation recommended that products for premature or low birthweight infants should include human milk fortifiers, and other modular products such as whey protein powder, energy supplements (carbohydrate and/or fat) and food thickener. Including this group of products would ensure that other requirements of the Code would apply as if an IFP.

Discussion

The purpose of all IFP is to be nutritionally adequate to serve as a sole or principal liquid source of nourishment for infants depending on an infant’s age during the first 12 months of life. This is proposed to be retained. As such, an IFPSDU would also need to be a sole or principal source of nutrition. In this context, *principal* refers to an intention for the product to be the highest contributor to daily dietary intake.

The need for IFP to be based on milk or other edible food constituents of animal or plant origin (such as soy) is another aspect of the definition. FSANZ notes that IFP based on milk ingredients contain variable amounts of skim milk, concentrates and/or isolates of milk fractions. Some highly specialised IFPSDUs include amino acid formulas that may not be considered to be **based on** milk or other edible food constituents of animal or plant origin. If not appropriate for IFPSDU, the description of base ingredients is proposed to be moved to a compositional requirement for general IF and FOF only, and no base ingredients be required for IFPSDU.

Submitters drew attention to the practice for some IFPSDUs to be commenced in infancy and use continued beyond infancy. If use beyond infancy were to be recognised in Standard 2.9.1, it is not clear whether such use would need to be addressed in the definition of IFP.

Proposed approach

The second part of the current definition of IFP relating to a product that 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,* is proposed to be retained. As an IFP, this definition will also apply to IFPSDU. The first part of the current definition relating to base ingredients is proposed to be applied only to the compositional requirements for general IF and FOF and removed from the definition of IFP. Extension of use beyond infancy is discussed in section 5.6.2 below. So far, the proposed definition is:

> An 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.

4.2 Definition of infant formula

The current definitions for infant formula are shown in Table 9. The Code’s current definition should be read in conjunction with the definition of IFP since all aspects of these definitions together define what an infant formula is.

Table 9: Current definitions of infant formula

Document	Definitions of Infant Formula
Standard 2.9.1	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 4 to 6 months.
Ministerial Policy Guideline	A breast milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.
Codex STAN 72-1981	Infant Formula means a breast milk substitute specially manufactured to satisfy, by itself, the nutrition requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.
Delegated Regulation EU 2016/127	A food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of complementary feeding.

Preliminary view

In 2016, FSANZ considered the various definitions in Table 9. The Codex and EU definitions differ from the Code and the Ministerial Policy Guideline by not including a reference to an age range for a sole source of nutrition. Instead, they refer to the time when complementary feeding is introduced to allow for regional differences. No definition overtly refers to the maximum time an infant formula is suitable.

Comment was sought on four options to replace the second part of the current definition to address the difficulty in interpreting the 4-6 months age range. The four options were:

(1) Satisfies by itself the nutritional requirements of infants less than 6 months of age.
(2) Satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding.
(3) Option 1 or 2 followed by “and, as part of a progressively diversified diet, of infants from 6 months of age”.
(4) No change.

Submitter views in 2016

The overlap of age ranges for feeding infant formula and follow on formula in the second half of infancy has given rise to different interpretations about the period for suitable use of infant formula i.e. only in the first 4–6 months prior to introduction of complementary feeding, or continuing through as a principal liquid source of nutrition to less than 12 months of age.

Sixteen submitters[8] provided mixed views on the options (Table 10). In addition to commenting on certain options, submitters suggested new text, particularly inserting ‘around’ before 6 months in Option 1, and/or including ‘under 12 months’ as the maximum age for feeding infant formula in Option 3. Nine submitters preferred combining the options in some way. These submissions are identified using an asterisk (*) next to the number of submitters in column 2 of the table below. Government submitters generally supported option 3 together with either option 1 or 2. In contrast, industry generally supported no change and suggested

[8] Industry organisations were counted in this number; support from individual member companies for these submissions is noted.

the definition not be amended until FSANZ reviewed the FOF provisions at a future time. Two submitters proposed alternative wording to align with the WHO International Code of Marketing of Breast-milk Substitutes (WHO 1981).

Table 10: Submitters' preferences for the definition of infant formula

Submitter preference	Submitter
Option 1	industry (1)
Option 2 *Option 2 with added text "**around** 6 months'	industry (1), government (1+1*)
Options 1 and 2 *Option 1 & 2 with added text '…..**. until 12 months of age [when formula is no longer needed]**'.	health professionals (2*)
Options 1 and 3 *Option 1 & 3 with added text '**from around 6 months'** and **'to 12 months of age'.**	government (1+1*)
Options 2 and 3 ***Option 2 & 3 with added text '**around 6** months' and/or '**to 12 months of age**' and/or '***when infant formula is no longer required***	government (4*) health professional (1*)
Option 4	industry organisations (3) including support from several member companies

*submission suggested the additional text in bold

Discussion

In suggesting amendments to the current definition, some submitters preferred consistency with wording from policies or guidelines of other organisations. FSANZ acknowledges that while there should be consistency with these documents, the purpose of a definition in food regulation is not intended as a policy statement or guidance for educators or consumers. Instead, the definition sets out the regulatory identity and purpose of infant formula, which then determines the appropriate compositional requirements and labelling to guide safe and intended use. As such, the definition must be unambiguous, precise and clear.

Option 1 refers to a single maximum age which allows for a more certain determination of nutritional adequacy from which to set compositional criteria. Option 2 replaces that single age with a milestone of introducing complementary feeding according to an infant's cues and carer's decision. As such, it is more variable and therefore not preferred. The use of 'around' 6 months in various options is also not preferred for the same reasons as Option 2.

Given the confusion in the current definition, it is appropriate to clarify the maximum age for the sole use of infant formula, and that subsequent use beyond its role as a sole nutritional source is intentional.

FSANZ considers Option 1 provides the most regulatory certainty and, to that end, proposes to refer only to 6 months in part (b) of the IF definition.

Submitters suggested various amendments to emphasise the maximum age of feeding IF as a principal source of nutrition. Some submitters supported additional text relating to an infant's maximum age for the use of infant formula. To that end, FSANZ notes that *infant* is defined as a person under the age of 12 months, and this definition applies wherever *infant* is used in the Code. Additional text taken from the definition of *infant* is not considered

necessary. However, to assist interpretation, the definition of *infant* in section 1.2.2—2 could be included in the note to section 2.9.1—3.

We also note the industry's support for Option 4 to await the review of the FOF provisions before changing the infant formula definition. Nutrient composition of FOF will be addressed in the 1st CFS to P1028 and any changes to the infant formula definition necessitated can be considered at that time.

Proposed approach

The definition of infant formula is proposed to be amended by removing '4–' in (b). FSANZ notes that the definition of infant is applicable in the definition of infant formula. To assist interpretation, it is proposed to insert the definition of *infant* into the note to section 2.9.1—3 to indicate the total period for which infant formula is suitable.

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.

4.3 Other definitions

Certain definitions used in Standard 2.9.1 and relevant to Division 4 are yet to be discussed. These are shown in Table 11.

Table 11: Other relevant definitions

Subject	Use	Definition in section 2.9.1—3
Soy-based infant formula	For a limit on aluminium Subclass of food additives for IF in Schedule 15.	An IFP in which soy protein is the sole source of protein.
Pre-term formula	For a limit on aluminium Subcategory of Division 4, Std 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.[9]	Triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

CP1[10] discussed particular food additives proposed to be permitted in Schedule S15 for IFPSDU. The new approach proposed for Division 4 (see section 5) will enable relevant conditions of use for specialised infant formulas such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, IEM or those partially hydrolysed. These conditions are taken from the EU food additive regulations. Most of these

[9] As discussed in 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 abbreviation may be retained in Standard 2.9.1 for these purposes.

[10] See Consultation paper 1 - Safety and Food Technology - 21 May 2021 at P1028 – Infant Formula (foodstandards.gov.au)

terms are not defined by the EU, although Delegated Regulation EU 2016/127 contains specific provisions for protein hydrolysates (protein denaturation <70%) for general IF.

FSANZ proposes to retain the definition of pre-term formula for the time being, particularly because it might need further differentiation from HMF. FSANZ considers that the other two definitions for soy-based infant formula and MCT are self-explanatory and are not needed, however we are open to retaining them in the Code if stakeholders find them useful. The new terms introduced in the conditions for some food additives in CP1 such as *gastrointestinal* were not proposed to be defined in CP1. However, this is now a question posed to submitters.

QUESTIONS

2) 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.

3) 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.

4) 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.?

5 Regulatory framework for IFPSDU

Division 4 of Standard 2.9.1 regulates IFPSDU in three subcategories. Currently, the subcategories outline different requirements for composition and labelling. When Standard 2.9.1 was developed, these requirements were considered appropriate to manage any potential risks with products in each subcategory. Noting the issues raised by submitters that relate to the current subcategories, the approach to these regulatory subcategories has been reviewed.

The scope of Division 4 is key to determining the range of products regulated as IFPSDU. This is particularly relevant to the interface between IFPSDU and FSMP regulated by Standard 2.9.5. Since the last review of Standard 2.9.1, Standard 2.9.5 – Food for special medical purposes came into effect in 2012 to define and regulate special purpose food. It has certain features similar to IFPSDU. However, the definition of 'food for special medical purposes' specifically excludes infant formula products (section 2.9.5—2).

Submitters previously outlined the problems with the current Division 4.

- 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 product 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.

- It is not well harmonised with the EU, which is the source of most products.

Submitters also described certain products whose regulatory category was not clear. These products included bovine-derived fortifiers of human milk for use in feeding pre-term infants, certain liquid modular products and medical formulas for use beyond infancy.

5.1 Description of IFPSDU in Division 4 of Standard 2.9.1

Division 4 of Standard 2.9.1 does not currently include a definition of IFPSDU but consists of three subcategories of IFPSDU (Table 12).

Table 12: Current regulation of IFPSDU and positioning on the market

IFPSDU subcategory	Provisions in the Code		Examples of current positioning of formula on the market
	Definition	Standard 2.9.1	
1. Products formulated for premature or low birthweight infants.	Yes - for pre-term formula Pre-term formula means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.	2.9.1—13 Compositional deviation from IF permitted. Labelling – use under medical supervision, name to include pre-term	In-hospital premature formula. Low birthweight formula. Post discharge premature formula.
2. Products for metabolic, immunological, renal, hepatic and malabsorptive conditions.	No	2.9.1—14(1) to 2.9.1—14(2) 2.9.1—14(3) to 2.9.1—14(6) Compositional deviation from IF permitted. Labelling – use under medical supervision, state disease etc., and nutritional modifications. Composition and labelling of low lactose and lactose free.	IEM Lactose free and low lactose ased on labelling advising use under medical supervision: For transient gastro conditions and feeding problems: - gastro-oesophageal reflux - colic - constipation.
3. Products for specific dietary use based on a protein substitute.	Yes – protein substitute is defined in Standard 1.1.2 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.	2.9.1—15 Composition: some are the same as for IF: - energy - potential renal solute load (PRSL) - protein - fat - chromium - molybdenum - added MCT.	Partially hydrolysed protein. Extensively hydrolysed protein. L-amino acid-based formula.

Table 12 shows how the subcategories have different types of provisions. Definitions are given for the first and third subcategories for premature or low birthweight infants and products based on a protein substitute, respectively, but not for the second subcategory of products for metabolic, immunological, renal, hepatic and malabsorptive conditions (referred to below as 'metabolic etc.'). The first and second (but not the third) subcategories set out labelling provisions that refer to use under medical supervision. The first and second subcategories must comply with the nutrient composition of IF or FOF unless different for the purpose of the product. In contrast the third category for protein substitutes has its own less restrictive compositional requirements without the need to label for use under medical supervision. The need to comply with the balance of compositional requirements for IF is not clearly expressed for the third subcategory.

FSANZ is aware of regulatory uncertainty and overlap related to the broad nature of the current subcategories, the range of products in each subcategory and related definitions. Table 12 also provides examples of products on the market. Products in the first subcategory are highly specialised, are available through hospitals and include products that can act as a sole source of nutrition. Some interpretations might include supplementary or modular products for use in combination with breastfeeding or infant formula to meet an individual infant's special requirements. A wide range of products are manufactured under the second subcategory. These products range from lactose-free to highly specialised formulas for rare conditions. Products in the third subcategory currently range from partially or extensively hydrolysed protein products to amino acid-based products, some of which are generally available.

Slightly specialised products for conditions such as reflux or colic that were proposed to be categorised in 2017 as products for transient gastroenterological conditions appear not to be clearly positioned in the market as IF or IFPSDU. This view is according to product labelling that advises both use under medical supervision and *breast milk is best for babies*, noting the latter statement is exempted for metabolic etc. formulas by section 2.9.1—19(2).

IFPSDU products are suitable from birth to less than 12 months; however, submitters informed FSANZ that some specialised products are also intended for use beyond 1 year of age. The range of available products poses different risks depending on their specialised nature. Some IFPSDU are not safe for use by healthy infants; others can be consumed by healthy infants with little risk of harm.

5.2 Options for regulatory framework

Preliminary view

To address the current uncertainty and possible health risk associated with the current subcategories, FSANZ sought comment in 2017 on the advantages and disadvantages of the three options below for a revised structure of Division 4.

Option 1. Delete the current subcategories in Division 4 and merge them with the definition of IFPSDU into one IFPSDU Division. This option deals with gaps and overlaps in the current system but may not improve the regulatory clarity if specific requirements for various subcategories are needed. As noted above, some highly specialised products may pose a risk if consumed regularly by a healthy infant. This option would not assist in differentiating products that manage that risk.

Option 2. Retain the three present subcategories and narrow their scope based on product use, highly specialised nature and risk. This could potentially transfer products for transient gastroenterological conditions or the partially hydrolysed protein formula into general infant formula if consuming these products posed a low risk to a healthy infant. The 'high risk' specialised products could then be more easily differentiated from general infant formula.

Option 3. Reconstruct the second subcategory 'products for metabolic, immunological, renal, hepatic and malabsorptive conditions' to better reflect the range of products on the market. This approach creates a new subcategory of infant formula products for special medical purposes within Division 4, which some submitters suggested in 2012. The approach aims to more clearly capture these highly specialised products to provide an appropriate level of compositional flexibility and labelling consistent with their risk. Figure 2 shows FSANZ's preferred approach, which arranges Division 4 into four product subcategories.

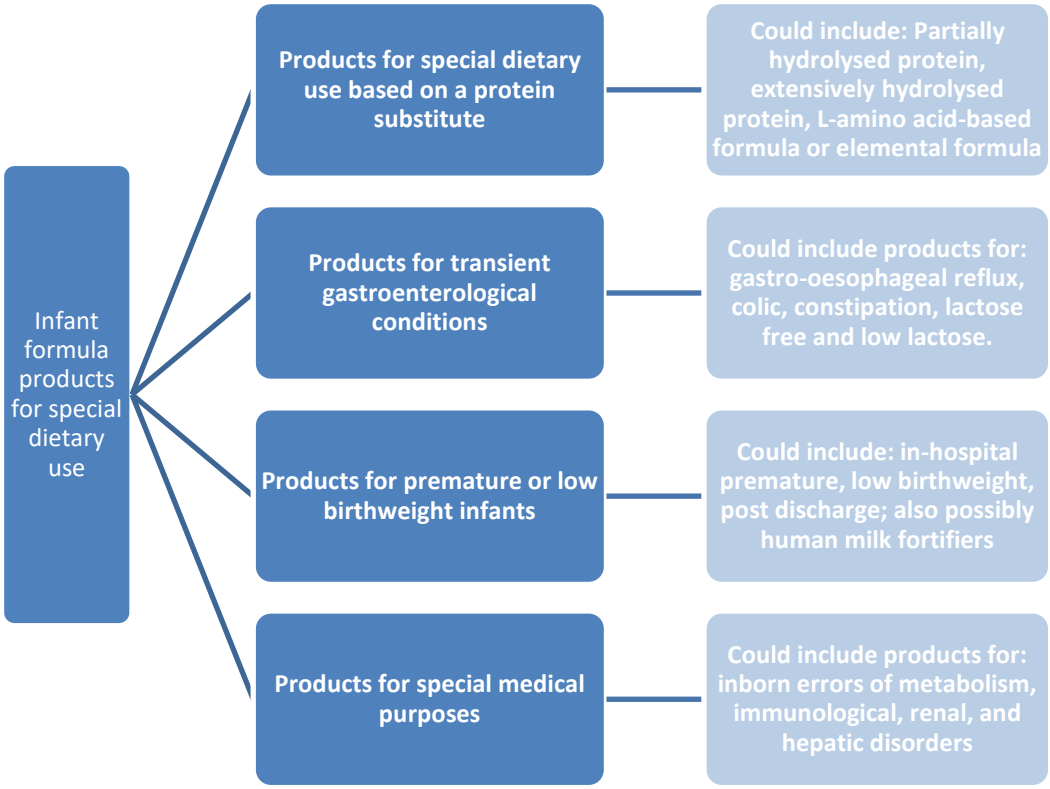

Figure 2 *Proposed regulatory classification for Division 4 in 2017*

Submitters' view in 2017

Submitters supported a clear differentiation between IF and special purpose formulas, however very few supported FSANZ's proposed option 3 and generally preferred a simpler structure.

The key issues raised in 2017 were:

- All special purpose formulas should be clearly differentiated from general infant formula.
- Consistency with EU and Codex is generally supported. Most specialised infant formula products are sourced and imported from overseas, therefore, to ensure an ongoing supply of such products, alignment with relevant international regulations is encouraged.
- The definitions should capture 'formula for special medical purposes', noting that these products are evidence-based and their appropriate use is supported by access limitations and the need for management by medical professionals.
- One overall category called infant formula for special medical purposes should be created. By including all infant formula for special dietary use into one category, specific requirements for the various subcategories may not be required. If all formulas are placed into an IFPSMP category, and the name IFPSMP is used, a definition for IFPSDU would not be required.

Eighteen submitters held a mix of views on variants of Options 1, 2 or a new option (Table 13). Some submitters preferred to separate a pre-term subcategory from the rest or create 3 subcategories of various products types. Industry supported three subcategories of premature, less serious (functional) disorders and serious disorders. Within all suggestions, some preferred to transfer transient gastroenterological conditions to IF. In contrast others preferred to separate partially and extensively hydrolysed protein formulas, the former transferred to IF, and the latter incorporated into medical formulas.

Table 13: Summary of submitters' preferences for Division 4 options in 2017

Submitter preference	Submitter	Comments
Option 1 **Merge into one category of IFPSDU**	government (5), health professionals (1)	Create one category and rename it as Infant Formula Products for Special Medical Purposes (IFPSMP) Some suggested including in the definition the need to be based on scientific evidence; some suggested transfer of transient gastroenterological conditions to general infant formula.
Option 2 **Retain three present subcategories**	industry (6); government (1); health professionals (1)	Suggestions for naming the 3 subcategories: • Premature, less serious (functional) disorders, serious disorders. • Premature, IFPSDU, IFPSMP. • Premature, IFPSMP, transient gastroenterological conditions. Some also suggested transfer of transient gastroenterological conditions and/or all or partially hydrolysed protein formulas to general infant formula if based on strong evidence; some suggest incorporate extensively hydrolysed protein into IFPSMP.
Option 3 **Construct four subcategories**	health professionals (1)	Supports in principle further development of option 3 with consideration of formula for infants with cows' milk allergy.
Option 4 **(not suggested in previous consultation)**	government (1); health professionals (2)	Create 2 subcategories: premature, expanded IFPSMP for all others.

Submitters varied in their preference for either an entire category renamed to infant formula products for special medical purposes (IFPSMP) or fewer subcategories of IFPSDU. Two groups of products not consistently supported as specialty products were protein substitutes and formulas for gastroenterological conditions because of a lack of sound evidence for their efficacy. Some support was given for pre-term products to remain as an existing subcategory. Consumer groups were concerned that transferring certain types of specialty formulas to IF could influence the premature cessation of breastfeeding if these products were accessible and sold where advice to use under medical supervision was not available.

Discussion and proposed approach

Due to the lack of support from submitters for FSANZ's proposed framework, and the level of support for Option 1, FSANZ will discontinue its 2017 proposal of four subcategories (Figure 2). From Table 12, the current provisions for the three IFPSDU subcategories are not consistent, and submitters found the delineation into the current subcategories confusing.

FSANZ proposes that subcategories should only be established if specific regulation beyond that set for all of Division 4 is needed. This may or may not need to be accompanied by definitions. This cannot be determined until further assessment of the current provisions of

each subcategory is undertaken in the section below. The relevance of Standard 2.9.5 and principles for the name, definition and framework for Division 4 is also discussed.

5.3 Principles for purpose, composition, use and sale of IFPSDU

Principles related to the purpose, composition, use and sale of IFPSDU are considered in this section. These principles do not replace the requirements of the FSANZ Act in which food regulatory measures must be based on regard for section 18 and section 59 assessment criteria, but are important to underpin and guide the framework of the regulation of IFPSDU in Division 4. The principles are discussed under separate headings. They were not canvassed in 2017.

5.3.1 Purpose

The principles related to the purpose of IFPSDU are derived from the definition of IFP, and the roles attributed in Standard 2.9.1 to general IFP i.e. IF as a substitute for human milk and FOF as a replacement of IF. The principles for IFPSDU are, therefore:

- to serve as a safe sole or principal source of nourishment
- to serve as a safe replacement for human milk, infant formula and follow on formula.

5.3.2 Nutrient composition and use under medical supervision

Relevant material from which to determine sound principles about the nature and use of IFPSDU are presented in Table 14. FSANZ notes that nearly all cited regulations in Table 14 refer to food/infant formula for special medical purposes.

Table 14: Basis for composition, scientific evidence and use under supervision

Regulation	Relevant provision
Policy Guideline	o) Infant formula products for special dietary uses must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of infant for whom they are intended. p) The composition of IFPSDU should be based on appropriate scientific evidence relevant to the purpose of the product.
Standard 2.9.5 definition of food for special medical purposes	2.9.5—2(1) Food for special medical purposes means 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. 2.9.5—2(2) Despite subsection (1), a food is not ***food for special medical purposes*** if it is:

	(a) formulated and represented as being for the dietary management of obesity or overweight; or (b) an infant formula product.
Codex Formula for Special Medical Purposes Intended for Infants, Section B	2.1.1 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 STAN 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.
	3.1.2 The composition shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infant for whom the formula is intended as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.
	3.1.3 The energy content and nutrient composition shall be based on the requirements for infant formula except for the compositional provisions which must be modified to meet the special nutrition requirements arising from the diseases, disorders or medical conditions for whose dietary management the product is specifically formulated, labelled and presented.
Regulation (EU) No 609/2013 The definition of foods for special medical purposes includes reference to infants. There is no definition of IFPSMP	(Article 2(1)(g)) 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.
Delegated Regulation (EU) No 2016/128 Food for special medical purposes (including for infants)	(Article 2(2)) The formulation of FSMP shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective for the persons for which they are intended on the basis of generally accepted scientific data. (Recital 5) Because of the wide diversity of FSMP, the rapidly evolving knowledge on which it is based, and the need to ensure adequate flexibility to develop innovative products, it is not appropriate to lay down detailed compositional rules for such food products. It is however important to set principles and requirements specific to them in order to ensure that they are safe, beneficial and effective for the purpose for whom they are intended on the basis of generally accepted scientific data. (Recital 6) The nutritional composition of FSMP for infants should be based on that of IF and FOF in order to take into account the specificities of the nutritional requirements of infants. However, taking into account that IF and FOF are intended for healthy infants, derogations should be provided for FSMP for infants when this is necessary for the intended use of the products. Annex 1 sets a reference vitamin and mineral composition which is similar but not the same as for IF or FOF. In other respects, the nutrient composition of these foods should comply with the requirements of IF and FOF.
US Infant Formula Regulation 21 CFR 107.50 Exempt Infant Formulas	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 IEM or low birthweight, or who otherwise have unusual medical or dietary problems.

From an analysis of the definitions and provisions in Table 14, several additional principles related to nutrient composition, scientific evidence, and appropriate use can be formulated such that IFPSDU products:

- should meet the nutritional requirements of infants to support growth and development
- are intended for the dietary management of infants with a specific disorder, illness or condition
- the nutrient composition should be based on
  - IF or FOF other than where necessary to meet the purpose of the product (compositional deviation)
  - appropriate scientific evidence
- should be used under medical supervision to manage the risk to unhealthy infants.

Of all these points, submitters were asked in 2017 (FSANZ 2017) to provide their views only on what benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation. Comments are summarised in Table 15.

Table 15: Submitter comments on requirements for IFPSDU in 2017

Submitter	Comments
Industry	An industry organisation supported by one manufacturer accepted that IFPSDU must have composition modifications that are based on acceptable scientific data that address the specific conditions. This is already referenced under Standard 2.9.1—14 (which relates to IFPSDU for metabolic etc. conditions). Manufacturers consider they are required to hold the scientific evidence that substantiates the nutritional suitability for the disease, disorder or medical condition.
	One manufacturer considered that the inclusion of a specific requirement for any IFSPDU to be demonstrated by generally accepted scientific data as safe, beneficial and effective in meeting the specific nutritional requirement of the intended infant subpopulation is already fairly representative of the current status quo without the need to explicitly express this in Standard 2.9.1.
Health professionals	One organisation considered that scientific evidence of safety, benefit and efficacy for all products formulations and ingredients is essential. The approach would require industry to provide robust proof of short and long term safety before any product is given to any infant. They also considered that there should be future liability to industry in respect to any adverse effects. The precautionary principle, and eliminating or limiting the risk of harm to infants is necessary, as is accountability of industry and appropriate consequences if harm is caused.
	Another organisation considered the classification of a product as IFPSDU must depend on their performance being fit for purpose, assessed through clinical trials and standardised, measured outcomes. It recommends strict protocols for any IFPSDU trials.
Government	Strongly supports the inclusion of a similar statement to EU recital 5 and 6 (see Table 14). This is not as strict as the US approach (where approval for the exempt status of an infant formula is required by the US FDA). It is important that the supplier of the product holds the information (or has access to) the data that supports the deviation. While this may already be a requirement under the Food Acts it is more explicit if contained in the Code. As it is already a requirement, this is not adding to the regulatory burden on suppliers and manufacturers. If the statement is not an explicit requirement, the Standard is more difficult to enforce.
	This is an imperative risk management strategy given the lack of prescribed compositional requirements, the particular vulnerability of this population and infants' reliance on these products as a significant source of nutrition. This is consistent with EU principles and Ministerial policy guidelines. Consumers and

	health professional alike would expect that a special purpose product would be beneficial for, or effective in, managing the intended condition.
	The requirement would be consistent with that for high level health claims to be substantiated by evidence, given IFPSDU are required to clearly specify on the label the medical use of the products.

Discussion

FSANZ notes that the Food Acts require manufacturers to ensure their products are safe. We also note the industry's position that relevant scientific evidence for their products is held and that no further regulation is needed. We also agree there is no explicit requirement in the Code for manufacturers to hold evidence supporting the suitability of the IFPSDU (or FSMP) in accordance with the intended purpose.

EU delegated regulation 2016/127, recital 6, states that all ingredients used in the manufacture of IF and FOF should be suitable for infants and their suitability should have been demonstrated when necessary by appropriate studies. It is the responsibility of food business operators to demonstrate such suitability and of national competent authorities to consider, on a case-by-case basis whether this is the case. They also refer to published guidance on the design and conduct of appropriate studies. However, the European regulation does not set out the specifics in relation to studies or their strength of evidence.

Noting concern from some submitters about the extent to which certain products are based on appropriate scientific evidence, and also noting the sources in Table 14, including the policy guideline, the proposed approach is also to include the need for IFPSDU to be:

- specially manufactured and formulated in accordance with appropriate scientific evidence that demonstrates the efficacy of the product in meeting its intended purpose.

5.3.3 Extension of use beyond infancy

Submitters drew attention to the use of some IFP that are commenced in infancy but are suitable for use beyond infancy. The practice for use beyond infancy is unclear whether it is advised on the label or in the province of medical advice or Australian Pharmaceutical Benefits Scheme (APBS) or New Zealand Pharmaceutical Management Agency (PHARMAC) listing. Standard 2.9.5 applies to products suitable for use from 12 months of age onwards. Equivalent products for infants are regulated by Standard 2.9.1. FSANZ considers there is merit in considering the continued use of IFPSDU beyond infancy. The principle is therefore:

- IFSPDU used in infancy and beyond should be accommodated in regulation.

5.3.3 Restriction on sale

Preliminary View

Currently, there is no restriction on the sale of IFSPDU. Some IFPSDU are available in supermarkets and standard retail locations; whereas others are only available through pharmacies and some of these only by prescription. Some IFPSDUs are provided through very limited pathways to consumers, healthcare professionals (dietitians, doctors) and responsible institutions (hospitals, pharmacies), and through home delivery services (initiated by healthcare professional referral). In contrast, FSMP are subject to a restriction on sale in Standard 2.9.5 which limits the sale to particular persons and premises. Submitters were asked in 2017 if they were aware of evidence about inappropriate access to IFPSDU and comments are summarised in Table 16.

Table 16: Submitter comments on restriction of sale for IFPSDU in 2017

Submitter	Comment
Government	Not aware of any evidence about inappropriate access. Supported applying limited access such at that given by Standard 2.9.5.
	Two government submitters provided published evidence from overseas research describing negative impacts of advertisements for lower risk IFPSDU on mothers' confidence of, and an expectation of failure, to breastfeed. Also cited anecdotal evidence from health professionals about the premature cessation of breastfeeding associated with self-diagnosis and general availability of low-risk IFPSDU. Submitters also drew attention to the increase in online purchasing from pharmacies including for FSMP and also noted the lack of access to pharmacy advice in large pharmacies. They supported further consideration of risk management of online purchasing from pharmacies. One government provided an example of excess IFPSDU being offered free through social media to others on presentation of a prescription for the same formula.
Health professionals	Noted that many high-risk IFPSDU are costly and available with government subsidy through pharmacies. Concerned about online sales from pharmacies which offer no support to purchasers. One provided evidence from focus groups of self-diagnosis (and lack of advice from health professionals) in relation to use of low-risk IFPSDU.
Industry	Not aware of any evidence about inappropriate access. Is open to restriction on trade and distribution for formulas for pre-term and (high risk) serious diseases only.

Discussion

Highly specialised products

Given the existing permission for compositional deviation of most IFPSDU from that of IF, the risk to the healthy infant depends on the extent of that deviation. The highly specialised products which pose a risk to health and safety do not appear to be available to the general population. Their specialised nature means they are only relevant to a small percentage of the population and they are not specifically marketed to the general public by companies. They are also more expensive than general infant formula, thus are usually accessed through the New Zealand PHARMAC and APBS from pharmacies.

Less specialised products

Less specialised products include those for gastro-oesophageal reflux, colic, and constipation (but not lactose-free/low lactose – see section 5.7.5). Some products comply with the ranges of macronutrients in IF but partially substitute different ingredient sources for some macronutrients (e.g. maltodextrin or corn starch for lactose) or serve the formula's named purpose. These less specialised products have been widely available to caregivers through supermarkets and pharmacies for over 20 years and appear not to have the same level of risk associated with their use. Most products carry labelling to differentiate the product from general infant formula and may indicate the products are not suitable for general use and should be used under medical supervision, but may also carry 'the breast milk is best' warning statement although this statement is not required for metabolic etc. products.

Protein substitutes are currently regulated as IFPSDU and include products based on partially hydrolysed protein, extensively hydrolysed protein, and L-amino acid-based formula. Several extensively hydrolysed and amino acid-based formulas are available on the APBS and PHARMAC listing, which limits their availability.

Some submitters were concerned about the ease of access to less specialised products that may lead to carers selecting these products over breastfeeding based on self-diagnosis. Many factors have been linked to early cessation of breastfeeding (Bond et. al. 2021). Whilst acknowledging this concern, FSANZ is unaware of evidence demonstrating that the availability of general or specialised infant formulas is a factor associated with breastfeeding cessation. One difficulty in characterising this issue is that research focuses on cessation of exclusive breastfeeding, which includes the introduction of solid foods to an infant's diet.

A restriction on sale was placed on FSMPs as part of their overall risk management strategy, given their minimal prescribed composition. This approach aimed to reduce the risks associated with potential unsupervised and inappropriate use and to discourage manufacturers or importers from taking advantage of the low compositional requirements in the standard. This was balanced against the need for consumers to have access to professional health advice and to ensure the supply chain is maintained. With the advent of online sales from pharmacies, as raised by some submitters, FSANZ acknowledges that product availability through these channels does not provide for professional health advice at the point of sale or protect against inappropriate use. FSANZ will seek further information about commercial practice in this regard.

To be consistent with the risk management strategy established for Standard 2.9.5, FSANZ considers that a restriction on sale should be imposed on IFPSDU. On this basis, another principle is:

- IFPSDU should be subject to a restriction on sale.

5.3.4 Proposed consolidated principles – purpose, composition, use, sale

The proposed principles guide the framework for the regulation of composition, use and access of IFPSDU. These consolidated principles are that IFPSDU:

- serve as a sole or principal source of nourishment (IFP definition)
- 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 FOF except where necessary to meet the intended purpose of the IFPSMP
- 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.

5.4 Name and definition of IFPSDU

Preliminary view

No defined term for IFPSDU exists in the Code. In 2017, FSANZ proposed to retain the name of IFPSDU for Division 4 and form a new definition of IFPSDU that would provide further clarity and reduce the ambiguity around the classification of some products at the interface between general and special IFPs. This also would provide a clear scope for the use of food additives and contaminant restrictions, microbiological safety and certain labelling provisions. The proposed definition of IFPSDU and its subcategory IFPSMP were:

Infant Formula Products for Special Dietary Use means an Infant Formula Product 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.

Infant Formula Products for Special Medical Purposes means an Infant Formula Product For Special Dietary Use that is specifically formulated for infants:

(a) who have
    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.

Submitters' views in 2017

Many submitters commented on the considerable overlap of the two definitions and preferred broadening them into one. Several submitters proposed definitions consistent with their views about the framework for Division 4 and the place of regulation of IFP for special medical purposes in the Code. An industry organisation supported FSANZ's proposed definition of IFPSDU with the deletion of 'special' in (b). Several government submitters proposed close variants of a revised definition of IFPSMP based on the Code's definition of FSMP, which was based on the EU definition. Health professionals submitted the need to include the excretion of metabolites in the definition consistent with the EU definition of FSMP.

Because of the level of support for IFPSMP instead of IFPSDU, submitters' proposed definitions for IFPSMP either as a subcategory of IFPSDU or as a separate category are presented in Table 17.

Table 17: Submitters' suggested definitions of IFPSDU or equivalent in 2017

Submitter	Suggested definitions
IFPSMP as a subcategory of IFPSDU	
Industry	IFPSMP applies only to serious diseases such that: Products for serious disorders, disease or medical conditions means products for special dietary use that are specially formulated for infants who have: ▪ specific disease or conditions that are clinically serious or potentially life-threatening and ▪ a need for specially formulated infant formula product not otherwise suitable for healthy infants.
Industry	Add a third criterion to FSANZ's proposed definition: ▪ Nutritional needs that cannot be covered by standard infant formula and/or for whom feeding with a standard infant formula can impair the health status.
Government	IFPSMP means an IFPSDU that is specifically formulated for infants who have a diagnosed disorder, disease or medical condition to meet the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.
Health professionals	IFPSMP means an IFPSDU, to be used under medical supervision, that is specifically formulated for infants who have ▪ medically determined nutrient requirements, or ▪ limited or impaired capacity to digest, absorb, metabolise or excrete food or certain nutrients contained therein or metabolites, including another type of IFP.
IFPSMP when a separate category from IF	

Health professionals	Base on EU definition of FSMP. There is no specific definition for 'Infant formula product(s) for special medical purposes' although the revised definition of foods for special medical purposes includes reference to infants.
	'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;
Government	IFPSMP means an IFP that is specifically formulated ▪ For the exclusive or partial feeding of infants with a specific medically determined; (i) limited or impaired capacity to digest, absorb, metabolise or excrete food, including other IFPs, or (ii) altered nutrient requirements, and ▪ Is beneficial and effective in the dietary management of specific medically determined conditions based on general accepted scientific evidence, and ▪ Is to be used under medical supervision.
Government	IFPSMP means an IFP that is specifically formulated ▪ For infants who have medically determined; (i) nutrient requirements, or (ii) limited or impaired capacity to digest, absorb, metabolise or excrete food, including another type of IFP, or certain nutrients contained therein ▪ To be used under medical supervision.
Government	IFPSMP means an IFP that is specifically formulated for infants ▪ who have a medically determined nutrient requirement, or ▪ limited or impaired capacity to digest, absorb, metabolise or excrete food, including another type of IF, and ▪ either partially or fully to satisfy the special nutritional needs of that infant, and ▪ is based on appropriate scientific evidence, and ▪ is to be used under medical supervision.
Government	IFPSMP means a product that: ▪ is specifically formulated for the partial or full dietary management of infants who have medically determined (i) altered nutrient requirements, or (ii) limited or impaired capacity to digest, absorb, metabolise or excrete food, including another type of IFP, ▪ Is considered to be safe, beneficial and effective in the dietary management of the specific condition based on generally accepted scientific data, and ▪ Is to be used under medical supervision.
Government	IFPSMP means an IFP that is ▪ specifically formulated for infants to satisfy either partially or fully, the special nutritional requirements for infants who have medically determined (i) nutrient requirements, or (ii) limited or impaired capacity to digest, absorb, metabolise or excrete food, including another type of IFP; ▪ safe, beneficial and effective for the medical condition of the infant based on generally accepted scientific data*, ▪ to be used under medical supervision.

Discussion

An appropriate name and definition will establish the scope of Division 4 and guide the provisions and any subcategories that might subsequently be needed.

Following submitter feedback and noting the Codex and overseas titles for the use of formula/food for special medical purposes for infants, FSANZ considers there is merit in changing the name of IFPSDU to **Infant Formula Products for Special Medical Purposes** (IFPSMP). A definition of IFPSMP similar to that for FSMP and accommodating relevant aspects of IFP would maintain internal consistency in the Code.

Government submitters based their suggested definitions of IFPSMP on FSMP to various extents. Some submissions also incorporated the specific principle from the Ministerial policy guideline that refers to the need for IFPSMP to be based on appropriate scientific evidence.

FSANZ considers that the definition of FSMP in Standard 2.9.5 is a suitable starting point with appropriate amendments as relevant. FSANZ substituted *infants* and *IFP* for the corresponding definitional elements for FSMP and included additional modifications suggested by submitters relevant to the context. This produced the following:

- IFPSMP is a food that is specially manufactured in accordance with appropriate scientific evidence for the dietary management of infants who have:
  - special medically determined nutrient requirements, or
  - limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs
- The dietary management of these cannot be completely achieved without the use of IFPSMP
- IFPSMP is a food that is intended to be used under medical supervision
- IFPSMP is a food that is represented as being an IFPSMP.

The definitional element relating to partial or exclusive feeding of FSMP was excluded because this aspect is covered by the definition of IFP as a sole or principal source of nourishment. Some elements such as supervision, representation and scientific evidence have been included but otherwise may lend themselves to being prescribed requirements and, as such, may not need to be included in a definition.

Proposed approach

FSANZ proposes to rename Division 4 as Infant Formula Products for Special Medical Purposes (IFPSMP) and consider the following definitional elements for IFPSMP taken from Standards 2.9.1 and 2.9.5. Therefore, a food that is represented as an IFPSMP:

- serves as a substitute for human milk, and replacement of infant formula and follow on formula
- is specially formulated for the dietary management of infants based on appropriate scientific evidence
- is for infants:
  - who have special medically determined nutrient requirements, or
  - who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and
  - whose dietary management cannot be completely achieved without the use of IFPSMP
- is a food that must be used under medical supervision.

The proposed approach shown schematically in Figure 3.

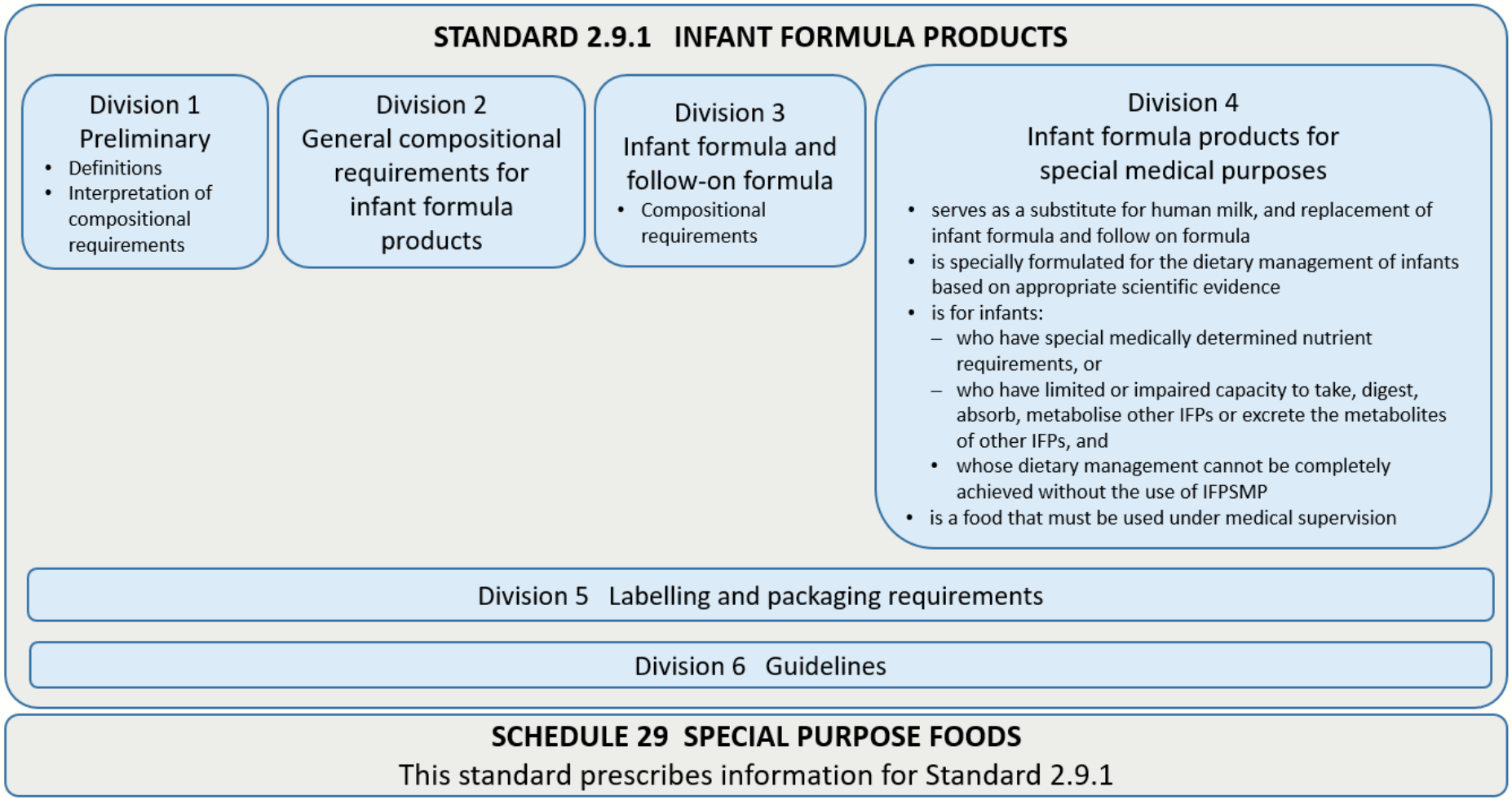

Figure 3 *The structure of the Code including the proposed Division 4 definitional elements*

5.5 Provisions for IFPSMP — composition

Now that the principles, proposed name, and definition are established, it is necessary to review the existing provisions for the three subcategories in Division 4 to determine whether they should be retained or amended or could be applied to the entire Division or removed altogether. This assessment also requires consideration of provisions in Standard 2.9.5 related to composition and restriction on sale. As previously indicated, FSANZ considers subcategories may be required only if specific requirements are needed beyond those that apply to the entire Division.

The current subcategories are:

- Products for pre-term and low birthweight infants
- Products for metabolic, immunological, renal, hepatic and malabsorptive conditions
- Products for specific dietary use based on a protein substitute.

The following section examines all compositional provisions in the three subcategories to determine their future use.

5.5.1 Products formulated for premature or low birthweight infants

Current regulation

The definition and regulatory provisions for this subcategory are given in Table 8 above. Pre-term formula is defined in section 1.1.2—3 (and the definition is provided in a note to section 2.9.1—3).

Previous consideration of definition

In 2017 (FSANZ 2017), the origin and intent of the definition were discussed, noting one request in a submission in 2012 to consider amending the definition to include age and weight parameters. It was noted that there are no regulatory definitions internationally, but there are clinical definitions across the world that may reference the WHO definitions. FSANZ noted that as the individual needs of each infant are monitored by specialist healthcare professionals in a clinical setting, there may be little benefit in modifying the definition to include age and weight parameters. In response to a question about this in 2017, a health professional submitter supported further differentiation of pre-term according to different gestational ages and weights. Submitters were also asked about the definition of pre-term and if any specific compositional requirements were needed for formulas for pre-term infants (Table 18). Submitters' comments in relation to human milk fortifiers are discussed in section 2.1.

Table 18 Submitter comments in relation to products for premature or low birthweight infants

Submitter	Comments
Industry	1) No issue with current definition 2) Recommended nutrient parameters not be introduced for any subcategories and supported the EU acknowledgment of the need to ensure adequate flexibility. Industry noted that the use of these products occurs under strict medical supervision in neonatal wards.

Health professionals	1) The definition should differentiate preterm products according to the WHO classification for pre-term infants to allow manufactures to target their product to different gestational ages and weights. For example: feeding lower volumes of currently available pre-term to ensure lower protein intake for older pre-terms is not ideal. This may not provide sufficient energy and other micronutrients for an infant and does not necessarily satisfy their hunger. 2) Confirms the importance of basing pre-term formulas on IF with appropriate deviation relevant to protein and energy.
Government	1) Questions the need for a definition or pre-term if IFPSDU is reframed as one category. Appropriate labelling statements referring to pre-term could be required without the need for a definition. 2) Expressed no firm view although one submitter considered that the current wording of deviation from IF composition is expressed ambiguously

In response to FSANZ's additional question about the availability of pre-term formula, Australian health professional submitters in 2017 advised FSANZ that pre-term formula is used only in hospital settings. However, industry mentioned that post discharge formula are available through patient registration schemes or selected pharmacies but are not listed on the PBS schedule. New Zealand health professionals advised access through a pharmacy is available to formula for pre-term infants funded by PHARMAC via a special authority authorised by a paediatrician. A health professional organisation considered that these products should not be available directly to the community, such as in pharmacies.

Discussion

This subcategory has permission to deviate from the compositional requirements of Standard 2.9.1, which means that, in other respects related to the intended purpose of the product, the formulation of these products must comply with compositional requirements for IF or FOF. In relation to further product differentiation, FSANZ considers it is not necessary to standardise this aspect in regulation, so to provide flexibility for industry to respond to demand, noting these products are imported.

Proposed approach

Based on submitters' support for the current arrangement and no suggestions for additional compositional requirements, the current arrangement to allow compositional deviation from the composition of IF is proposed to be retained.

5.5.2 Products for metabolic, immunological, renal, hepatic and malabsorptive conditions

The regulatory provisions for this subcategory are given in Table 12. This subcategory is not defined but has permission to deviate from the compositional requirements of IF or FOF. In addition, a guideline maximum for manganese is set that is much lower than for IF and FOF, i.e. 7.2 µg/100 kJ compared to 24 µg/100 kJ.

The 'no detectable lactose' criterion for lactose-free IFPSDU is the same as for general-purpose foods and FSMP. The 0.3 g lactose/100 mL limit for low lactose IFPSDU differs in the amount that can be present and in units (per 100 mL rather than per 100 kJ).

Submitters' views

In 2017, FSANZ asked if there were particular compositional requirements that applied to this subcategory. Industry submitted that the range of products was extensive and there were no compositional requirements common to all products in this subcategory. A government submitter commented that the existing compositional requirements for lactose-modified products appear not to be risk-based. Furthermore, it was commented that it is unclear why

these requirements would be regulated while the composition of products for more serious conditions is not. No submitter commented on the specific criteria for low lactose or lactose-free, or the guideline maximum amount for manganese.

Discussion

Guideline maximum amounts for minerals added to IF were discussed in CP2 – Nutrient Composition. The maximum for manganese in IF is proposed to be amended to a guideline amount. Given this subcategory has permission to deviate from the composition of IF, and submitters made no comment, it is proposed to remove the specific guideline maximum amount for manganese in this subcategory in favour of that for IF.

When provisions for lactose-free and low lactose formulas were established in the Code, FSANZ noted that, unlike other IFPSDU, these formulas are suitable for general use. Subsection 2.9.1—14(3) reflects this intent by stating a compositional or labelling requirement of Standard 2.9.1, other than a requirement related to lactose content, applies to lactose-free or low lactose formula.

These compositional criteria were established for safety reasons. In relation to lactose-free, FSANZ noted in Proposal P93 that lactose maldigestion occurs secondary to gastroenteritis in infants and can be life-threatening (ANZFA 1999). The 'no detectable lactose' criterion was adopted because it affords infants the highest level of protection as it requires the most advanced method of analysis to be used at all times. For low lactose, the 0.3 g lactose/100 mL criterion was determined to protect lactose intolerant infants from adverse symptoms.

Codex has no specific standard for infant formula prepared for the lactose maldigestion infant. In the European Union, lactose-free formulas are not regulated as FSMP. Article 9.2 of EU regulation 2016/127 requires lactose-free formulas to have a lactose content not greater than 2.5 mg/100 kJ[11] (10 mg/100 kcal) however, there are no requirements for low lactose formulas.

The same 'no detectable lactose' criterion was adopted for FSMP for medical reasons for consumers of FSMP, certainty for health professionals, and consistency with general purpose food claim conditions. FSANZ also noted in the Proposal P242 Final Assessment Report (FSANZ 2012b) the previous advice from the Australian Competition and Consumer Commission (ACCC) that 'free' claims mean 'no presence of'. That Report also stated that specifying a threshold level of lactose in the Code to be permitted in 'lactose-free' foods would be contrary to fair trading law which requires that information is not false, misleading or deceptive. Therefore, similar to lactose-free FSMP, any imported lactose-free IFPSMP would need to comply with the 'no detectable' criterion.

Submitters made no comment in relation to the specific lactose criteria. FSANZ considers that both these criteria could be retained. Since products in other subcategories also could be low lactose or lactose-free, these criteria could be applied to the entire category of IFPSMP, if appropriate.

QUESTIONS

[11] FSANZ estimates this to be equivalent to 6.8 mg/100mL based on the energy content of 272 kJ/100 mL (midpoint of the range in the EU regulation)

5) To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

6) To industry submitters: How many and what types of low lactose IFPSDU are on the market? What is their maximum level of lactose? Please provide supporting detail and data, where available.

5.5.3 Products for specific dietary use based on a protein substitute

Definition of category

The definition and regulatory provisions for this subcategory are given in Table 12 above. Protein substitute is defined in Standard 1.1.2 and as a note to section 2.9.1—3.

The Codex infant formula standard and the EU regulations do not include definitions for protein substitutes, protein hydrolysates, amino acid formula or hypoallergenic formula. However, Regulation (EU) 2016/127 for IF and FOF prescribes whey protein sources with a protein denaturation of <70% and a method for protein processing. The regulation enables manufacturers to describe the role of infant formula manufactured from protein hydrolysates in reducing the risk of developing an allergy to milk proteins (under certain conditions).

The 2017 paper asked for submitter comment on any issues with the current definition of protein substitutes and the following terms:

- hypoallergenic formula
- partially hydrolysed formula
- extensively hydrolysed formula
- amino acid-based formula.

These are summarised in Table 19.

Table 19: Submitter comments on terms for protein substitutes

Submitter	Comments
Industry	Opposes a categorisation based on form or ingredient use in IFPSDU There is no benefit in defining any of the suggested terms because there is no international consensus on criteria for the suggested terms. The current definition is limiting because of reference to the proteins on which IFP is *normally* based i.e. cows, goats and soy formulas. For example, it does not include rice which is used for the dietary management of allergic conditions. This category should not exist as it overlaps with others such as pre-term or metabolic etc.
Health professionals	This category should not exist as it overlaps with others such as pre-term or metabolic etc. Recommends urgent re-evaluation of all hydrolysed formula in light of research evidence confirming its ineffectiveness. Reference was also made to the ASCIA recommendation against partially and extensively infant formula for the prevention of allergic disease. One other submitter agreed there were benefits for the suggested terms and supported a description of the degree of protein hydrolysis on the label to assist clinicians.
Government	Does not consider there is a need for the suggested terms, noting science is advancing quickly and such terms may become outdated. Does not support the use of *hypoallergenic* as it is confusing and poses a potential risk of misuse. Suggests partially hydrolysed protein

	and soy-based products should be potentially excluded from IFPSMP as the medical benefit provided is unclear.

QUESTIONS

7) To industry and government submitters: What types of partially hydrolysed IFP are on the market? And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available.
8) To health professionals: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available.

Based on submitters' comments, the definition and subcategory may be removed depending on the need to retain certain compositional requirements as discussed below.

Conditions for certain nutrients are prescribed for this subcategory, some of which are the same as for general IF or FOF. No explicit deviation from the prescribed nutrient composition is permitted as for other subcategories, and submitters commented that Schedule 2.9.1[12] was unclear as to whether the other requirements for IF or FOF applied to this subcategory. Table 20 lists the compositional requirements for protein substitutes and IF and FOF.

Table 20: Compositional requirements for protein substitutes and IF and FOF

Nutrient	**Requirement**	
	Protein substitutes	**IF or FOF as appropriate**
Energy	IF: 2500 – 3150 kJ/L	IF: 2500 – 3150 kJ/L
	FOF: 2500 – 3550 kJ/L	FOF: 2500 – 3550 kJ/L
PRSL and method of calculation (S29—4)	Max 8 mOsm/100kJ	IF: No conditions FOF: Max 8 mOsm/100kJ
Protein	0.45 – **1.4** g/100 kJ	IF: 0.45 – 0.7 g/100 kJ FOF: 0.38/0.45 – 1.3 g/100 kJ
Fat	**0.93** – 1.5 g/100 kJ	1.05 – 1.5 g/100 kJ
Chromium	0.35 – 2.0 µg/100 kJ	Guideline max 2.0 µg/100 kJ
Molybdenum	0.36 – 3.0 µg/100 kJ	Guideline max 3.0 µg/100 kJ
Amino acids	As for IF and FOF	As for IF and FOF
May contain MCT as defined	No conditions	Only if naturally present or in added vitamin preparations.

In 2017, submitters were asked if any compositional requirements were needed for this subcategory (Table 21).

Table 21: Submitter comments on compositional requirements for protein substitutes.

[12] At the time, compositional requirements were listed in Standard 2.9.1. Following a Code revision in 2016, most compositional requirements are now listed in Schedule 29.

Submitter	Comments
Industry	The current specific requirements for maximum protein, minimum fat, PRSL, and permission for MCT and molybdenum and chromium differs from IF and are not necessary as they are out of date. Protein substitutes should be permitted to have compositional deviation from IF as currently for other subcategories.
Health professionals	Composition needs to take account of matrix and permitted forms of nutrients Reference was made to a paper to unexpected widespread hypophosphatemia and bone disease associated with elemental formula in infants and children.
Government	The existing compositional requirements for hydrolysed protein products appear not to be risk based. It is not clear why these requirements would be regulated while the composition of products for more serious conditions is not.

Specific compositional requirements

Minimum fat and maximum protein

These values differ from IF and FOF such that:

- the minimum protein is the same as IF but higher than the recently reduced minimum for FOF (FSANZ 2019)
- the maximum protein is higher than the maximum for FOF based on limited evidence and products on the market at the time the regulation was previously reviewed
- the minimum fat is lower than that of IF and FOF based on products on the market at the time the regulation was previously reviewed
- maximum fat is the same as for IF and FOF.

Industry submitters in 2017 proffered the view that these requirements were unnecessary and that protein substitutes should be allowed to deviate their composition as needed for the purpose of the product based on the composition of IF and FOF.

Potential renal solute load (PRSL) and method of calculation (S29—4)

The same maximum PRSL is prescribed for FOF as for protein substitutes based on the higher permitted protein maximum. The calculation of PRSL for milk- and soy-based FOF and protein substitutes is set out in section S29—4.

In 2017 industry proffered the view that specific requirements for PRSL were not necessary for protein substitutes in line with the removal of the protein maximum and applying compositional deviation as for pre-term and metabolic etc. products.

Noting that most of these products are imported, FSANZ considers that there is no need to specifically regulate the protein and fat levels or PRSL in protein substitutes and that the current approach for pre-term and metabolic etc. products would be appropriate and a more flexible approach for imported protein substitutes.

Molybdenum and chromium in protein substitutes

Molybdenum and chromium content is not, and is not proposed to be, regulated in IF on the assumption that sufficient amounts are provided naturally by product ingredients. The permission for addition of molybdenum and chromium does not apply to pre-term and metabolic etc. formula for the same reason. However, general protein ingredients are not used in protein substitutes based on amino acids. Paragraph 2.9.1 – 15(2)(e) prescribes minimum and maximum levels of molybdenum and chromium to be achieved naturally and/or by addition to protein substitutes. Chemical forms of molybdenum and chromium permitted for this purpose are listed in section S29–7. The levels are similar to those in Codex standard section B – Formula for special medical purposes intended for infants (0.4 – 2.4 µg/100kJ)

but are not mandatory, rather they can be taken into account where appropriate. Table 22 summarises comments from submitters in relation to this issue.

Table 22: Submitter comments molybdenum and chromium in protein substitutes

Submitter	Comments
Industry	One submitter did not support the inclusion of a minimum or maximum amount of chromium or molybdenum in IFSDU and proposed these limits should be removed. *Minimum amount*. Noted Codex's minimum is for use where appropriate and considers the addition is optional, but the minimum limit applies if added. Notes that EU has not set a minimum based on EFSA's opinion about the unproven essentiality of chromium. No strong evidence that justifies molybdenum as essential, and therefore, a minimum is not necessary. *Maximum amount* Since both Codex and EU present chromium as a non-mandatory addition, and with no ULs or adverse effects established for chromium, there is no evidence to support the inclusion of any maximum amount. Neither Codex nor EU mandate molybdenum with no ULs and toxicity data available.
	A maximum amount for chromium or molybdenum is difficult to manage due to natural variation in raw materials. Currently, no maximum amount was established by FSANZ for chromium in infants aged 0-12 months. Similarly, such a value does not exist in EU or US due to the absence of adequate data reporting adverse effects. Therefore, setting a maximum value but keeping it large enough to avoid excessive technological constraints would be a valuable option; if the maximum is unable to be established, it should be kept open to align with EU or US.

Allowing deviation from the nutrient composition of IF and FOF for these two trace elements is not possible for any of the current subcategories as the reference composition for IF or FOF does not include them. Having minimum and maximum levels of molybdenum and chromium in protein substitutes has the effect of prohibiting the addition of these two trace elements to the other two subcategories because these trace elements are classified as nutritive substances (minerals). If Division 4 were to become one category, the following options for regulation of molybdenum and chromium are available:

1. Retain current mandatory requirement to be met naturally and/or through addition for protein substitutes – status quo
2. Permit voluntary addition within compositional limits to be met naturally and/or through addition for all IFPSMP
3. Permit voluntary addition without any compositional limits for all IFPSMP
4. Delete the requirement altogether which then serves to prohibit addition since molybdenum and chromium are classified as nutritive substances, and their permitted forms in section S29–7 become redundant.

QUESTION

9) Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available.

Medium Chain Triglycerides

MCT is defined in Standard 1.1.2 (and the definition is provided in a note to section 2.9.1—3) as triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

In relation to IF and FOF, MCT is permitted only if present as a natural constituent of milk-based ingredients, or in association with fat-soluble vitamins added to IF or FOF. This approach was proposed to be retained in Consultation paper 2 (FSANZ 2021).

In the current Division 4, products based on protein substitutes are permitted use of MCT (without limitation) but the other two subcategories are silent regarding its use. MCT is a substitute for other types of ingredient fats that also would be relevant to use in the metabolic etc. subcategory. MCT is not regarded as a novel ingredient given its long history of use. If Division 4 were to become one category, MCT could be considered to require permission, given its restriction for IF and FOF as proposed in CP2, or to be a general ingredient, in which case the current permission for protein substitutes could be removed. In 2017, industry submitters proffered the view that specific requirements for using MCT in protein substitutes were unnecessary.

If Division 4 were to become one category, the options in relation to the use of MCT are that permission is:

1. Applied to the entire IFPSMP category, with or without limits
2. Removed from protein substitutes with the effect that Division 4 is silent and possibly unclear with respect to its use but noting the restriction proposed for IF in Consultation paper 2 (FSANZ 2021).

QUESTIONS

10) To industry submitters: What type of products contain MCT oil? For what purpose and at what levels? Please provide supporting detail and data, where available.

11) To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available.

5.5.4 Proposed approach – Composition of IFPSMP

From a review of the current approaches to composition for pre-term, metabolic etc., and protein substitutes, FSANZ's view is to retain the permission for compositional deviation generally and extend it to all IFPSMP. This would permit the nutrient composition of all IFPSMP to reflect that of IF or FOF except where necessary to meet the intended purpose of the product. Similar to vitamins and minerals in Standard 2.9.5, this arrangement would regulate the reference nutrient composition of IF and FOF but not the particular compositional deviations necessary to meet the purpose of the product; this would be the responsibility of the manufacturer under the Food Acts.

In light of the above approach, the current provisions in Table 12 that apply to the energy range, maximum protein, minimum fat, PRSL in protein substitutes and the guideline level for manganese in metabolic etc. products are proposed to be removed. However, the following matters need further assessment to determine whether they could apply to the entire category of IFPSMP, or be removed, or be retained for a particular or new subcategory:

- criteria for low lactose applicable to all IFPSMP if relevant products exist
- permission/requirement for molybdenum and chromium in all or some IFPSMP
- permission for use of MCT oil in all IFPSMP.

FSANZ will further consider the approach to regulation of these matters after receiving submitter responses in response to posed questions above.

5.6 Provisions for IFPSMP — purpose, use and sale

Section 5.4 proposes a new regulatory framework and definition for IFPSMP. As this is newly introduced in this consultation paper, the following preliminary views and/or questions for provisions related to purpose, use and sale are put forward:

5.6.1 Scientific evidence of purpose

It is proposed to enshrine in regulation the principle that IFPSMP are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose. This would then become the basis for classification of a product either as a general IF or as an IFPSMP. This is particularly relevant to products for less serious conditions such as reflux, colic, hungry babies.

Adoption of this principle for Standard 2.9.1 has several possible outcomes. It could remain only as a principle that is expected to be followed, or it could be more overtly expressed and inserted as a provision into Division 4. Such a provision could be a simple statement of requirement without further detail on how the requirement should be met. This is akin to the approach taken by Codex and EU. Under this arrangement, industry would be expected to hold the evidence for a product's efficacy in line with its represented purpose, and determination of a product as IF or IFPSMP would become the responsibility of enforcement agencies.

Alternatively, the requirement could be accompanied by guidance either in the Code, similar to Schedule 6 for health claims, or elsewhere such as a code of practice, on how the requirement should be met. Further work could provide more details about what would constitute generally accepted scientific evidence relevant to the purpose of the product.

Preliminary view

Scientific evidence to support the categorisation of products as IFPSMP is to be enshrined in regulation. In regulatory terms, this might mean a requirement that: manufacturers of IFPSMP must have established the efficacy of the product as an IFPSMP; and retain evidence that demonstrates both that they have undertaken that step and the efficacy of the product as an IFPSMP. This is consistent with current international regulations. Further provisions to how this requirement would be met will be examined in the 1st CFS. For further assessment, FSANZ requests the following information:

QUESTIONS

12) To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)?

13) If so, what type of scientific evidence is held by companies and what is its strength of evidence?

5.6.2 Extension of use beyond infancy

FSANZ is open to permitting the use of IFPSMP beyond infancy in the regulation of IFP but needs further information to determine what requirements are needed to allow for such use. For example, is there a maximum age or other parameters that indicates when the product is no longer appropriate?

Preliminary view

FSANZ considers that extension of use beyond infancy may be appropriate in some circumstances but requests the following additional information:

QUESTIONS

14) What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

5.6.3 Lactose-free and low-lactose formulas

The name of the food must include the words 'lactose-free' or 'low lactose' (paragraph 2.9.1—14(6)(a) and statements about the amount of lactose and galactose expressed in g/100 mL are required (paragraph 2.9.1—14(6)(b)).

Until now, FSANZ has not consulted on labelling provisions for lactose-free and low lactose formulas. In response to the 2017 Consultation paper, one submission from a consumer group considered phrases such as 'suitable for lactose intolerant babies who are recovering from diarrhoea associated with lactose intolerance could be seen by consumers as a therapeutic benefit.

FSANZ notes this type of statement relates to the provision in paragraph 2.9.1—14(2)(c) for IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (i.e. a statement indicating the product is not suitable for general use and should be used under medical supervision). However, the Proposal P93 Inquiry Report (ANZFA 1999) states that 'with the exception of formulas targeted to lactose intolerant infants, special purpose formulas are not suitable for general use and are to be labelled as such'. The intent is that specific labelling requirements for IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions do not apply to lactose-free and low lactose formulas. This approach is consistent with the EU, which does not regulate lactose-free formulas as FSMP and prohibits this type of statement (section 5.5.2). However, FSANZ acknowledges that provisions in section 2.9.1—14 do not clearly reflect this intent and suggests they could be clarified.

As noted in section 5.5.2, there are no Codex provisions relating to lactose claims. The European Union permits lactose-free statements (but not low lactose statements) for infant formula and follow-on formula if specific compositional criteria are met. Article 9 of Regulation EU 2016/127 also requires the statement 'not suitable for infants with galactosaemia' for infant formula and follow-on formula manufactured from protein sources other than soy protein isolates.

FSANZ considers an additional advisory statement referring to galactosaemia is not warranted. The declaration of galactose content performs a similar function to an advisory statement by providing information to caregivers to determine how much of the food, if any, is suitable for infants with galactosaemia.

Preliminary view

Based on the above arguments, FSANZ's preliminary view in relation to lactose free and low lactose formulas is to:

- maintain existing labelling requirements
- clarify IFPSMP labelling provisions would not apply.

5.6.4 Distribution and access

Section 5.3.3 explains the proposed principle for IFPSMP, that to be consistent with risk management approaches within Standard 2.9.5, a restriction on sale is appropriate for the sale of IFPSMP. Given this restriction, it is appropriate to review section 2.9.5—5, which sets out the restriction on the persons by whom, and premises at which FSMP may be sold to determine its applicability to IFPSMP. Section 2.9.5—5 prohibits the sale of FSMP to a consumer except from or by a medical practitioner or dietitian, or medical practice, pharmacy or responsible institution, or a majority seller under certain circumstances. Various terms in this section are defined by the Code: medical practitioner, responsible institution, and majority seller.

Currently, some products for transient gastroenterological conditions such as reflux are available from some supermarkets. Adopting a restriction on sale and classification of these products according to scientific criteria for efficacy may result in the withdrawal of these products from supermarkets, or their representation as general IF. These products could still be accessible through medical practitioners, responsible institutions, or permitted sellers, as outlined above.

Submitters drew attention to product being available from pharmacies without access to health professional advice. This situation would also apply to products sold over the internet. FSANZ appreciates that for certain groups in the community, online sale is a more convenient option particularly for regional and remote members of the community. We consider that the risk would be low as any IF that did not require a prescription or used in hospital setting (e.g. IF for serious conditions) would be based on compositional requirements of IF for the healthy infant and therefore safe .

One stakeholder commented that internet access to products for special dietary use to be in the category of unethical direct marketing (of medication) to consumers. It is assumed that this comment is in reference to highly specialised IF products (such as those for preterm and low birthweight infants) which would normally only be available in a clinical setting or with prescription.

Preliminary view

Based on the above arguments, FSANZ's preliminary views in relation to distribution and access to IFPSMP are:

- Supermarket sales of IFP will be restricted to general IF.
- Access to IFPSMP will be restricted to those medical practitioners, responsible institutions, or permitted sellers (to be defined in the Code, similar to Standard 2.9.5).

5.7 Labelling of IFPSMP

In the 2017 Consultation paper, consideration of specific labelling requirements for IFPSDU was deferred until the approach for product categories, definitions and names of the food were finalised. However, FSANZ took the opportunity to seek stakeholder views on several matters. These included:

- the need for prescribed names for the IFPSDU category and subcategories
- whether or not specific FSMP labelling requirements in Standard 2.9.5 applied to all IFPSDU or certain subcategories
- whether the prescribed wording of the warning statement for pre-term IFPSDU about using the product under medical supervision could be replaced with flexible wording to harmonise with international and overseas requirements, and
- if there are any additional specific labelling requirements for the safe preparation and use of IFPSDU that contradict general requirements.

FSANZ also put forward preliminary views in 2017 that:

- the exemption for IFPSDU products for metabolic, immunological, renal, hepatic or malabsorptive conditions to carry the warning statement 'Important notice, Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice' should remain
- the exemption for pre-term formula from the statement about offering additional foods to infants beyond six months of age should remain.

Much of the initial discussion and assessment in the 2017 Consultation paper and subsequent stakeholder responses are superseded by the proposed regulatory framework outlined in this paper. As noted in the 2017 Consultation paper (and confirmed by industry stakeholders), most IFPSDU are imported into Australia and New Zealand, predominantly from the EU. To FSANZ's knowledge, this continues to be the situation. In line with all initial views, labelling requirements in the Code must ensure sufficient information is provided to health professionals and caregivers about the purpose of these products and be sufficiently flexible to prevent interruptions to their supply.

The following section discusses how labelling could apply in the context of a single IFPSMP category under the proposed regulatory framework without being trade restrictive. Preliminary views are included on this basis. FSANZ has also considered previous submitter comments in response to the 2016, 2017 and 2021 (CP1) Consultation papers (where relevant) and overseas regulations and Codex.

5.7.1 FSMP statements

In sections 5.3 and 5.4, FSANZ has proposed a name and definition for specialised IFP (IFPSMP) in addition to some proposed consolidated principles to underpin their purpose, composition, use and sale. Both sections have drawn on FSMP elements in Standard 2.9.5. FSANZ has reconsidered how labelling could apply to IFPSMP as a single category (as proposed in section 5.4).

The current Standard 2.9.1 contains labelling requirements specific to certain IFPSDU subcategories. These requirements are:

- for IFPSDU formulated for premature or low birthweight infants, a warning statement 'Suitable only for pre-term infants under specialist medical supervision' (paragraph 2.9.1—13(2)(a))
- for IFPSDU suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, statements in paragraphs 2.9.1—14(2)(c)-(e) indicating the:
  - product is not suitable for general use and should be used under medical supervision
  - condition, disease or disorder for which the product has been specially formulated, and
  - nutritional modifications, if any, which have been made to the product.

Subsection 2.9.5—10(1) requires FSMP to be labelled with the following advisory or warning statements:

(a) a statement to the effect that the food must be used under medical supervision
(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated
(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose
(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group

(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition
(g) a statement to the effect that the food is not for parenteral use and any additional statements describing any nutritional modifications made.

The approach taken in the 2017 Consultation paper was to review the existing requirements in Division 4 of Standard 2.9.1 as they related to certain subcategories and discuss whether additional requirements from Division 4 of Standard 2.9.5 could be applied.

Discussion

Overall, submitter views about each of the labelling requirements in subsection 2.9.5—10(1) varied. All submitters supported the need for a statement to the effect that the food must be used under medical supervision. However there were diverging views about how the statement should be worded for different subcategories (under the existing regulatory framework).

There was general support for applying statements about precautions and contraindications, medical purpose and properties or characteristics. However industry submitters preferred the statement about properties or characteristics to be optional due to label space restrictions. Further, several government submitters considered that the list of nutritional modifications and ingredients should not be permitted on the front of the label for marketing purposes.

An industry submitter indicated that existing age-related labelling provisions in Standard 2.9.1 (e.g. prescribed names, may be used from birth statement, voluntary age and stage labelling) suggest a statement relating to a specified age group is unnecessary.

Several government and health professional submitters supported (none opposed) the statement about whether the IFPSDU was suitable for use as a sole source of nutrition. In contrast, the FSMP labelling requirement that the food is not for parenteral use (and any associated statements) received little support. One industry submitter said they were unaware of instances where these products were used inappropriately for infant feeding.

Several submitters noted they would support the application of FSMP labelling to IFPSDU.

FSANZ notes that, except for lactose-free and low lactose provisions, existing labelling requirements for IFPSDU pre-term and metabolic, immunological, renal, hepatic and malabsorptive conditions subcategories (sections 2.9.1—13 and 14) could be replaced by the majority of FSMP provisions (subsection 2.9.5—10(1)) for all IFPSMP. This is because FSMP labelling requirements offer more flexibility through less prescriptive wording.

Harmonisation with EU regulations is desirable, particularly given the EU regulate IFPSMP as FSMP, and there is already good alignment between Code provisions in subsection 2.9.5—10(1) and FSMP requirements in the EU. An example is provided in Table 23 below.

Table 23: Current provisions for ‘use under medical supervision’ in the Code, Codex and EU regulations

Food Standards Code	Codex	European Union	FSANZ comments
STANDARD 2.9.1 IFPSDU **2.9.1—13(2)(a)** *(Pre-term only)* Warning statement 'Suitable only for pre-term infants under specialist medical supervision.' **2.9.1—14(2)(c)** *(Metabolic only, immunological, renal, hepatic or malabsorptive conditions only)* A statement indicating the product is not suitable for general use and should be used under medical supervision. **STANDARD 2.9.5 FSMP** **2.9.5—10(1)(a)** Statement to the effect that the food must be used under medical supervision	**CXS 180-1991** **Section 4.4.1 (CXS 180-1991)** Statement 'Use under medical supervision'	**COMMISSION DELEGATED REGULATION (EU) 2016/128** **Article 5(2)(a)** 'Important notice' Statement that the product must be used under medical supervision	Adopting the FSMP provision in paragraph 2.9.5—10(1)(a) provides consistency for all IFPSMP, harmonises with Codex and EU regulations and provides greater labelling flexibility for imported products. Removing references to 'specialist medical supervision' and 'not suitable for general use' could be justified given the proposed regulatory approach for restriction on the sale of IFPSMP. Under this scenario, FSMP statements are particularly relevant to health professionals for the purposes of appropriate product identification and use. In 2017 there was some stakeholder support for the adoption of the FSMP provision in paragraph 2.9.5—10(1)(a).

An approach where the majority of FSMP labelling requirements in subsection 2.9.1—10(1) was adopted would ensure there is consistent labelling across all IFPSMP.

FSMP statements could also replace other existing provisions in Standard 2.9.1. For example, the statement to the effect that the food is intended for persons within the specified age group could be used in place of:

- a prescribed name (see section 5.7.5), and
- the generic statement indicating the infant formula product may be used from birth (see section 5.7.8).

Similarly, a restriction on the sale of IFPSMP (section 5.6.4) would:

- ensure the appropriate use of IFPSMP
- address submitter concerns that caregivers of healthy infants would be influenced by IFPSMP labelling, and
- negate the need for prescribing the location of certain FSMP statements on the label, as suggested by some government submitters.

FSANZ considers the FSMP statements in paragraph 2.9.1—10(1)(g) that the food is not for parenteral use (and any associated statements) is unnecessary given IFPSMP will be used under medical supervision, and there is no evidence that such products are being used inappropriately. However, the presence of such statements on imported products would not be prohibited.

The adoption of FSMP labelling provisions in paragraphs 2.9.1—10(1)(a) to (f) would support the consolidated principles for the purpose, composition, use and sale of IFPSMP proposed in section 5.3.4.

Preliminary view

Based on the considerations above, FSANZ's preliminary view is to replace the labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (except for lactose-free and low lactose formulas) with FSMP provisions in paragraphs 2.9.5—10(1)(a) to (f).

5.7.2 Other advisory and warning statements in Standard 2.9.5

FSMP provisions in subsections 2.9.5—10(2) and (3) relate to advisory statements about bee pollen, aspartame or aspartame-acesulphame salt, guarana or guarana extracts, propolis and certain polyols or polydextrose above specified limits, declarations for specific allergens and a warning statement about royal jelly.

Discussion

FSANZ did not discuss these FSMP provisions in the 2017 Consultation paper, and submitters made no comments about them.

The requirements in subsections 2.9.5—10(2) and (3) have now been reviewed to determine if a similar approach should be applied to IFPSMP. Except for mandatory allergen information, none of these requirements is relevant to IFPSMP. Allergen declaration requirements in Standard 1.2.3 still apply without the need to replicate them in Standard 2.9.1. FSANZ considers there is no need to adopt the provisions in subsections 2.9.5—10(2) and (3) in Standard 2.9.1.

After considering the above, FSANZ's preliminary view is that replicating allergen declaration requirements and advisory and warning statements in subsections 2.9.5 —10(2) and (3) in Standard 2.9.1 for all infant formula products is unwarranted.

5.7.3 Information relating to ingredients

Infant formula products, including IFPSDU, are subject to generic ingredient labelling requirements in Standard 1.2.4 Information requirements – statement of ingredients.

Section 1.2.4—4 requires a statement of ingredients to identify each ingredient using a name by which the ingredient is commonly known, a name that describes its true nature, or a generic name listed Schedule 10.

Use of generic ingredient labelling requirements in the context of IFPSDU has not been discussed in previous consultations for Proposal P1028.

Discussion

Standard 2.9.5 provides flexibility for FSMP to comply with Code ingredient labelling requirements or with ingredient declaration requirements in European or United States regulations. Subsection 2.9.5—11 requires information relating to ingredients to be labelled as:

- a statement of ingredients (according to requirements in Standard 1.2.4), or
- information that complies with Articles 18, 19, 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, or
- information that complies with 21 CFR § 101.4.

Flexibility in how ingredient declarations are to be made would enable imported products to be labelled in accordance with European Union or United States requirements and ensure

their continued supply. As noted previously, most IFPSMP are imported from the European Union and would comply with FSMP requirements listed above.

Submitters to the 2017 Consultation paper did not refer to this FSMP provision about ingredient declarations. However, several industry submitters and a government submitter supported consistency with FSMP requirements more generally.

Preliminary view

Based on the considerations above, FSANZ's preliminary view is to adopt an approach consistent with section 2.9.5—12 for information relating to ingredients to be made in accordance with Standard 1.2.4 or information that complies with European or United States regulations.

5.7.4 Date marking information

Infant formula products must be labelled with a best-before date or a use-by date in accordance with section 1.2.5—3 of Standard 1.2.5 Information requirements – date marking of food for sale. Subsection 1.2.5—3(2) provides an exemption for a best-before date if the food is two years or more after the date is determined. However, this exemption does not apply to infant formula products.

Subsection 2.9.5—12(2) requires date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry Date' or similar words to be used on the label.

Discussion

Submitters to the 2017 and 2021 (CP1) Consultation papers were supportive of FSANZ's proposed approach to maintaining existing date marking requirements for infant formula products. However, industry submitters to both papers commented that similar to FSMPs, the words 'Expiry date' or similar words may be used on imported IFPSDU labels. One government submitter to the 2017 Consultation paper noted they would support aligning with all FSMP labelling requirements.

FSANZ agrees it would be a more flexible and practical approach for IFPSMP, given that the majority of these products are regulated as FSMP in the European Union and the Code already accommodates labelling requirements for FSMP products.

Preliminary view

For the above reasons, FSANZ's preliminary view is to adopt an approach consistent with subsection 2.9.5—12(2) for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used on the label.

5.7.5 Prescribed name

Paragraph 2.9.1—13(2)(b) requires products formulated for premature or low birthweight infants to bear the words 'pre-term' as part of the name of the food.

There is no specific prescribed name for the IFPSDU category or remaining IFPSDU subcategories (protein substitutes and products manufacture for metabolic, immunological, renal, hepatic and malabsorptive conditions). However, the prescribed name 'Infant formula' still applies to all IFPSDU.

Discussion

Under the approach proposed in section 5.4, the pre-term subcategory would cease to exist, and these products would become IFPSMP. An FSMP labelling approach, as indicated in section 5.7.1, would still require labelling of the medical purpose, properties and characteristics, specific age group and the requirement for these foods to be used under medical supervision. Further, these products would not be available for retail sale (section 5.6.3).

In the 2017 Consultation paper, FSANZ noted the requirement for the prescribed name 'Infant formula' currently applied to IFPSDU, although the discussion focussed on whether there was a need to prescribe names for the IFPSDU category and subcategories. In the 2021 (CP1) Consultation paper, FSANZ proposed to maintain the prescribed name 'Infant formula' more generally, based on submitter comments to the 2016 Consultation paper.

FSANZ now suggests it may be unnecessary to apply the current prescribed name 'Infant formula' or a more specific prescribed name (for example, 'Infant formula product for special medical purposes') to products regulated under a single IFPSMP category.

The original rationale for the prescribed name 'Infant formula' was to assist consumers to make safe product choices for their infants. More recently in 2017, most government and some health professional submitters supported prescribing an overarching name for IFPSDU to clearly distinguish these products from general purpose infant formula, thus reducing consumer confusion.

FSANZ notes the application of certain FSMP statements would ensure IFPSMP are distinguishable from general purpose formula and provide sufficient information about their medical purpose and characteristics to health professionals and caregivers. Further, the suggested approach in section 5.6.3 to restrict their sale would address submitter concerns that caregivers of healthy infants may be confused by these products.

FSANZ noted in the 2017 Consultation paper that there is no consistency internationally regarding the wording of an overarching prescribed name for IFPSDU. Two government submitters and two industry submitters had opposed prescribing a name for this reason, with industry submitters noting Codex provides for an appropriate designation indicating the true nature. Therefore adopting the same approach of not prescribing a name for other FSMP products would not impact supply.

FSANZ suggests the generic name of food provisions in paragraph 1.2.2—2(1)(b) would apply, that is, a name or description of the food to be sufficient to indicate the true nature of the food. Further, the absence of a prescribed name requirement would not preclude imported IFPSMP and other FSMP from being named in accordance with international and overseas requirements.

Finally, as noted in section 5.6.2, some submitters advised certain specialised products are intended for use in both infancy and beyond one year of age. Removal of the prescribed name 'Infant formula' would provide regulatory clarity for these products. Proposed FSMP labelling in section 5.7.1 would require statements indicating whether or not the food is suitable for use as a sole source of nutrition and if the food is intended for persons within a specified age group (if one applied). Base composition requirements for infant formula products would still apply.

Industry submitters to the 2017 Consultation paper also noted that a prescribed name would be trade restrictive and existing labelling (medical purpose and use under medical supervision) would be sufficient to distinguish these products from general purpose formulas. The application of FSMP labelling would also enable health professionals and enforcement agencies to identify products as IFPSMP.

Preliminary view

Based on the considerations above, FSANZ's preliminary view is that the prescribed name 'Infant formula' should not be required for IFPSMP and that no overarching name should be prescribed for this category. Generic provisions in paragraph 1.2.2—2(1)(b) would apply to IFPSMP.

5.7.6 Exemption from 'breast milk is best for babies' warning statement

Subsection 2.9.1—19(2) exempts products for metabolic, immunological, renal, hepatic and malabsorptive conditions from having to carry the mandatory warning statement required in paragraph 2.9.2—19(1)(d) for the statement 'Important Notice, Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.

Discussion

In the 2017 Consultation paper, FSANZ noted the EU and US do not require a statement about breastfeeding on the labels of IFPSDUs. Codex specifies that labels of IFPSDUs should not discourage breast feeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical conditions(s) for which the product is intended. FSANZ's preliminary view was that it was appropriate for the exemption from the warning statement to remain for IFPSDU regulated in subsection 2.9.1—19(2).

A government submitter indicated they would support an exemption from the 'breast milk is best' statement for IFPSMP if this statement was required. Some health professional and consumer group submitters opposed the exemption because there may be situations where breastfeeding is not contraindicated, for example, in combination with pre-term formula. FSANZ is proposing the labelling statement to the effect of 'use under medical supervision' could apply to all IFPSMP (see section 5.7.1), and health professionals would still be able to recommend breastfeeding when it is appropriate.

FSANZ also notes that the restriction on the sale of IFPSMP (section 5.6.3) would ensure the labelling of these products do not influence the purchasing decisions of caregivers of healthy infants.

The proposed approach for a single IFPSMP category (see section 5.4) would align with international and overseas requirements and therefore, ensure the supply of imported IFPSMP would not be affected.

Preliminary view

For the above reasons, FSANZ's preliminary view is to apply the exemption from the 'breast milk is best' warning statement to all IFPSMP.

5.7.7 Exemption from statement about offering foods in addition to IFPs

Subsection 2.9.1—19(5) of Standard 2.9.1 exempts pre-term formula from the requirement in paragraph 2.9.1—19(4)(c) to carry a labelling statement recommending that infants from the age of 6 months should be offered foods in addition to the infant formula product.

Discussion

In the 2017 Consultation paper, it was FSANZ's preliminary view that the exemption should remain. No submitters commented on this issue. However, several industry submitters made general comments seeking less prescriptive requirements for IFPSDU, noting the use of such prescription could restrict trade.

In the 2021 (CP1) Consultation paper, FSANZ considered the statement was still appropriate for infant formula products, although there was no specific discussion about its application to pre-term IFPSDU. Submitters supported this preliminary view but made separate comments about how the age was represented (this issue will be considered in the 1st CFS).

Under the proposed approach in section 5.4, the subcategory for pre-term formula would be removed, and a new IFPSMP category would be adopted. The statement about offering foods in addition to infant formula products is inconsistent with international and overseas requirements and could pose a trade barrier. As noted in the 2017 Consultation paper, the EU and US have no similar requirements in their regulations. Further, the Codex Standard does not specify IFPSDU be labelled with information to the effect that infants should receive complementary foods in addition to formula. FSANZ notes that some industry submitters indicated support for less prescription.

IFPSMP would be used under medical supervision, and caregivers would receive appropriate advice about introducing other foods from health professionals. As suggested in section 5.7.1, IFPSMP would be required to carry FSMP statements to inform health professionals about the product's suitability. Further, a restriction of sale (in section 5.6.3) would mean caregivers of healthy infants would not be missing important advice to reduce the risk of ill health due to poor nutrition. FSANZ considers it inappropriate to require a statement about offering foods on those products intended for use in both infancy and beyond one year of age.

Preliminary view

After considering the above, FSANZ's preliminary view is to extend the exemption from the statement about offering other foods in addition to IFPs to all IFPSMP.

5.7.8 Statement that the infant formula product may be used from birth

Paragraph 2.9.1—19(4)(a) requires a statement indicating that the infant formula product may be used from birth, in the case of infant formula. As noted in the 2021 (CP1) Consultation paper, the statement applies to both general purpose infant formula and IFPSDU. The current definition of infant formula includes that the product meets the nutritional requirements of infants under the age of 4 to 6 months.

Discussion

FSANZ proposed to maintain this requirement for all infant formula products on the basis that it enables caregivers to correctly identify the appropriate formula for their infants aged from birth. All submitters to the 2016 and 2021 (CP1) Consultation papers supported FSANZ's proposed approach.

FSANZ has now reconsidered whether this requirement should apply to IFPSMP for reasons similar to those noted above in section 5.7.5 – Prescribed name. European Union FSMP regulations do not require a similar statement, indicating this requirement would be trade restrictive. Codex provisions (noted in the 2021 (CP1) Consultation paper) indicate FSMP products should be labelled in such a way to avoid the risk of confusion between infant formula, follow-up formula and formula for special medical purposes, but do not specify how this should be achieved. FSANZ notes that FSMP labelling statements would be used to help

distinguish between general purpose infant formulas and IFPSMP. If the product is formulated for use by a specified age group, the associated statement would indicate the appropriate age group. Further, the approach proposed in section 5.6.3 for restriction on the sale of IFPSMP would ensure these products are not accessible in the same manner as general purpose infant formulas.

Preliminary view

Based on the considerations above, FSANZ's preliminary view is to exempt IFPSMP from the requirement for a statement that the infant formula product may be used from birth.

5.7.9 Labelling information on safe preparation and use

In the 2017 Consultation paper, FSANZ noted that the general labelling requirements in subsection 2.9.1—19(3) for preparation and use directions applied to all infant formula products, including IFPSDU. The wording of these mandatory instructions is not prescribed. Further, additional, more specific instructions would not be prohibited by the Code if included voluntarily on the label.

However, in response to earlier submitter comments (in 2012 and 2016), FSANZ sought further information about what specific labelling requirements for the safe preparation and use of IFPSDU were being used that contradict these general requirements.

Discussion

Most submitters that responded were unaware of any contradictory labelling relating to the preparation and use instructions, and supported the status quo for IFPSDU. Some of these submitters noted the flexibility of current general statements and the lack of restrictions on additional information as reasons for their support. A health professional submitter and a consumer group submitter stated the WHO guidelines[13] applied.

One health professional submitter observed variations in recommendations for reconstituting infant formula by international and domestic expert bodies, and that products available in the domestic market appear to promote WHO, ESPGHAN and NHMRC guidelines (WHO 2007, ESPGHAN 2020, NHMRC 2012). The same submitter also noted wide variation in clinical practice, including when the formula powder is reconstituted before a feed (ranging from immediately before to up to 24 hours) and methods used to ensure cooled, potable water is available. FSANZ notes the existing directions in paragraphs 2.9.1—19(3)(b) and (c) accommodate these variations and proposed in the 2021 (CP1) Consultation paper they be retained with the addition of the word 'cooled' to the direction relating to the water used for reconstitution.

Two submitters representing industry and government considered suggested instructions that would need to be modified if human milk fortifiers were brought in scope of IFPSDU. Under section 3.2 above, FSANZ notes that human milk fortifiers do not meet the current definition of IFP and considers these products should be regulated under Standard 2.9.5.

Preliminary view

For the above reasons, FSANZ's preliminary view is that the general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated.

5.7.10 Summary of preliminary views relating to IFPSMP labelling

Based on the proposed approaches for a single IFPSMP category and a restriction on the sale of these products, FSANZ's preliminary views for specific labelling of IFPSMP (and more broadly for IFP where indicated) are summarised below:

- replace the labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (except for lactose-free and low lactose formulas) with FSMP provisions in paragraphs 2.9.5—10(1)(a) to (f).
- replicating allergen declaration requirements and advisory and warning statements in subsections 2.9.5 —10(2) and (3) in Standard 2.9.1 for all infant formula products is unwarranted
- adopt an approach consistent with section 2.9.5—11 for information relating to ingredients to be made in accordance with Standard 1.2.4 or information that complies with European or United States regulations
- adopt an approach consistent with section 2.9.5—12 for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used on the label
- for lactose-free and low lactose formulas, maintain existing labelling requirements and clarify that IFPSMP labelling provisions would not apply
- the prescribed name 'Infant formula' does not apply to IFPSMP, and that no overarching name should be prescribed for this category. Generic provisions in paragraph 1.2.2—2(1)(b) would apply to IFPSMP
- extend the exemption from the 'breast milk is best' warning statement to all IFPSMP
- extend the exemption from the statement about offering other foods in addition to IFPs to all IFPSMP
- exempt IFPSMP from the requirement for a statement that the infant formula product may be used from birth
- the general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated.

QUESTION

15) Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available.

List of questions for submitters

FSANZ invites stakeholders to provide comment on the proposed approaches and preliminary views outlined in this paper. To assist in addressing the FSANZ Act section 18 and section 59 assessment criteria in the 1st CFS, we request supporting evidence be provided in your response.

As with previous Consultation papers, responses to these questions will also inform a Consultation Regulatory Impact Statement (should one be required) or cost/benefit analysis in accordance with the FSANZ Act.

Therefore we ask submitters to consider the following general questions.

General questions

- How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available.
- Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available.
- How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.

If there are other issues that FSANZ should consider including within the scope of this Paper, FSANZ requests details and the reasons why FSANZ should consider them to be provided.

Specific questions

Specific questions have been asked in certain sections of this paper and are listed below. As above, supporting detail in submitted responses will assist FSANZ in ensuring that proposed options are based on the best available evidence.

Questions related to the use of novel foods in infant formula products, food for infants and formulated supplementary food for young children (section 2.2)

1) To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.

Questions related to definitions for specialised infant formulas (section 4.3)

2) 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.
3) 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.
4) 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.?

Questions related to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 5.5.2)

5) To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

6) To industry submitters: How many and what types of low lactose IFPSDU are on the market? And what is their maximum level of lactose? Please provide supporting detail and data, where available.

Questions related to products for specific dietary use based on a protein substitute (section 5.5.3)

7) To industry submitters: What types of partially hydrolysed IFP are on the market? And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available.

8) To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available.

Questions related to specific compositional requirements (section 5.5.3)

9) Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available.

10) To industry submitters: What type of products contain MCT oil? For what purpose and at what levels? Please provide supporting detail and data, where available.

11) To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available.

Questions related to scientific evidence of purpose for IFPSMP (section 5.6.1)

12) To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)?

13) If so, what type of scientific evidence is held by companies and what is its strength of evidence?

Questions related to extension of use beyond infancy for IFPSMP (section 5.6.2)

14) What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

Question related to labelling of IFPSMP (section 5.7)

15) Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available.

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