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Supporting document 4

Special medical purpose products for infants

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.

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products and Schedule 29 – Special Purpose Foods in the Australia New Zealand Food Standards Code (the Code). Other standards in the Code also contain provisions related to labelling, safety and food technology for infant formula, such as Standards 1.3.1 – Food Additives and 1.4.1 – Contaminants and Natural Toxicants.

Following the 2021 Consultation papers FSANZ reconsidered the regulatory framework for Standard 2.9.1 and concluded that the standard would comprise of two categories: Infant Formula Products and Special Medical Purpose Products for infants (SMPPi). This Supporting Document (SD) considers the compositional and labelling requirements of SMPPi that deviate from requirements specified for infant formula products within SD1, SD2 and SD3.

SMPPi must be safe for infants to consume, and must provide for the specific nutritional requirements of infants, modified to satisfy the particular disease, disorder or medical condition. SMPPi are formulated to be suitable for infants <12 months of age, however some of these specialised products may be also be suitable and consumed up to 3 years of age or older.

During 2021, FSANZ released three consultation papers that discussed the regulatory options for Standard 2.9.1 and Schedule 29, to help inform the 1st Call for Submissions (CFS). This Supporting Document (SD) is one of six developed to accompany the 1st CFS, and focuses on compositional and labelling requirements for SMPPi. It is organised into two parts.

The first part considers stakeholder views, international regulations and FSANZ's preferred regulatory approaches for the compositional requirements of SMPPi. FSANZ has proposed that SMPPi composition should meet the composition prescribed for infant formula products (IFP), except where deviation is required to address the specific disease, disorder or medical condition the product is intended for, and in doing so any deviation meets international regulations, such as the EU, Codex or US.

FSANZ has also proposed other compositional requirements as follows:

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

The second part of this SD considers the applicability of Standard 2.9.5 – Foods for Special Medical Purposes (FSMP) labelling requirements to SMPPi. Specific labelling requirements in Standard 2.9.1 were also considered to determine whether they should also apply to SMPPi. Submitter comments to FSANZ 2021 CP3 on aspects of labelling of SMPPi have also been considered.

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

- the requirement to label food as 'genetically modified' in section 1.5.2—4
- inner packages in subsection 2.9.5—8(3)
- transportation outers in subsection 2.9.5—8(4)
- mandatory labelling information in section 2.9.5—9
- mandatory statements and declarations in section 2.9.5—10
- nutrition information requirements in subparagraphs 2.9.5—13(b)(i) and (ii)
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

Labelling requirements that would not apply to SMPPi, or where SMPPi are exempt are:

- name of business address in section 1.2.2—4
- characterising ingredients and components in Standard 1.2.10
- prescribed names 'Infant formula' and 'Follow-on formula' in section 2.9.1—17
- a prescribed name for SMPPi
- warning statements for IFP in subsection 2.9.1—19(1)
- directions for preparation and use for IFP in subsection 2.9.1—19(3)
- age-related statements for IFP in subsection 2.9.1—19(4)
- a protein source statement in paragraph 2.9.1—23(1)(a)
- prohibited representations for IFP in section 2.9.1—24
- nutrition information requirements in subparagraphs 2.9.5—13(b)(iii) or (iv)
- requirements for claims in relation to lactose and gluten content in sections 2.9.5—14 and 15 and the existing conditions for 'lactose free' and 'low lactose' for IFP (see section 5.1 of SD3).

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Abbreviations and glossary

Amino acids	In this paper, refers to L-amino acids which are the only forms that are biologically active/available.
ANZ	Australia and New Zealand
Breast milk	A general term for human milk provided from a mother's breast (described as mature milk to distinguish it from colostrum).
Codex	Refers to Codex Alimentarius
Codex CXS 72-1981	Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
Codex Draft Standard for FuFOI	Refers to the Proposed Draft Revised Standard for Follow-up Formula, Section A: Follow-up Formula for Older Infants (see 22REP/NFSDU Appendix III)
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).
EFSA	European Food Safety Authority
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
EU	European Union
EU 2016/127	European regulation on compositional and information requirements for infant formula and follow-on formula
EU 2016/128	European regulation on food for special medical purposes
FAO	Food and Agriculture Organization of the United Nations
Follow-on formula (FOF)	An infant formula product that is represented as either a breast milk substitute or replacement for infant formula and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months, as defined in Standard 1.1.1 of the Code.
Follow-up formula (FUF)	Under CODEX STAN 156-1987, this is a food intended for use as a liquid part of the weaning diet for older infants (age 6-12 months) and for young children (age 12 -36 months).
FSMP	Food for Special Medical Purposes
Generally accepted scientific data	Peer-reviewed data reflecting the best available scientific evidence.
GL	Guideline level
GUL	Guidance upper level
Infant	A person under the age of 12 months, as defined in Standard 2.9.1
Infant formula (IF)	An infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months, as defined in Standard 1.1.1 of the Code
Infant formula product (IFP)	A 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; as defined in Standard 1.1.1 of the Code
JECFA	FAO/WHO Joint Expert Committee on Food Additives
MCT	Medium chain triglycerides
MoH	Ministry of Health (New Zealand)
NHMRC	National Health and Medical Research Council (Australia)
NRV	Nutrient reference value established by NHMRC & MoH (2006)
N.S.	Not stated
rNRV	Regulatory nutrient reference value
SD	Supporting document
Soy-based formula	An infant formula product in which soy protein isolate is the sole source of protein, as defined in Standard 2.9.1
SMPPi	Special Medical Purpose Products for infants
TFA	Trans fatty acids
The Code	Australia New Zealand Food Standards Code
UL	Upper Level of intake
US	United States of America
US FDA	US Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

The 1st Call for Submissions paper sets out the preferred options for the regulatory framework and definitions for Standard 2.9.1. It presents the considerations that underpin the proposed new category of *Special Medical Purpose Products for infants* (SMPPi).

A **Special Medical Purpose Product for infants** means a food that is

(a) specially formulated for the dietary management of infants

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

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

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

(c) represented as being

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

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

SMPPi are also underpinned by the following principles:

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

Based on the above principles SMPPi are considered similar in nature and use to products regulated under Standard 2.9.5 – Foods for Special Medical Purpose (FSMP) in the Code, as well as relevant Codex Standards and EU legislation. FSANZ considers this approach to be more clearly aligned with the intended purpose of specialised medical products. The revised approach also retains SMPPi currently regulated within Standard 2.9.1 – Infant formula products, that comply with the revised definition. Stakeholders supported this approach within the 2021 consultation.

Further information on the regulatory framework and definitions is provided in the CFS.

SMPPi may differ substantially from infant formula products (IFP) due to deviation in nutrient composition and labelling to support the products intended special medical purpose. The purpose of this Supporting Document (SD) is to provide additional details on composition and labelling elements for the SMPPi category.

Submissions regarding SMPPi in response to FSANZ 2021 CP3, and conclusions in 2012, 2016 and 2017, have also been addressed in this SD.

2 Composition

The composition of SMPPi may differ substantially depending on the specific disease, disorder or medical condition the product is intended for. SMPPi may also constitute the sole source of nourishment or may be used as a supplementary incomplete product depending on the intended use. Despite the variation between products, all SMPPi are to be used under medical supervision and are not for use by healthy infants.

The composition of SMPPi requires substantial flexibility due to the diverse conditions the products account for. Each SMPPi is formulated based on medically determined nutrient requirements to aid the dietary management of the condition, typically where the infants nutrition cannot be achieved without modification of the normal diet. The essential nutrient composition prescribed for IFP (detailed in SD2) should form the basis for SMPPi to ensure the specific nutritional requirements to support infant growth and development are met. However, as these products are intended for healthy infants, any compositional deviations for SMPPi should be based on sound medical and nutritional principles which satisfy the specific nutritional requirements of those infants requiring the SMPPi.

SMPPi that are used as the sole source of nourishment for the infant are products such as:

- Extensively hydrolysed formulas
- L-amino acid based and elemental formulas
- Pre-term/low birth weight formulas
- Formulas for renal, hepatic and diagnosed allergy and immunological conditions.

SMPPi that are not used as the sole source of nutrition, must still take into account the specific nutrition requirements of infants. However, as these products are not nutritionally complete, nor suitable to be the sole source of nourishment, it is not required for such products to be based on the composition of infant formula products. These are products such as:

- Formulas for inborn errors of metabolism
- Liquid modular products specifically formulated for infants
- Bovine derived human milk fortifiers.

For all SMPPi, use in accordance with the manufacturer's instructions, must be safe, beneficial and effective in meeting the special medical purpose for which the formula is intended, as demonstrated by generally accepted scientific data.

The proposed framework for SMPPi has taken into account stakeholder’s views to both the 2017 and 2021 consultations. Relevant stakeholder comments from the 2021 consultation that pertain to composition issues are summarised below in each section.

2.1 General nutrient composition

2.1.1 Stakeholder views

Table 2.1.1 General composition issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
Standard for SMPPi permits nutrients to deviate from the 'baseline' IFP composition to address the special medical purpose and to comply with key credible regulations, specifically Codex, EU and USA.	3 submission (3 industry, 1 government)	FSANZ agrees that composition for SMPPi will be flexible to allow: (1) deviation from baseline composition, prescribed in Standard 2.9.1, to address the special medical purpose (2) alignment with international standards and regulations (i.e Codex, EU, and USA). As such, FSANZ proposes a composition which will ensure there are no unintentional restrictions for import and supply from international manufacturers.
Support drafting that specifically excludes optional ingredients from permissions for SMPPi, unless required for the special medical purpose.	1 submission (1 government)	FSANZ agrees that the composition of SMPPi should only vary as required for the special medical purpose.
Support drafting that clearly specifies the requirement for pre-market approval remains for nutritional modifications that would involve the addition of a substance not approved in infant formula generally.	1 submission (1 government)	FSMP regulations should be flexible enough to accommodate new ingredients or future innovation for the specific disease, disorder or medical condition for which the food has been formulated. As mentioned above, it is FSANZ preferred option to allow deviation from the baseline composition to address the special medical purpose of the formula. These deviations must also be supported by scientific evidence. See discussion below for further information.
Subcategories are not required.	1 submission (1 government)	Following the 2021 consultation, FSANZ has reviewed the regulatory framework for infant formula products and subcategories are no longer being proposed. However, SMPPi are still able to deviate based on the specified condition.

2.1.2 Discussion

As noted within table 2.1.1, FSANZ is proposing that the composition for SMPPi is flexible enough to allow for deviation from IFP baseline composition prescribed in Standard 2.9.1 to address the special purpose of the product. This is current practice within section 2.9.1—13(1) and 2.9.1—14(1), which state '*compositional requirement of this Standard does not apply to the extent that it would prevent the sale of an infant formula product that has been specifically formulated for*' premature or low birthweight infants and to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions. FSANZ proposes that a provision to this effect will be applied to all SMPPi through the drafting.

FSANZ is also proposing that the compositional requirements for SMPPi are flexible enough to ensure undisrupted access to these special medical purpose products, as the wellbeing

and sustenance of infants rely on their availability. As the majority of SMPPi are imported from the EU and US it is pertinent that the products are able to be imported into Australia and New Zealand (ANZ) and as such, FSANZ proposes there will be no unintentional restrictions for import and supply from international manufacturers. This approach will enable this subgroup of infants timely access to the best possible products.

The addition of optional substances to SMPPi will require pre-market approval, unless the addition is made for the products special medical purpose. Any deviation from the baseline IFP composition must be based on scientific evidence. Further to this, FSMP regulations, including SMPPi, should be flexible enough to accommodate new ingredients or future innovation for the specific disease, disorder or medical condition for which the food has been formulated. This is the current approach embedded into Standard 2.9.5 – Foods for Special Medical Purposes. Permitting this flexibility enables the ANZ population timely access to the latest medical purpose foods, which is essential in clinical care and treatment. FSANZ also notes that all SMPPi products are to be used under medical supervision and are primarily accessed via prescription.

2.2 Composition for premature or low birthweight infants

2.2.1 Stakeholder views

Table 2.2.1 Composition issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
No additional composition requirements are required for products formulated for premature or low birthweight infants.	5 submitters (4 industry, 1 government)	FSANZ agrees. Products formulated for premature or low birthweight infants will be regulated as SMPPi and can deviate from the IFP baseline composition where needed for the products special medical purpose.

2.2.2 Discussion

Currently section 2.9.1—13 regulates SMPPi formulated for premature or low birthweight infants, which notes that compositional requirements of Standard 2.9.1 do not apply to these formulas and requires the formulas to comply with specific labelling provisions.

Submitters to FSANZ 2021 CP3, noted that no additional compositional requirements are needed for products formulated for premature or low birthweight infants to which FSANZ agrees.

SMPPi formulated for premature or low birthweight infants will be required to comply with the baseline composition prescribed in 2.9.1, however FSANZ prefers not to propose any specific nutrient composition requirements for the condition.

2.3 Composition for metabolic, immunological, renal, hepatic and malabsorptive conditions

2.3.1 Stakeholder views

Table 2.3.1 Composition issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
Manganese guideline maximum for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.	4 submissions (1 industry, 3 public health)	One industry submitter supported removal of the guideline maximum. One public health submitter noted the importance of maintaining the Code in line with EU and US standards due to imports. Another public health submitter noted they were not aware of any health concerns or risks related to manganese content of SMPPi. FSANZ's preferred option is to remove the guideline maximum for manganese (7.2 µg) from S29—10, which is specific for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

2.3.2 Discussion

As SMPPi are able to deviate from the IFP baseline composition to address the products special medical purpose including aligning with equivalent international standards, FSANZ considers the manganese guideline maximum is no longer required. Manufacturers will be able to tailor the manganese content of SMPPi where appropriate to meet the formulas special medical purpose or to comply with international regulations.

2.4 Composition for specific dietary use based on a protein substitute

2.4.1 Stakeholder views

Table 2.4.1 Composition issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
This category and its compositional requirements are not required.	4 submissions (3 industry, 1 government)	FSANZ agrees. See discussion below for further information.

2.4.2 Discussion

Following FSANZ 2021 CP3, FSANZ has reconsidered the regulatory framework for IFP and SMPPi. Partially hydrolysed proteins are now classified as IFP, instead of IFPSDU. Any other product formulated for specific dietary use based on a protein substitute, not included within the prescribed sources, will need to comply with SMPPi requirements or undergo pre-market assessment as an IFP. Extensively hydrolysed formulas are considered SMPPi and their composition can vary as needed to address the medical purpose of the product. Due to the new compositional requirements for SMPPi, FSANZ considers the compositional requirements noted in section 2.9.1—15 are no longer required.

2.5 Composition Medium Chain Triglycerides

2.5.1 Stakeholder views

Table 2.5.1 Composition issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
Specific permissions for medium chain triglycerides (MCT) should be applied to all SMPPi, with drafting that indicates addition is only permitted to address the products special medical purpose.	2 submissions (2 government)	FSANZ agrees. See discussion below for further information.

2.5.2 Discussion

The majority of submitters to the FSANZ 2021 CP3 provided responses which substantiated the clinical benefits of MCT within SMPPi, especially in products formulated for premature infants. MCT have high water solubility and are easily absorbed by preterm infants with an immature digestive system and even by those with low intraluminal bile salts and pancreatic lipase levels (Koletzko 2021, Perretta 2021, Łoś-Rycharska 2016). Based on the submissions provided, FSANZ considers there is evidence to support the inclusion of MCT within SMPPi. FSANZ also acknowledges that even though MCT are present as a natural constituent of milk based ingredients, there is not permission for the addition of MCT in IFP. FSANZ's preferred option is to include a permission for the addition of MCT to SMPPi to address the products medical purpose. However, specific compositional limits will not be set and are to be determined based on the products special medical purpose, supported by generally accepted scientific data.

2.6 Composition for molybdenum and chromium

2.6.1 Stakeholder views

Table 2.6.1 Composition issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
Permit voluntary addition without any compositional limits for all SSMPi.	5 submissions (5 industry)	FSANZ agrees. See discussion below for further information
Retain current mandatory requirement to be met naturally and/or through addition for protein substitutes.	2 submissions (1 public health, 1 government)	Due to changes in the regulatory framework this option is no longer fit for purpose.
Chromium chloride and ammonium molybdenum to be included as permitted forms for SMPPi to allow for international alignment.	1 submission (1 industry)	FSANZ will not permit specific forms of chromium and molybdenum. However, varying forms are permitted to address the medical purpose of the product.

2.6.2 Discussion

As outlined in the CFS, SMPPi are specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition

and are to be used under medical supervision. The SMPPi division no longer includes specific nutrient composition for products formulated for specific dietary use based on a protein substitute. If the protein source deviates from sources prescribed in Standard 2.9.1 the formula will be required to comply with either SMPPi requirements or undergo pre-market assessment as IFP. As there is no longer a division for these specific formulas the permissions for molybdenum and chromium are no longer fit for purpose.

FSANZ's preferred option is to allow the voluntary addition of molybdenum and chromium in SMPPi where required to address the specific disease, disorder or medical condition. Similar to MCT, FSANZ will include a permission for the addition of molybdenum and chromium to SMPPi to address the products medical purpose. However, specific compositional limits will not be set and are to be determined based on the products special medical purpose, supported by generally accepted scientific data.

FSANZ will also not permit other forms of molybdenum and chromium in the Code. If these forms are required for the medical purpose of the product they will be allowed to be used under the SMPPi requirements.

2.7 Measuring scoop for SMPPi

Submitter comments to FSANZ 2021 CP1 regarding the measuring scoop are discussed in SD2. However, comments pertaining to measuring scoops used in SMPPi are noted below.

2.7.1 Stakeholder views

Table 2.7.1 Measuring scoop issues raised by stakeholders

Summary of the issue	Raised by	FSANZ response
SMPPi are exempt from the requirement for a scoop	2 submissions (2 industry)	FSANZ agrees. See discussion below for further information.

2.7.2 Discussion

SD2 to this CFS concluded that FSANZ's preferred option is to not standardise the scoop size or dilution ratio, and instead maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.

The overarching principle for SMPPi, that where needed to address the special medical purpose the product may deviate from the baseline requirements for IFP. This principle is also applied to the measuring scoop, and where needed the product may deviate from the measuring scoop requirement. This will be of particular relevance to pre-prepared products and those prepared in clinical settings.

2.8 Food additives

Similar to the nutrient composition requirements for SMPPi, permissions for food additives may differ substantially from IFP depending on the specific disease, disorder or medical condition the product is intended for. SD1 to this CFS addresses food additive permissions and outlines FSANZ preferred regulatory options.

3 Labelling

3.1 Approach

Labelling information provided on SMPPi must facilitate the safe and effective use of these products with infants whose medical conditions make them more vulnerable than healthy infants. However, labelling requirements also need to be sufficiently flexible to ensure continued supply, given the majority of these highly specialised products are imported.

For this reason, FSANZ has considered the applicability of the labelling requirements in Standard 2.9.5 – Food for Special Medical Purposes to SMPPi. The labelling framework for FSMPs was developed in 2012 through Proposal P242 – Foods for Special Medical Purposes, with the intent of balancing provision of information to enable the safe and appropriate use of FSMP whilst minimising potential barriers to trade (e.g. re-labelling costs) that could impact on the supply of FSMP to Australia and New Zealand. FSANZ considers this framework is suitable for SMPPi given the similarities with FSMP in their nature and use.

FSANZ has also considered whether any specific labelling requirements for IFP in Standard 2.9.1 should also apply to SMPPi.

In undertaking this assessment of labelling provisions, FSANZ has had regard to submitter comments (n=24) that were provided in response to FSANZ 2021 CP3. In general, submitters supported FSANZ's preliminary approach, although there were differing views about the use of a prescribed name for SMPPi, the type of directions for use that should apply and regarding the proposed exemption from the label statement about offering other foods in addition to IFPs.

3.2 Application of Standard 2.9.5 labelling requirements

A key aspect of the labelling framework in Standard 2.9.5 is an exemption from generic labelling requirements in *Part 1.2 – Labelling and other information requirements* of the Code, and then the application of those Part 1.2 provisions that are relevant to FSMPs.

FSANZ considers this approach is also suitable for SMPPi and is proposing the mandatory labelling information as required by section 2.9.5—9 would apply to SMPPi:

- name or description sufficient to indicate the true nature of the food (see further discussion in section 3.3.1 below)
- lot identification
- information relating to irradiated food
- required advisory statements, warning statements, other statements and other declarations (see discussion in section 3.2.1 below)
- information relating to ingredients
- date marking, including allowing flexibility to use 'Expiry Date' or similar words
- directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons, (see discussion in section 3.3.3 below) and
- legibility requirements (i.e. Division 6 of Standard 1.2.1).

FSANZ is also proposing the labelling requirements for inner packages and transportation outers in subsections 2.9.5—8(3) and (4) would apply to SMPPi.

Similar to FSMP, the remaining generic labelling requirements from Part 1.2 that are proposed not to apply to SMPPi are:

- name of business address (section 1.2.2—4)
- characterising ingredients and components (Standard 1.2.10).

FSANZ has considered the application of other generic labelling requirements more broadly in Chapter 1 of the Code. Specifically the requirement for food to be labelled as 'genetically modified' in accordance with section 1.5.2—4. FSANZ notes this existing labelling requirement applies to all food for sale, including FSMP and SMPPi. As noted in section 2.3 of SD3, FSANZ's preferred option is to maintain this labelling requirement for IFP, and considers the same approach is appropriate for SMPPi.

3.2.1 Mandatory statements and declarations

As noted in section 3.2 above, FSANZ is proposing to apply the required advisory statements, warning statements, other statements and declarations (paragraph 2.9.5—9(1)(d)) to SMPPi. The specific mandatory statements applying to FSMPs are provided in subsection 2.9.5—10(1) and these are proposed to apply to SMPPi:

- a statement to the effect that the food must be used under medical supervision
- a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
- 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
- a statement describing the properties or characteristics which make the food appropriate for the medical purpose
- 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
- a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- for products represented as the sole source of nutrition, the statement to the effect that the food is not for parenteral use, and additional statements about the nutritional modifications made to the product.

In relation to the 'not for parenteral use' statement as required by paragraph 2.9.5—10(1)(g), FSANZ notes most IFP, including SMPPi, are formulated for use as the sole source of nutrition for infants (even products for infants older than six months). When developing Standard 2.9.5, FSANZ determined this statement was necessary due to the potential risk of mistaking FSMPs intended as a sole source of nutrition as a parenteral formula in a clinical setting. In FSANZ 2021 CP3, FSANZ suggested this statement should not apply to SMPPi because the scope of SMPPi at that time included modified IFP. However, these products under the revised regulatory framework (see section 2.4.2 of the CFS) are now proposed not to be included in the SMPPi category. Therefore, FSANZ considers the statement 'not for parenteral use' is applicable for those SMPPi used as a sole source of nutrition, as the risk of mistaking these products for parenteral formulas is the same as for FSMPs.

The provision in paragraph 2.9.5—10(1)(g) also requires additional statements indicating:

- the nutrient or nutrients which have been modified, and
- unless provided in other documentation about the food - whether each modified nutrient has been increased, decreased. or eliminated from the food, as appropriate.

These additional statements will apply to SMPPi, when the product has been modified to vary from the baseline compositional requirements for IFP in Standard 2.9.1 and Schedule 29 (see Section 2.1 for the approach for SMPPi composition).

Generic requirements as indicated in subsections 2.9.5—10(2) and (3) relating to advisory or warning statements about the presence of bee pollen, propolis, guarana and aspartame and the declaration of allergens are also proposed to apply to SMPPi.

3.2.2 Nutrition information

Paragraph 2.9.5—13(a) and subparagraphs 2.9.5—13(b)(i) require nutrition information expressed per given amount of food in relation to the minimum or average energy content; and the minimum amount or average quantity of protein, fat and carbohydrate; and any vitamin, mineral or electrolyte that has been used as a nutritive substance in the food.

FSANZ is proposing these requirements apply to SMPPi without the specific format requirements for nutrition information as proposed for IFP labels (see section 3.3 of SD3). FSANZ considers this approach provides flexibility to accommodate the differing overseas nutrition information requirements on imported products.

Subparagraphs 2.9.5—13(b)(iii) and (iv) require the declaration of any substance used as a nutritive substance listed in the table to section S29—20, as well as declaring the amount of any other substance in respect of which a nutrition content claim has been made. However FSANZ has determined these requirements should not apply because the table to section S29—20 is specific to FSMP composition, and nutrition content claims are prohibited on IFP, including SMPPi. FSANZ is proposing a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose (see Section 2.1.2 general nutrient composition).

3.2.3 Nutrition content and health claims

All IFP are prohibited from making nutrition, health and related claims (paragraph 1.2.7—4(b)). This prohibition is consistent with policy guidance on IFP the scope of which covers SMPPi.

FSANZ considers provisions in sections 2.9.5—14 and 15 for claims in relation to lactose and gluten content should not apply to SMPPi. Further, the conditions for lactose free and low lactose IFP as modified IFP will not apply (see section 5.1 of SD3).

FSANZ also notes that if a SMPPi is formulated for a specific disease, disorder or medical condition, and lactose or gluten content is a feature of that formulation, the information would be provided in the statement describing the properties or characteristics which make the food appropriate for the medical purpose.

3.2.4 Preferred option

FSANZ's preferred option is to apply the labelling requirements to SMPPI as listed:

- the requirement to label food as 'genetically modified' in section 1.5.2—4
- inner packages in subsection 2.9.5—8(3)
- transportation outers (in subsection 2.9.5—8(4)
- mandatory labelling information in section 2.9.5—9
- mandatory statements and declarations in section 2.9.5—10
- nutrition labelling requirements in subparagraphs 2.9.5—13(b)(i) and (ii)

- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

The labelling requirements that would not apply are:

- name of business address in section 1.2.2—4
- characterising ingredients and components in Standard 1.2.10
- nutrition information requirements in subparagraphs 2.9.5—13(b)(iii) or (iv)
- requirements for claims in relation to lactose and gluten content in sections 2.9.5—14 and 15 and the existing conditions for 'lactose free' and 'low lactose' for IFP (see section 5.1 of SD3).

3.3 Application of Standard 2.9.1 labelling requirements

Currently Standard 2.9.1 contains certain labelling requirements that generally apply to IFP, including SMPPi. FSANZ has considered the application of these labelling requirements to SMPPi, and in some cases is proposing to continue current labelling requirements whereas in other cases given the specialised nature of SMPPi is proposing not to apply the existing labelling requirements. The specific labelling provisions are discussed in the following sections.

3.3.1 Prescribed name

Section 2.9.1—17 requires the use of 'Infant formula' and 'Follow-on formula' as prescribed names for IFP. In Division 4 Infant formula products for special dietary use products formulated for premature and low birthweight infants are required to include the words 'pre-term' in the name of the food, that is, 'Pre-term Infant formula' (paragraph 2.9.1—13(2)(b)).

FSANZ's preliminary view in FSANZ 2021 CP3 (see section 5.7.5) was to: cease the pre-term subcategory and have pre-term formulas become SMPPi; not to require the prescribed name 'Infant formula' for SMPPi; and not to prescribe a specific name for these foods. Instead, generic food name provisions in paragraph 1.2.2—2(1)(b) (i.e. a name or description sufficient to indicate the true nature of the food) were considered sufficient to apply to SMPPi. This preliminary view was in context of a proposed regulatory framework that grouped modified IFP and highly specialised SMPPi together in a single category. At that time, follow-on formula was not in scope.

Four government submitters did not support FSANZ's preliminary view, stating prescribed names are necessary to indicate the true nature of the food and its intended purpose. Their comments were primarily focussed on the need for a prescribed name because, despite the approach to restrict the sale of SMPPi, they considered specialised formula must be distinguishable from standard formula to prevent caregiver confusion. Other reasons for supporting a prescribed name included the need for regulatory clarity and for enforcement purposes (due to the broad spectrum of products captured and the lack of compositional requirements for the intended condition), and that it is similar to the approach adopted by the European Union.

FSANZ has re-considered its preliminary view based on submitter comments and has revised the proposed regulatory framework (section 2.4 of the CFS) to separate modified products from the SMPPi category. Based on this, FSANZ maintains section 2.9.1—17 should not apply to SMPPi and that a prescribed name is not required. Other labelling risk management measures proposed for SMPPi will ensure these products can be distinguished from standard formula (e.g. restriction on the sale, the statement 'use under medical supervision', a statement indicating the medical purpose of the food, a statement on the

properties that make the product suitable for the medical condition, and (if relevant) a statement to the effect that the food is intended for persons within the specified age group).

3.3.2 Warning statements

Paragraph 2.9.1—13(2)(a) states the warning statement 'Suitable only for pre-term infants under specialist medical supervision' applies to products formulated for premature or low birthweight infants.

FSANZ sought stakeholder views in the FSANZ 2017 CP about applying the more flexibly worded statement in paragraph 2.9.5—10(1)(a), that is, a statement to the effect that the food must be used under medical supervision. The majority of submitters (4 government, 3 health professionals, 2 industry, 1 consumer group) supported the requirement in paragraph 2.9.1—10(1)(a) applying to pre-term formula. Another government submitter supported a prescribed statement for all SMPPi, including pre-term formulas stating 'the product must be used under supervision of a suitably qualified health professional'. A third professional submitter proposed the words 'this product must only be consumed by pre-term infants in hospital under medical and dietetic supervision'.

FSANZ notes submitters generally supported the application of this statement and notes this approach aligns with the proposed approach in section 3.2.1 to apply all FSMP statements subsection 2.9.5—10(1) to SMPPi (which includes pre-term formula).

Paragraphs 2.9.1—19(1)(a) to (c) mandate the use of warning statements on IFP labels that instruct caregivers to follow instructions exactly when preparing either a powdered, concentrated or ready-to-drink IFP for use. The wording of these warning statements is prescribed.

FSANZ has not previously consulted stakeholders about the application of these warning statements to SMPPi. FSANZ considers these warning statements should not apply to SMPPi because they are not required by either the European Union regulations or specified by Codex and prescribed wording would present a trade barrier. FSANZ is instead proposing to apply paragraph 2.9.5—9(1)(g) for directions for the use or the storage of the food. FSANZ also notes SMPPi are also intended for use under medical supervision, and so the risks that this statement manages are addressed.

Paragraph 2.9.1—19(1)(d) requires IFP labels to include a heading that states 'Important Notice' (or words to that effect), with under it the warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.

FSANZ's preliminary view in the FSANZ 2021 CP3 was that it is appropriate for SMPPi to be exempt from this statement. There was general submitter agreement. Exempting SMPPi from the breastfeeding statement is consistent with European and United States regulations. FSANZ also notes SMPPi are intended for use under medical supervision, and considers health professionals to be best placed to advise when to breastfeed infants with medical conditions, rather than relying on SMPPi labels for this information.

3.3.3 Directions for preparation and use

Directions (in words and pictures) for the preparation and use of the IFP are mandated in subsection 2.9.1—19(3). These general labelling requirements currently apply to all IFP, including SMPPi. 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.

FSANZ's preliminary view in the FSANZ 2021 CP3 was that these general directions were appropriate for SMPPi and that there are no additional specific directions that should be mandated. Two industry submitters were opposed to this preliminary view, stating that the information requirements of 2.9.1—19(3) do not align internationally, and that this alignment is important for SMPPi intended for use with potentially severe or life-threatening diseases, disorders or medical conditions.

FSANZ notes these concerns and now considers that paragraph 2.9.5—9(1)(g) regarding directions for preparation and use should apply to SMPPi as part of the overall approach to adopt FSMP labelling (see section 3.2 of this report).

3.3.4 Age-related statements

Paragraph 2.9.1—19(4)(a) to (c) includes required statements for IFP indicating that:
a) for infant formula, a statement indicating that infant formula may be used from birth
b) for follow-on formula, a statement indicating follow-on formula should not be used for infants aged under 6 months
c) it is recommended that infants from the age of 6 months be offered foods in addition to the infant formula product (for IFP, however this statement does not apply to packages of pre-term formula).

These statements currently apply to all IFP, including SMPPi. FSANZ has not previously consulted on the first two statements. In relation to the third statement, FSANZ's preliminary view in FSANZ 2021 CP3 was to extend the exemption applying to pre-term formulas to all SMPPi. A health professional submitter opposed this preliminary view on the basis that infants over the age of 6 months and toddlers (including many with medical conditions) should consume an increasingly varied diet with solid foods.

As indicated in section 3.2 above, FSANZ is now proposing FSMP statements in Standard 2.9.5 apply to SMPPi. Age-related statements in paragraphs 2.9.1—19(4)(a) and (b) are addressed by the FSMP requirement for a statement that the food is intended for persons within a specified age group.

FSANZ considers applying the statement about offering additional food to be inappropriate because the provision of additional foods may be contraindicated and supervising health professionals are best placed to advise caregivers on introducing a varied diet to an infant specific to their individual dietary management. Further, this requirement is inconsistent with Codex, European and United States labelling of SMPPi.

3.3.5 Protein source statement

Paragraph 2.9.1—23(1)(a) requires a statement of the specific source, or sources, of protein in the product immediately adjacent to the name of the product. FSANZ has not previously consulted on the application of this labelling requirement to SMPPi.

FSANZ is proposing to maintain this requirement for the name of the food (the prescribed name 'Infant formula' or 'Follow-on formula' to be co-located with the protein source statement, and that information must appear in a prominent position on IFP labels (see section 7.14 in SD1).

Codex CXS 72-1981 states that if cow's milk protein is the only source of protein, the product may be labelled 'Formula for Special Medical Purposes Intended for Infants Based on Cow's Milk". EU 2016/128 has no similar provision for SMPPi. Therefore given the need to maintain flexibility on the protein composition (see section 2.4 above) and to avoid creating a trade barrier, FSANZ considers the requirement for a protein source statement in accordance with paragraph 2.9.1—23(1)(a) will not apply to SMPPi.

3.3.6 Prohibited representations

Section 2.9.1—24 includes prohibitions on labels displaying pictures of infants, pictures idealising infant formula use; humanised / maternalised words; words promoting human milk oligosaccharides; statements about the suitability of infant formula for all infants; a reference to the nutrition of breast milk; and a reference to nutrients and nutritive substances outside of the nutrition information statement, statement of ingredients or a statement relating to lactose.

These prohibited representations apply to all IFP, including SMPPi. FSANZ considers prohibited representations on IFP should not apply to SMPPi because these are highly specialised products for use under medical supervision and which are not marketed to caregivers of healthy infants. FSANZ is also proposing that their sale be restricted. Further, the provisions in paragraphs 2.9.1—24(1)(a) to (e) do not align with European regulations or Codex provisions for SMPPi.

3.3.7 Preferred option

FSANZ's preferred option is to:

- not apply prescribed names 'Infant formula' and 'Follow-on formula' in section 2.9.1—17
- not apply a prescribed name for SMPPi
- exempt SMPPi from warning statements for IFP in subsection 2.9.1—19(1)
- exempt SMPPi from age-related statements for IFP in subsection 2.9.1—19(4)
- not apply the protein source statement in accordance with paragraph 2.9.1—23(1)(a)
- not apply provisions relating to prohibited representations for IFP in section 2.9.1—24
- for directions for preparation and use, requirements in paragraph 2.9.5—9(1)(g) will prevail over requirements for IFP in subsection 2.9.1—19(3).

3.4 Summary of labelling requirements for SMPPi

FSANZ's preferred option is to apply the labelling requirements to SMPPi as listed:

- the requirement to label food as 'genetically modified' in section 1.5.2—4
- inner packages in subsection 2.9.5—8(3)
- transportation outers in subsection 2.9.5—8(4)
- mandatory labelling information in section 2.9.5—9
- mandatory statements and declarations in section 2.9.5—10
- nutrition information requirements in subparagraphs 2.9.5—13(b)(i) and (ii)
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

Labelling requirements that would not apply to SMPPi, or where SMPPI are exempt are:

- name of business address in section 1.2.2—4
- characterising ingredients and components in Standard 1.2.10
- prescribed names 'Infant formula' and 'Follow-on formula' in section 2.9.1—17
- a prescribed name for SMPPi
- warning statements for IFP in subsection 2.9.1—19(1)
- directions for preparation and use for IFP in subsection 2.9.1—19(3)
- age-related statements for IFP in subsection 2.9.1—19(4)

- a protein source statement in paragraph 2.9.1—23(1)(a)
- prohibited representations for IFP in section 2.9.1—24
- nutrition information requirements in subparagraphs 2.9.5—13(b)(iii) or (iv)
- requirements for claims in relation to lactose and gluten content in sections 2.9.5—14 and 15 and the existing conditions for ‘lactose free’ and ‘low lactose’ for IFP (see section 5.1 of SD3).

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