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[20–17]

Consultation paper – Proposal P1028

Regulation of Infant formula – Infant formula products for special dietary use

FSANZ is calling for submissions to help us assess a Proposal to consider the regulation of infant formula products specifically, infant formula for special dietary use.

This paper has considered issues related to the regulation of infant formula products for special dietary use including: categories, definitions, composition, labelling and access to products in the *Australia New Zealand Food Standards Code*, and we now call for submissions to assist the full assessment of the Proposal and the preparation of a draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#). All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 28 September 2017

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

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Executive summary

Although breastfeeding is the recommended way to feed an infant, a safe and nutritious substitute for human milk is needed for infants who are not breastfed. Standard 2.9.1 – Infant Formula Products of the Australia New Zealand Food Standards Code (the Code) regulates the following infant formula products:

- infant formula (for infants aged 0–<12 months)
- follow-on formula (for infants aged from 6–<12 months)
- infant formula products for special dietary use (for infants aged 0–<12 months).

Although the standards for infant formula products in the Code are functioning adequately, there is scope to improve the clarity of some standards and also to consider the application of Ministerial policy guidance and alignment with international regulations.

The purpose of this Consultation paper

Proposal P1028 has been expanded to assess infant formula for special dietary use (IFPSDU) in response to submitter comment. Our 2016 Consultation paper considered issues relating to general infant formula only. Since we previously consulted on the regulation of IFPSDU in 2012, FSANZ now needs to develop a detailed record and understanding of contemporary regulatory issues relating to IFPSDU and to confirm whether issues raised at that time remain relevant.

What this paper covers

This paper presents FSANZ’s preliminary assessment of key issues and for other issues; we are inviting further information to assist our understanding.

Issues related to IFPSDU in this paper address:

- regulatory framework
- organisation of products subcategories
- definitions, product categories and prescribed name
- approach to composition
- food additives
- safety: contaminants, renal solute load, safe preparation and use
- labelling
- distribution and access.

Next steps

Submissions to this paper will be used to inform FSANZ’s assessment. That assessment will form the basis for the Proposal’s first Call for Submissions under the FSANZ Act.

This paper focuses on issues with the regulations relating to infant formula products for special dietary use

Questions to submitters are posed throughout the report, and we are seeking your feedback to inform the next steps.

Not all questions will be relevant to all stakeholders. You do not need to respond to all questions if they are not relevant.

Abbreviations and 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
ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
Amino acids	In this paper, refers to L-amino acids which are the only forms that are biologically active/available
ANZFA	Australia New Zealand Food Authority; the predecessor of FSANZ
ATDS	Australian Total Diet Study
CAC	Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFH	Codex Committee on Food Hygiene
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
Codex	Abbreviation for Codex Alimentarius
Complementary feeding	Complementary feeding is 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).
GEMS	Global Environment Monitoring System
Health	Australian Department of Health
EC	European Commission
EC SCF	European Commission Scientific Committee on Food
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FNB:IOM	Food and Nutrition Board, US Institute of Medicine
FSMP	Refers to Code definition of Food for special medical purposes
FsSMP	Refers to Codex definition of Foods for special medical purposes
FSMPI	Refers to Food for special medical purposes for infants (for EU and Codex)
GL	Guideline Level
GMP	Good Manufacturing Practice
GUL	Guideline Upper Level
HBGV	Health-based Guidance Value

Abbreviation or term	Meaning
IFPSDU	Infant formula products for special dietary use
Infant	A person under the age of 12 months as defined in Standard 2.9.1
Infant formula	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 2.9.1
Infant formula product	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 2.9.1
INS	International Numbering System (for food additives)
IOM	US Institute of Medicine
JECFA	FAO/WHO Joint Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
LOR	Limit of Reporting
ML	Maximum Level
MPL	Maximum Permitted Level
NHMRC	National Health and Medical Research Council (Australia)
NFA	National Food Authority; the predecessor of ANZFA
TDS	Total Diet Survey/Study
The Code	Australia New Zealand Food Standards Code
US	United States of America
US FDA	US Food and Drug Administration
UK FSA	United Kingdom Food Standards Agency
WHO	World Health Organization

1 Introduction

1.1 History of regulation of infant formula products for special dietary use

Before the Australia New Zealand Food Standards Code (the Code) was introduced, both countries individually regulated infant formula for special or medical purposes. When the joint Code came into effect, these highly specialised products were mostly imported and could not fully comply with the general labelling or compositional requirements for infant formula. Thus Division 3 of [Standard 2.9.1 – Infant Formula Products](#) was created under [Proposal P93](#) to more appropriately regulate three categories of infant formula products for special dietary use (IFPSDU).

1.2 Proposal P1028

Proposal P1028 aims to ensure that standards for infant formula are appropriate, clear and function well for the future. Further consideration of current issues and stakeholder response, the application of Ministerial policy guidance and alignment with updated international regulations will inform the revision. This is a large and complex project prepared under section 113(6) of the FSANZ Act and assessed under the Major Procedure.

The 2016 (first) [P1028 Consultation paper](#)¹ focused on general infant formula and so excluded IFPSDU from scope. However, several submissions requested IFPSDU be included because requirements for IFPSDU are founded on those for general infant formula. FSANZ notes the efficiencies to be gained by incorporating IFPSDU into the scope and has agreed to consider IFPSDU within this Proposal.

1.3 Consultation paper

This paper summarises our current understanding of the regulatory issues associated with the specialised infant formula products for infants whose nutritional needs differ from healthy infants because of a disease, disorder or condition. FSANZ last consulted on IFPSDU in a [2012 Consultation paper](#). Thus the purpose of this 2017 paper is to gather information on the specific regulatory issues related to IFPSDU to enable consideration of regulatory options for these products alongside issues for regulation of general infant formula.

Information gathered from submissions to this paper will be used to inform FSANZ's assessment of the Proposal. That assessment and subsequent Call for Submissions will consider the issues with the regulations for both general infant formula and IFPSDU.

Similar to last year's paper, this Consultation paper provides FSANZ's preliminary view on potential amendments to the Code and seeks stakeholder comments to further assist FSANZ's consideration of issues. However, the paper does not conclude a view in terms of possible approaches or amendments to the Code nor does it contain a summary of a formal assessment of the Proposal, a record of decisions on amendments to the Code or a consultation regulation impact statement (cRIS).

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>

1.4 Current IFPSDU market

IFPSDU are traded globally. FSANZ understands from industry stakeholders that many products are imported into Australia and New Zealand in low volume predominantly from the European Union (EU) and possibly the United States (US). On this basis, previous submitter comments supported consideration of alignment with regulations in the EU and US. Therefore, this paper has compared the Code with Codex and EU regulations and where possible, has considered the US Code of Federal Regulations for IFPSDU.

1.5 Approach to regulation of IFPSDU

Since Standard 2.9.1 was last reviewed, [Standard 2.9.5 – Food for special medical purposes](#) (FSMP) has come into effect to define and regulate food that has similar features to IFPSDU. However, the definition of ‘food for special medical purposes’ specifically excludes infant formula products (section 2.9.5—2). As for FSMP, some IFPSDU might be similar to products regulated by the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). However in both countries, products designed to nourish people with medical conditions are not considered to be medicines because they are not used for a therapeutic purpose i.e. they help to improve or maintain the nutritional condition of a person rather than being used to treat or cure any disease state.

IFPSDU and FSMP have similar features in that they both may be imported from overseas in very small volumes. For both categories, the Code provides flexibility for manufacturers to formulate products consistent with the purpose of the product. However IFPSDU compositional requirements are less flexible than for FSMP because, in all other respects, the requirements for general infant formula or follow-on formula apply. This current approach is proposed to be retained.

1.6 Current regulatory environment

Requirements for IFPSDU in overseas markets vary; however most standards are developed with reference to Codex Alimentarius (Codex). Given the extent of importation from source regions, Codex standards and EU and 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 (in the US) as ‘exempt infant formulas’.

1.6.1 The Code

Provisions for IFPSDU are now located in Division 4 of Standard 2.9.1 and [Schedule 29 – Special Purpose Foods](#). This approach is consistent with the Codex STAN 72 – Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex infant formula standard) in which Section B is specific to formula for special medical purposes intended for infants.

The Code allows IFPSDU to be specially formulated for a particular use, such as for pre-term infants or those with metabolic or immunological conditions. Their composition is permitted to deviate from the mandatory compositional requirements for infant formula or follow-on formula consistent with the purpose of the product but in all other respects must comply with the provisions in Standard 2.9.1.

Other standards in the Code also contain specific provisions for infant formula products 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

Regulatory frameworks for IFPSDU operate differently in different countries. Details of these regulations relevant to IFPSDU are described below and considered throughout this paper.

Codex Alimentarius

Codex Alimentarius through the Codex Committee for Nutrition and Special Dietary Uses (CCNFSDU) updated its infant formula standard in 2007 including new provisions in Part B for formula for special medical purposes intended for infants. Part B sets out the composition, quality, labelling and safety requirements by referencing the requirements for infant formula in Part A. It also draws on the Codex provisions for labelling of foods for special medical purposes (FsSMP). For example, the Codex definition of special purpose infant formula is a composite of the definitions/descriptions of FsSMP² and infant formula³.

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

- Codex STAN 72-1981 – Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants; revised 2007 and amended 2011 (Codex infant formula standard).
- 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 most special purpose infant formulas as food for special medical purposes specifically designed for infants (FSMPI). EU legislation is currently in transition thus several relevant pieces of regulation are summarised in Table 1.

² Foods for special medical purposes are a category of foods for special dietary use which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other specially medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary use or by a combination of the two.' Clause 2 *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (STAN 180-1991)

³ '.....which are 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.' Clause 2.1.1 Section B Codex STAN 72-1981

Table 1: EU laws for FSMP

Legislation/Regulation	Description	Note/Comment
CURRENT		
Regulation (EU) No 609/2013 on food intended for infants and young children, FSMP, and total diet replacement for weight control	The overarching Regulation	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 Directive 1999/21/EC on dietary foods for special medical purposes.	Outlines the rules for the composition and labelling of foods intended for the dietary management (under medical supervision) of individuals who suffer from certain diseases, disorders or medical conditions.	Rules apply until 22 Feb 2019
Commission Directive 2006/141/EC on infant formulae and follow-on formulae.	Establishes detailed and complete compositional and labelling rules for products intended to infants from birth up to 12 months of age.	Rules remain applicable until 22 February 2020
Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries	Establishes the rules for infant formulae and follow-on formulae exported or re-exported from the EU to third countries.	
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.	
INCOMING		
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. This supplements EC Regulation No 609/2013.	Adopted 25 September 2015 to apply on 22 February 2020
Commission Delegated Regulation (EU) 2016/128	Outlines the specific compositional and information requirements for FSMP for infants. This supplements Regulation (EU) No 609/2013	Adopted 25 September 2015 to apply on 22 February 2019

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 Act defines 'exempt infant formula' and the regulations specify that infant formulas that are represented and labelled for use by 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. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to 'exempt infant formulas'. Medical foods may also include infant formulas used for IEM which are regulated as exempt infant formulas under section 412(h)(1) of the FD&C Act; 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.

Questions to Submitters:

Q1 Are any other overseas regulations relevant to IFPSDU?

2 Regulatory framework

2.1 Appropriate Standard

During 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, there was some overlap with the features of 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.

Under [Proposal P242 – Foods for Special Medical Purposes](#) (which led to the development of [Standard 2.9.5](#)) FSANZ considered the option of incorporating these highly specialised infant formula products into the new FSMP standard. However, FSANZ proposed instead to consider infant formula for special medical purposes in a forthcoming review of Standard 2.9.1. The rationale noted that infants are a unique population group and that regulating IFPSDU under Standard 2.9.5 could result in inconsistency, potential confusion and difficulty for enforcement purposes. Therefore, for clarity and consistency, it was decided to specifically exclude infant formula products from Standard 2.9.5, so that such products would continue to be regulated by the one standard at that time, namely Standard 2.9.1.

2.1.1 Previous stakeholder views

In previous consultations (2012 and 2016), stakeholders generally supported co-locating provisions for IFPSDU in Standard 2.9.1 to ensure that the general provisions for infant formula applied to these products. Industry submissions noted several factors relating to the appropriateness of the current location of IFPSDU provisions in Standard 2.9.1.

The ease of recipe harmonisation was considered to be facilitated by the current location of IFPSDU given that formulations may change to address specific conditions but in all other respects the products must comply with the provisions in Standard 2.9.1. If IFPSDU provisions were to be located elsewhere, cross referencing to Standard 2.9.1 would be more cumbersome.

2.1.2 Discussion

Standard 2.9.1 sets out base composition, safety and labelling requirements relevant to infant formula. Standard 2.9.5 does not specify any composition requirements for FSMP. FSANZ considers that it is not appropriate for the safety and composition of IFPSDU to be specified. FSANZ notes 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.

2.1.3 Proposed approach

Given the requirement for IFPSDU to comply with the provisions of Standard 2.9.1, FSANZ proposes retaining the provisions for IFPSDU in Standard 2.9.1. This avoids the need to duplicate or cross-reference the infant formula provisions in another standard. This approach is also consistent with Codex.

2.2 Product categories

A broad range of infant formula products fall under the special dietary use category. Currently Division 4 of Standard 2.9.1 includes three subcategories of IFPSDU, as shown in Table 2. Generally IFPSDU products are suitable for the age range from birth to <12 months; however some specialised products are intended for use up to 3 years of age or older. The range of available products may pose 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.

FSANZ is aware of some areas of regulatory uncertainty related to the broad nature of the current subcategories, the range of products in each category and related definitions. Table 2 shows that 'products for specific dietary use based on a protein substitute' currently ranges from partially hydrolysed protein products to amino acid-based protein substitute products. There is a wider range of products under the subcategory 'products for metabolic, immunological, renal, hepatic and malabsorptive conditions'. These range from slightly specialised products for transient conditions such as constipation to highly specialised products for rare conditions. Products formulated for premature or low birthweight infants are highly specialised and may include products that can act as a sole source of nutrition as well as supplementary or modular products that can be used in combination to meet an individual infant's special requirements.

Table 2: Current regulation of IFPSDU in Standard 2.9.1 and examples of how current products on the market are positioned

IFPSDU subcategory	Defined term in the Code?	Which section of Standard 2.9.1?	Examples of current positioning of formula on the market
Products for specific dietary use based on a protein substitute	Yes – protein substitute is defined in Standard 1.1.2	2.9.1—15	Partially hydrolysed protein
			Extensively hydrolysed protein
			L-amino acid-based formula or elemental
Products for metabolic, immunological, renal, hepatic and malabsorptive conditions	No	2.9.1—14(3) to 2.9.1—14(6) 2.9.1—14(1) to 2.9.1—14(2)	Lactose free and low lactose
			Inborn errors of metabolism For transient gastro conditions and feeding problems <ul style="list-style-type: none"> - gastro-oesophageal reflux - colic - constipation
Products formulated for premature or low birthweight infants	Yes for pre-term formula	2.9.1—13	In-hospital premature formula Low birthweight formula Post discharge premature formula

2.2.1 International and overseas regulation

Section B of the Codex infant formula standard does not specifically list product subcategories.

In Europe, formula based on protein hydrolysates as a source of protein are regulated as a general infant formula by Commission Directive 2006/141/EC and [Regulation \(EU\) 2016/127](#). Commission Directive 2006/141/EC notes that infant formulae based on protein hydrolysates are distinct from semi-elemental diet products based on high degree hydrolysates used for the dietary management of diagnosed medical conditions.

The EU regulations (Commission Directive 1999/21/EC and [EU Regulation 2016/128](#)) outline the specific composition and information requirements for FSMP, including FSMP developed to satisfy the nutritional requirements of infants. FSMP are classified into the following three categories:

- (a) nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended
- (b) nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended
- (c) nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

In the US, exempt infant formulas are categorised into the following:

- Infant formulas generally available at the retail level: formulas that can be generally purchased from retail store shelves and are readily available to the public. These formulas are also typically represented and labelled for use to provide dietary management for 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 disorders.
- Infant formulas not generally available at the retail level: formulas that are typically prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and state or federal agencies. These formulas are also generally represented and labelled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time.

The US FDA also maintains a list of products currently on the market that are not linked to these categories but are grouped by purpose (i.e. pre-term, metabolic) and manufacturer.

2.2.2 Previous stakeholder views

Summary of key points raised in submissions
There is considerable variation in the specialised nature of the products that fall under this category. The highly specialised products are evidence-based and their appropriate use is supported by the need for management by medical professionals.
Some stakeholders indicated that the overarching category of IFPSDU should incorporate formula for special medical purposes which would assist with aligning with Codex and international terminology.
The IFPSDU Division does not capture all available formulas for special medical purposes, nor does it accommodate special dietary or medical purposes in the future that may be identified requiring these types of products. It was proposed that the subcategory heading be amended to “Products for <i>diagnosed conditions including</i> metabolic, immunological, renal, hepatic and malabsorptive conditions”.
Product categories for specific disease, condition or disorders may restrict future innovations. Manufacturers should be able to freely develop products for conditions that may arise in the future or as required by the health system in Australia.
Several noted that it is not clear which Division applied since some products do not appear to fit under the IFPSDU Division. Some were concerned about the numbers of products falling into a grey area between general infant formula and IFPSDU, and the names these products are given. It was unclear if some current products (such as those for colic, reflux, constipation, and hungry babies) fall into the special product category and if health professionals support the need for their use. Some stakeholders raised concerns around the need and evidence for their use.
Some expressed concern that products marketed for specific conditions and sold alongside general infant formula products in supermarkets may be recognised as special dietary use products.
The level of innovation is limited in Standards 2.9.1 and 2.9.5 and in Codex by the scope of the standards. Standard 2.9.1 is the most restrictive and Codex the least restrictive. Neither Codex nor the EU categorises the conditions that the IFPSDU might address.

2.2.3 Discussion

2.2.3.1 Approach to determination of subcategories

As noted in the sections above (2.2 and 2.2.2), there is some regulatory uncertainty around the current subcategories. Some information from stakeholders suggests that the current subcategories may not be appropriate or reflect how the risks associated with the various products could best be managed. Currently, the subcategories outline different requirements for composition, labelling and some food additive permissions. At the time 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 stakeholders relate to the current subcategories, it appears these regulatory subcategories could be improved. FSANZ has considered options for appropriate options, these are discussed below.

1. Delete the current subcategories in Division 4 and merge them into one IFPSDU Division. This option deals with gaps and overlaps but may not improve the regulatory clarity if specific requirements for the various subcategories are retained. 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 to manage that risk.
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 based on the low risk to a healthy infant from consumption of these products. The 'high risk' specialised products could then be more easily differentiated from general infant formula.
3. Divide 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* (IFPSMP) within the IFPSDU Division, which was suggested by some submitters in 2012. The approach aims to more clearly capture these highly specialised products in order to provide an appropriate level of compositional flexibility and labelling consistent with their risk. Figure 1 shows a possible approach that arranges the Division into four product subcategories.

FSANZ understands that products for premature and low birthweight infants are generally used under medical supervision. In addition the nutritional requirements of an infant will be determined on a case-by-case basis taking into account a number of factors. Given the range of products that could fall into this category, and their use in hospital settings, it has been suggested that pre-term products could be captured as an infant formula product for special medical purposes rather than as its own category of pre-term products. FSANZ is seeking views on this suggestion.

FSANZ considers the third option may more clearly differentiate the various types of products while also capturing them as special purpose products (rather than general infant formula). This approach could also enable some generic IFPSDU labelling or composition requirements to apply to all subcategories. For example, for less specialised products such as partially hydrolysed formulas, products for transient gastroenterological conditions or feeding problems, the intent that all IFPSDU should be used only with guidance from a healthcare professional could be strengthened. For the highly specialised products that are not suitable for general use, some further alignment with FSMP requirements (Standard 2.9.5) may be required to ensure uninterrupted supply of products in Australia and New Zealand.

However the final arrangement of subcategories will also depend on the necessary variations in prescribed composition and labelling. FSANZ is seeking further information on the practical operation of these options, in particular the need to create a separate IFPSMP subcategory.

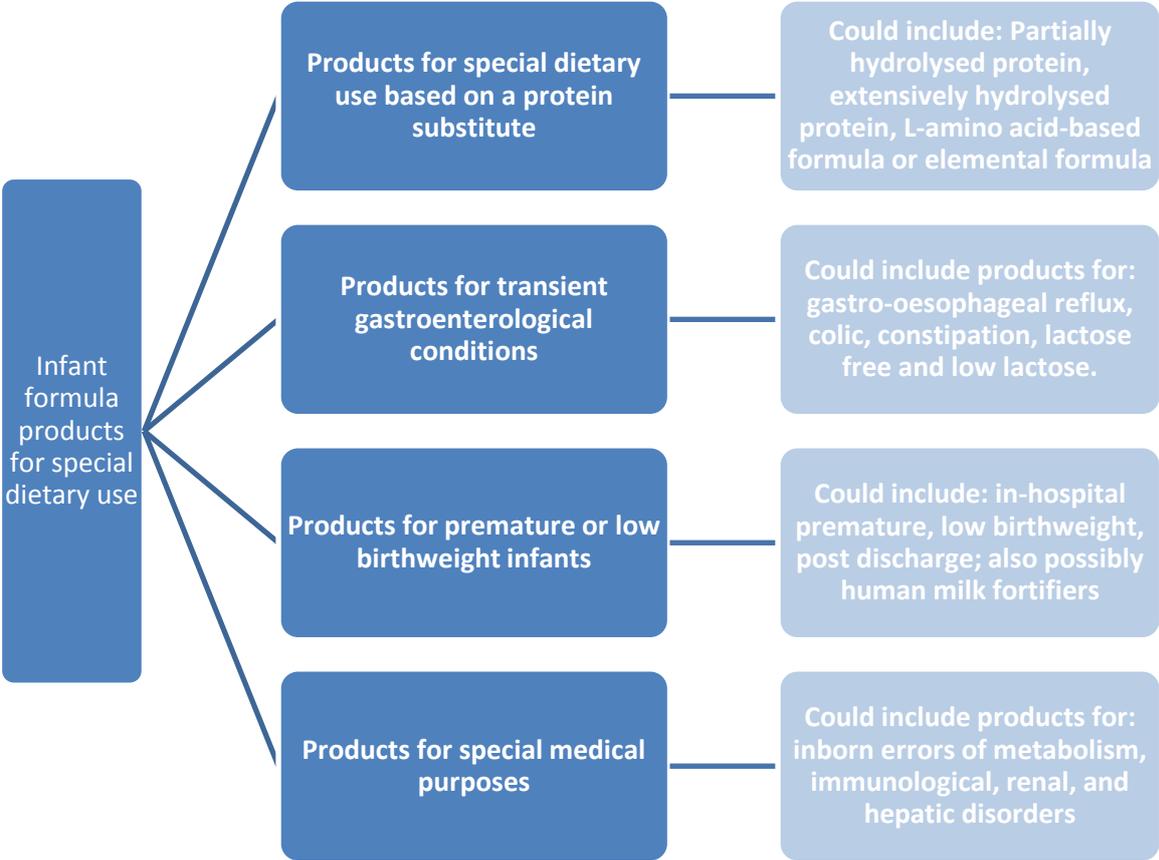


Figure 1 Possible new regulatory classification of IFPSDU

Questions to Submitters:

Q2 What are the advantages and/or disadvantages of these options, in particular creating an ‘infant formula product for special medical purposes’ subcategory? If you support creation of a separate category for IFPSMP, should products developed for pre-term and low birthweight infants be included or retained as a separate subcategory? Please provide your rationale.

2.3 Definitions

2.3.1 New definition of category: Infant Formula Products for Special Dietary Use

No defined term exists in the Code for the Division relating to products that could be classified as ‘infant formula products for special dietary use’. Stakeholders noted that the current definition of ‘infant formula product’ does not capture important elements of many of the formulas used for medical conditions, leading to a lack of clarity and potential enforcement issues (refer to section 2.3.1.2).

2.3.1.1 International and overseas regulation

As shown in Table 3 below, not all regulations include a definition for IFPSDU (or similar term).

Table 3: Definitions for IFPSDU

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

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

- are intended to be used under medical supervision
- may be a substitute for human milk, infant formula, follow-on formula
- are for exclusive or partial feeding
- are specially manufactured
- are intended for the dietary management of infants with a specific disorder, illness or condition.

2.3.1.2 Previous stakeholder views

Stakeholder views are summarised below. Stakeholders commented on the lack of definition, with general support for the inclusion of an IFPSDU definition to improve clarity of the regulation. Stakeholders also noted that the current definition of 'infant formula product' does not capture important elements of many of the formulas used for medical conditions, leading to a lack of clarity and potential enforcement issues. They also provided suggestions for the elements that should be captured in such a definition.

Summary of key issues raised in submissions

The lack of definition of IFPSDU in Standard 2.9.1 results in a lack clarity around these products. It also relies on the descriptions of the different products listed in the Division which is unclear.

Summary of key issues raised in submissions

Current Code definitions that do not reflect the definition of IFPSDU can all lead to ambiguity at the enforcement level. Such products:

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

The definition should

- consider both Codex and EU definitions since these definitions are more applicable to future developments
- align with both Codex definition of IFPSDU and the Code's definition of FSMP in Standard 2.9.5. This is important as some IFPSDU are suitable beyond infancy for up to 3 years or even up to 10 years of age either as a supplement or a sole source of nutrition depending on the medical condition/disorder or as determined by the healthcare professional
- capture products intended for infants 0–12 months of age that offer nutritional support for transient conditions and those infants with limited capacity to consume ordinary foodstuffs, as well as have the capacity to offer nutritional support to more debilitating conditions.

2.3.1.3 Proposed category definition

FSANZ considers introducing a definition for the 'infant formula products for special dietary use' category would provide further clarity. Such a definition should reduce the ambiguity relating to the classification of some products; it should also provide a clear scope for the use of food additives and contaminant restrictions and certain labelling provisions. In drafting this definition, FSANZ considered the Codex definition of formula for special medical purposes intended for infants, and the European FSMP definition (see Table 3). Both definitions have common elements, many of which have been highlighted by stakeholders.

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.

2.3.2 Possible definition of subcategory: Infant Formula Products for Special Medical Purposes

Stakeholders noted the current definition of 'infant formula product' does not capture important elements of many of the formulas used for medical conditions, leading to a lack of clarity and potential enforcement issues.

Summary of key issues raised in submissions

The 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.

Given the previous stakeholder support, FSANZ has drafted a definition for a new subcategory, if created that could provide a clear differentiation for the highly specialised products including those that may pose a risk to healthy infants. FSANZ again considered relevant definitions which included:

- the Code's FSMP definition
- the Codex definition of formula for special medical purposes intended for infants
- EU FSMP definition.

The additional important elements for this product subset build on those of the IFPSDU definition to include where an:

- infant has a disordered capacity to take, digest, absorb, metabolise or excrete nutrients or metabolites or has medically determined nutrient requirements
- infant's dietary management cannot be completely achieved without using the product.

2.3.2.1 Possible subcategory definition

Infant formula product 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, or
 - (ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula product

Questions to submitters:

- Q3 Do you support including a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?
- Q4 If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

2.3.3 Products for specific dietary use based on a protein substitute

A definition of protein substitute exists in the Code. The term 'protein substitute' is intended to cover a range of protein components either singly or in combination. FSANZ is not aware of any relevant definitions used internationally or overseas.

In the Code, 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.

2.3.3.1 Previous consideration

Other terms such as protein-modified, proximate modified and synthetic amino acids were considered during Proposal P93. None of these were supported in submissions (ANZFA, 1999). Stakeholders proposed that definitions should be developed for 'extensively hydrolysed protein' and 'partially hydrolysed protein' to enable differentiation between the two types. Since there were no internationally agreed definitions at the time, these definitions were considered unnecessary because hydrolysed protein (regardless of the extent of hydrolysis) would be permitted as a protein substitute.

2.3.3.2 International and overseas regulation

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](#) prescribes sources and a method for protein processing; the regulation also enables manufacturers to describe the role of infant formula manufactured from protein hydrolysates in reducing the risk of developing allergy to milk proteins (under certain conditions).

2.3.3.3 A view in one submission

As shown in Table 4, additional definitions for the products that conform to the protein substitute definition were suggested by one submitter.

Table 4: Definitions related to protein substitute suggested by one submitter

Product	Proposed definition
Hypo-allergenic formula	Infant formula in which the protein source has been partially modified to reduce the amount of intact protein present, with the aim of reducing allergenicity and hypersensitivity reactions.
Extensively hydrolysed formula	Infant formula in which the protein source (whether predominantly whey, casein or soy proteins) has been extensively modified to reduce the amount of intact protein present, with the aim of preventing hypersensitivity reactions.
Elemental infant formula	Elemental infant formula is infant formula in which the protein is supplied by synthetic amino acids, for use by infants unable to tolerate other forms of protein without hypersensitivity reactions.

2.3.3.4 Discussion

FSANZ is not aware of specific concerns with the current definition of protein substitute. As noted above, FSANZ is not aware of any definitions for the different protein substitute products, either in Australia and New Zealand or internationally. We are seeking views on the need for revising the protein substitute definition or for any additional definitions.

Questions to submitters:

Q5 Are there any issues with the current definition for protein substitutes?

Q6 Is there a benefit to defining one or more of the following in the Code:

- Hypo-allergenic formula
- Partially hydrolysed formula
- Extensively hydrolysed formula
- Amino acid-based infant formula?

If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?

2.3.4 Pre-term formula

Standard 2.9.1 defines pre-term formula to mean ‘an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.’ FSANZ notes that some of the products used for premature or low birthweight infants may not currently meet the definition of an ‘infant formula product’ as they may not “serve as the sole or principal liquid source of nourishment for infants”.

2.3.4.1 Previous consideration

The pre-term subcategory and definition were introduced during Proposal P93. At that time, several stakeholders recommended a definition for pre-term formula based upon, or referenced, the weight of an affected infant. This was because the amount of pre-term formula fed to such an infant was determined by an infants’ weight.

For example

- extremely low birthweight infant, less than 1000 g in weight
- pre-term infant, 1000–1750 g in weight.

Other stakeholders suggested a maximum age such as < 36 or 38 weeks’ gestation. These categories were not adopted because FSANZ concluded that details about age or weight in the definition were unnecessary for the purposes of setting a food standard category for premature infants or those of low birthweight.

2.3.4.2 International and overseas regulation

FSANZ is not aware of any relevant definitions in Codex standards, European or US regulations.

2.3.4.3 A view in one submission

One submission to the 2012 Consultation paper suggested that the definition for pre-term products be modified to consider including parameters for both age and weight (for example, pre-term, < 33 weeks; low birthweight, less than 1.5 kg).

2.3.4.4 Discussion

The World Health Organization (WHO) defines pre-term infants as ‘babies born alive before 37 weeks of pregnancy are completed’. Subcategories of pre-term birth, based on gestational age are:

- extremely pre-term (<28 weeks)
- very pre-term (28 to <32 weeks)
- moderate to late pre-term (32 to <37 weeks).

WHO also defines low birthweight as ‘a birth weight of a live born infant of 2,499 g or less, regardless of gestational age’. Subcategories are:

- very low birthweight – less than 1500 g (3 pounds 5 ounces)
- extremely low birthweight – less than 1000 g (2 pounds 3 ounces).

However, these WHO definitions are used for comparative health statistics and are not considered appropriate for clinical care. It is recommended that for clinical purposes, individual countries may choose alternative cut-off values (United Nations Children’s Fund and World Health Organization, 2004). Given that 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. FSANZ is seeking views on whether there is any benefit in modifying the current definition of pre-term formula.

Questions to submitters:

- Q7 Are there any issues with the current definition for pre-term products?
- Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

2.3.5 Human milk fortifier and pre-term supplement products

Fortifiers derived from cow's milk are added to human milk as a nutritional supplement for premature and low birthweight infants 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.

Currently, human milk fortifiers are not clearly captured by any subcategory in Division 4 of Standard 2.9.1 or by Standard 2.9.5 (related to infants, but not as an infant formula product). FSANZ notes that these fortifiers might not be defined as an infant formula product under the current definition because they are not designed to provide a sole or principal source of nourishment.

One submission requested that a definition of 'human milk fortifier products' (derived from animal milk) be included in the Code as "these products are vital for immune-compromised or premature babies". Although the main use of these products appears to be for premature and low birthweight infants, FSANZ is seeking information on other purposes and uses which may then influence the definition or choice of an appropriate subcategory.

Questions to submitters:

- Q9 What is the general composition of human milk fortifiers for premature or low birthweight infants? What are the uses of these products other than premature or low birthweight infants?

2.4 Prescribed name or names

Generic requirements for the prescribed name 'infant formula' currently apply to IFPSDU. In addition, paragraph 2.9.1—13(2)(b) of Standard 2.9.1 requires products formulated for premature or low birthweight infants to bear the words 'pre-term' as part of the name of the food (i.e. pre-term infant formula). There is no specific prescribed name for the other two product subcategories. For products that are manufactured for metabolic, immunological, renal, hepatic and malabsorptive conditions, there is no specific prescribed name.

There is a requirement for the label to include a statement explaining the "condition, disease or disorder for which the product has been specially formulated; and the nutritional modifications, if any, which have been made to the product." (paragraph 2.9.1—14(2)(b)). The intent of this statement is to enable appropriate identification of the products.

Products for specific dietary use based on a protein substitute are also not required to be identified using a prescribed name. Further, these products do not have the same requirement for a statement as do products for metabolic, immunological, renal, hepatic and malabsorptive conditions under paragraph 2.9.1—14(2)(b). However, it is unclear whether appropriate identification of these products is an issue for caregivers.

2.4.1 International and overseas regulation

For IFPSDU, the Codex infant formula standard specifies the name ‘Formula for special medical purposes intended for infants’, or any appropriate designation indicating the true nature of the product, in accordance with national usage. This would not preclude a reference to ‘pre-term’ in the product name. If cow’s milk is the only source of protein, the product may be labelled ‘Formula for special medical purposes intended for infants based on cow’s milk’.

The EU⁴ requires dietary foods for special medical purposes including those for infants and young children to be labelled “Food(s) for special medical purposes”.

There is no explicit requirement to also name the products that are intended for infants as ‘infant formula’ or ‘follow-on formula’. However there is a requirement to state that the product is intended for a specific age group. The EU does not specifically require ‘pre-term’ to be declared, although the regulations refer to using a ‘descriptive name’ which is defined as a name providing a description of the food, and if necessary of its use, which is sufficiently clear to enable consumers to know its true nature and distinguish it from other products with which it might be confused.

In the US there are no specified naming requirements for ‘exempt infant formula’. However labelling and representational requirements depend on whether the exempt infant formula is available at the retail level or prescribed by a physician. US regulations state that specific information targeting the intended population and describing the characterising properties of the food to be information about the basic nature of the food that must be included as part of the statement of identity. [Labelling guidance for infant formula](#) (US FDA 2016)⁵ includes specific information to describe formula intended for pre-term infants as an example of this provision.

2.4.2 Previous stakeholder views

Submitters to the 2012 and 2016 Consultation papers made comments relating to product categories and definitions, but did not go so far as to suggest that product category and/or subcategory names be prescribed. Some submitters previously highlighted that the name of products should not contravene the infant formula product regulations or be misleading under consumer protection laws.

2.4.3 Discussion

There is no consistency internationally with respect to the wording of an overarching prescribed name for IFPSDU. Furthermore, neither the EU nor Codex requires a prescribed name for subcategories of IFPSDU, although Codex does specify the wording option of formula ‘based on cow’s milk’.

FSANZ is aware that some IFPSDU available in Australia and New Zealand are labelled as ‘food for special medical purposes’ to align with EU labelling requirements; several of which are also suitable for children up to 3 years of age.

These are generally the highly specialised products that are imported and are labelled to align with overseas requirements (i.e. EU). FSANZ does not intend these products to be non-compliant with the Code and considers that the drafting can incorporate products to bear a label stating the product is a food for special medical purpose.

⁴ Article 4, Commission Directive 1999/21/EC and Article 4, Regulation (EU) 2016/128

⁵ <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/default.htm>

FSANZ is already seeking stakeholder views in relation to the proposed inclusion of a:

- category definition for IFPSDU, and
- a subcategory definition for Infant Formula for Special Medical Purposes (refer to section 2.3).

One option would be to require a prescribed name on the label to further distinguish the overarching IFPSDU category from infant formula for general use. However, FSANZ notes that the wording of this category definition would differ from international and overseas wording requirements.

Alternatively, if the subcategory Infant Formula Product for Special Medical Purposes is defined as proposed under section 2.3, a prescribed name to this effect could distinguish between certain IFPSDU categories and it would offer greater consistency with EU requirements and Codex specifications. However, some subcategories may not be captured as an Infant Formula Product for Special Medical Purposes under this prescribed name, as indicated in section 2.3.

The labelling requirements in the Code differ from overseas and international regulations in that it mandates 'Pre-term Infant Formula' as a prescribed name. International and overseas regulations do not prescribe a specific term and thus provide some flexibility in product identification. The lack of flexibility afforded by the Code may impede the supply of IFPSDU imported into Australia and New Zealand.

FSANZ is interested in stakeholder views regarding the need for a prescribed name for IFPSDU as a category distinct from infant formula for general use, and whether there should be prescribed names for subcategories if IFPSDU.

Questions to submitters:

Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

Q11 Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

3 Composition

3.1 General approach to composition (including current requirements)

The Code allows IFPSDU to be specially formulated for a particular use within the three subcategories. This means their composition may deviate from the mandatory compositional requirements for infant formula or follow-on formula consistent with the purpose of the product but in all other respects must comply with the provisions in Standard 2.9.1. This ensures products provide for the general nutritional requirements of infants.

The permitted variations for each of the three subcategories of IFPSDU are as follows.

- Section 2.9.1—13(1) provides for products formulated for premature or low birthweight infants to deviate from the compositional requirements of the standard when this is necessary for the intended use of the products for premature and low birthweight infants.

- Section 2.9.1—14(1) provides for products if they are specially formulated for a specific condition to deviate from the general requirements to satisfy the nutritional requirements of infants when this is necessary for the intended use of the product
- Section 2.9.1—14(3) permits only a variation to the lactose content requirements for low lactose and lactose free products
- Sections 2.9.1—15(2) and (4) outline more specific requirements for products for specific dietary use based on a protein substitute to ensure that the products are safe and suitable for the population.

This approach is based on the expectation that any compositional changes will be based on medical and nutritional principles and are safe and effective in meeting the specific nutritional requirements of the infants for whom it is intended.

3.1.1 International and overseas approaches

Codex takes a similar approach; Part B of the Codex infant formula standard specifies that the composition requirements for IFPSDU are based on the composition of infant formula:

The energy content and nutrient composition of Formula for Special Medical Purposes intended for infants shall be based on the requirements for infant formula as given in sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.

The EU FSMP Directives (1999/21/EC, 128/2016) states the composition of FSMP developed for infants must comply with the compositional requirements of standard infant formula (i.e. for healthy infants) unless this is contrary to the requirements dictated by the intended use of the FSMP. The EU regulations acknowledge the need to ensure adequate flexibility to develop innovative products, and state that it is not appropriate to lay down detailed compositional rules for such food products. However it is considered important to set principles and requirements specific to the infant population and to allow deviations from the requirements for FSMP for infants when necessary for the intended use of the product. Notwithstanding this approach, the EU does specify the method to be used to manufacture protein hydrolysates and requires any new formula from protein hydrolysates to be evaluated by EFSA before being placed on the market.

The US also follows the principle that exempt infant formula should be based on the composition requirements of infant formula. The regulations (§107.50(b)(4)) require a manufacturer to submit information to the US FDA for review for any product that varies from the compositional requirements for infant formulas. Information is required to be provided on the rationale and description of the reformulation and a detailed description of the medical conditions for which the infant formula is represented for. This includes the medical, nutritional, scientific, or technological rationale with appropriate animal or human clinical studies.

3.1.2 Previous consideration

Several issues were discussed during the development of this Division during Proposal P93. It was proposed that more specific compositional provisions for pre-term formula would be developed in a new proposal after Standard 2.9.1 was gazetted.

Partially hydrolysed products (particularly whey protein hydrolysates) and amino acid-based formula were relatively new products when Standard 2.9.1 was under development. At the time, a literature review on the safety of these products identified potential risks to growth

and development of infants. The review proposed several specific composition elements for products produced from protein substitutes. In addition it was recognised that the use of the refined ingredients used in protein substitutes lead to a possible absence of chromium and molybdenum; as a consequence the Standard required both minerals to be present.

3.1.3 Previous stakeholder views

Summary of key issues raised by stakeholders
Compositional harmonisation with Codex – compositional harmonisation is especially crucial for IFPSDU.
Do not support compositional criteria tied to product categories. This approach is consistent with the conclusions of 1997 EU SCF Opinion on foods for special medical purposes: that it would be very difficult to establish compositional criteria for such diverse FSMP products and that it would be difficult to keep such criteria under review and up to date. For the same reason, Codex does not include provisions for the composition of FSMP products.
Highly specialised IFPSDUs can often be utilised for young children beyond the age of 1 year e.g. products can be suitable for infants and children with long chain fatty acid oxidation disorders and disorders/disease where fat malabsorption occurs as a sole source of nutrition up to the age of 10 years. From industry, healthcare professional and parent/carer perspectives, it would add unnecessary complexity to require IFPSDUs to formulate for different ages of infants.
Flexibility should be continued to be retained regarding the compositional requirements as specified in Subdivision 2 for IFPSDUs. This principle for flexibility is also captured in Codex and EU legislation.
Encourage FSANZ to take into account the latest scientific recommendations/guidelines when revising the compositional requirements for IFPSDUs (e.g. Vitamin D reference intakes), and be consistent with product regulations in other major markets (e.g. the EU market).
Propose that any revisions in nutritional composition for IFPSDUs should: <ul style="list-style-type: none"> • have alignment to Codex and EU Infant Formula legislation • permit flexibility where required based on the medical condition as permitted in Part B of the Codex Infant Formula Standard • have common nutritional composition for 0–12 months • permit the voluntary addition of optional ingredients currently specified in the current FSANZ Standard 2.9.1
Substances added to formulas that are promoted as being for colic, reflux etc. should be checked for safety and suitability for infants and whether they have a substantiated beneficial role.

3.1.4 Discussion

An approach that specifies minimal compositional requirements allows IFPSDU to be formulated and based on evolving medical and scientific knowledge and provides flexibility to develop innovative products. No specific compositional requirements are established for products intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions. However, subsections 2.9.1—(13)(1) and 2.9.1—(14)(1) require products to comply with general requirements except those for which a deviation is necessary to satisfy the particular nutritional requirements of these infants.

This is not the case for formula for specific dietary use based on protein substitutes. Specific energy, protein and fat ranges together with a maximum renal solute load apply to these products. Section 2.9.1—15 specifies the same energy ranges and amino acid requirements as for general infant formula products but has raised the protein maximum and lowered the fat minimum in comparison. Medium chain triglycerides are also permitted.

Despite these provisions, there appears to be ambiguity about which other provisions of the Standard apply since one similar to subsections 2.9.1—(13)(1) and 2.9.1—(14)(1) does not exist.

With the suggestion of a new subcategory of formula for special medical purposes, consideration is needed on any specific compositional macronutrient parameters that might apply. Noting the overseas approaches, FSANZ is seeking further information on this question. Both the EU and US legislation contains a specific requirement for the 'special formulation' of the IFPSDU type product to be based on sound medical and nutritional principles and for the use of the product to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended population. As discussed above a similar intent is captured in Standard 2.9.1, however stakeholders have suggested that this intent could be strengthened in the revised Division as for IFPSDU. FSANZ is seeking further information on this suggestion.

Questions to submitters:

- Q12 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?
- Q13 Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?
- Q14 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?
- Q15 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?

3.2 Micronutrients and nutritive substances

Standard 2.9.1 and several sections in Schedule 29 list the vitamin, mineral, electrolyte, amino acid and nutritive substance minimum, guideline or maximum amounts and their permitted forms in infant formula (and follow-on formula). These provisions apply to IFPSDU generally, unless a deviation is warranted, together with specific ranges for chromium and molybdenum in IFPSDU based on protein substitutes.

3.2.1 Previous consideration

In assessing Proposal P93, it was considered that the vitamin, mineral, electrolyte, amino acid and nutritive substance requirements for general infant formula were appropriate for IFPSDU. However, it was recognised that an infant formula based on milk ingredients would not require added chromium or molybdenum because these trace minerals are naturally present in milk ingredients. On this basis, provision was made for the addition of chromium and molybdenum to infant formula products based upon protein substitutes. This was because these formula may be elemental in some cases (i.e. not based upon food constituents), and thus devoid of chromium or molybdenum and unsuitable for infants.

3.2.2 International and overseas regulation

Codex

Part B of Codex STAN 72-1981 specifies that the nutrient composition of Formula for Special Medical Purposes Intended for Infants (FSMPI) shall be based on the requirements for infant formula except for the “compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented”.

Further, Part B sets out a minimum level and Guidance Upper Level (GUL) for chromium and molybdenum, noting these should be taken into account where appropriate as these are not required in Part A of the standard. Minimum levels are specified (0.4 µg/100 mL for both), and while no maximum levels are stipulated; a GUL is provided at 2.4 µg/100 mL for both trace nutrients.

European Union

The EU regulations also set basic rules for the vitamin and mineral content and substances used in the FSMP intended for infants. Minimum and maximum amounts are specified for the products for infants. Modifications are permitted for one or more of these nutrients when rendered necessary by the intended use of the product.

FSMP intended for infants are required to contain both molybdenum and chromium, however no minimum values are specified for these minerals. For chromium a maximum of 2.4 µg/100 kJ and for molybdenum a maximum of 3.3 µg/100 kJ is specified.

3.2.3 Previous stakeholder views

One submitter proposed a review of the minimum and maximum amounts for chromium and molybdenum for IFPSDU based on protein substitutes. This was on the basis that Codex states FSMPI “shall take into account minimum levels and guidance upper level for chromium and molybdenum where appropriate”. Another submitter supported the review of these nutrients to determine if scientific evidence supports their inclusion (and if so, the appropriate levels) in IFPSDU products based on protein substitutes.

3.2.4 Discussion

FSANZ has not assessed the appropriateness of the specific compositional requirements for IFPSDU in this paper. At this stage we are seeking stakeholder views on whether there are any problems with the current approach.

Chromium and molybdenum

The requirements for chromium and molybdenum in general infant formula were discussed in the 2016 Consultation paper. Neither Codex nor Standard 2.9.1 sets a minimum for chromium and molybdenum, or permits the addition of these nutrients to general infant formula. As noted above, the incoming EU regulation for FSMP for infants requires the presence of both minerals but only specifies a maximum amount.

Since the development of Standard 2.9.1 an Adequate Intake (AI) has been set for both nutrients in Australia and New Zealand. EFSA recently concluded that there is insufficient evidence to consider chromium an essential nutrient, thus addition of chromium in infant formula was not necessary and did not recommend a minimum amount (EFSA 2014). Recent EFSA scientific opinion proposed a minimum of 0.1 µg/100 kJ; intakes at this minimum would meet the AI for both infant age groups.

The 2016 consultation paper noted that minimums are not specified in the Code as there is naturally occurring chromium and molybdenum in milk ingredients. Thus we sought information on the amounts in infant formula to consider whether there is a need to set a minimum requirement. Given the specialised nature of many IFPSDU FSA NZ is now seeking information on the need to specify a permitted range of both chromium and molybdenum in different types of IFPSDU.

Questions to submitters:

- Q16 Are there issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?
- Q17 Do you have any information to support including a minimum and maximum amount of chromium in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?
- Q18 Do you have any information to support including a minimum and maximum amount of molybdenum in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

4 Food additives

The information in this section builds on that provided in section 8 of SD2 (Safety and Technology) of the 2016 Consultation Paper - Infant formula. Since this paper, certain changes to international food additive provisions for infant formula products have been made; these are only noted where relevant. The focus of this discussion is on food additive permissions specifically for IFPSDU as some differences occur in the food additive permissions in the Code and in international and overseas regulations.

This section examines the differences in food additive permissions for IFPSDU in the Code, Codex, EU and US regulations. FSA NZ is considering whether there is a need to update permissions in the Code to improve international consistency and to assist international trade in IFPSDU.

4.1 Current regulation

4.1.1 The Code

Schedule 15 – Substances that may be used as food additives, lists the food additive permissions for infant formula products under a hierarchical system of food categories (as discussed in SD2 section 8.1.1.1 of the 2016 paper). Thus the food additive permissions relevant for IFPSDU include the general infant formula categories (items 13.1 – *Infant formula products*, 13.1.1 – *soy-based infant formula* and 13.1.2 – *liquid infant formula products*) and those listed in category 13.1.3 – *Infant formula products for specific dietary use based on a protein substitute*.

Food additives must comply with specifications which should include information to adequately identify the food additive, including origin, and acceptable criteria of purity. Sections S3—2 and S3—3 of Schedule 3 – Identity and Purity outline the relevant sources for specifications.

4.1.2 Codex Alimentarius

Two Codex standards are relevant: Codex infant formula standard and the Codex General Standard for Food Additives (GSFA).

Section A, Part 4, of the Codex infant formula standard lists certain food additive permissions for infant formula (either all types of infant formula or specifically for hydrolysed protein or amino acid-based formulas). Section B of that standard relates to 'Formula for special medical purposes intended for infants' and refers back to the relevant food additives in Section A. New food additives that apply to all types of infant formula products (including IFPSDU) were updated in this standard in 2016, occurring after the release of the 2016 paper. The GSFA was also updated in 2016 to include new food additives for several infant formula food categories. Although the GSFA also uses a hierarchical food category system, its food categories do not directly align with those used in the Code.

The List of Codex Specifications for Food Additives (CAC/MISC 6-2015) details all the specifications for food additives adopted by reference by Codex. The specifications have been prepared by JECFA and are published in the Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 and subsequent monographs (2015, monograph 17).

4.1.3 European Union

Several regulations related to food additives exist in the EU. [Regulation \(EC\) 1333/2008](#) sets the rules on all aspects of food additives: definitions, conditions of use, labelling and procedures. It also contains several annexes outlining the technological functions of food additives and lists food additives approved for use. [Regulation \(EU\) 231/2012](#) contains the specifications for food additives listed in Annexes II and III to Regulation (EC) 1333/2008.

Annex II of [Regulation \(EU\) 1129/2011](#) (which amends Annex II to Regulation (EC) 1333/2008) contains the list of food additives approved for use in food and their conditions of use. This list is also organised into a hierarchical food category system.

All food additives listed in the EU's positive list (in the EU regulations) must be authorised and listed with conditions, namely, that:

- a safety assessment has been performed
- the technological need has been justified
- the use of the additive will not mislead consumers.

European regulations refer to E numbers (European food additive numbers) which are essentially the same as the Codex INS numbers and the same as the food additive numbers used in the Code, e.g. E 338 is equivalent to INS 338 and is the food additive number for phosphoric acid.

4.2 Consideration of harmonisation with international and overseas regulations for IFPSDU

As discussed in the 2016 paper, FSANZ is considering whether to align the infant formula food additive provisions in the Code with those of Codex (as the global reference point). FSANZ is aware that most highly specialised IFPSDU products are imported into Australia and New Zealand from the EU and a small number of other countries. Continued supply of these specialised products is a priority as they are essential for the small sub-population of infants who have specific physical or physiological conditions, diseases or disorders.

In considering regulation in other markets that might supply Australia and New Zealand, Codex and EU regulations provide for suitable comparison particularly as Europe is a major source of IFPSDU products. Although some IFPSDU products may be manufactured in the US, the USFDA CFR does not contain a single standard or regulation that lists permitted food additives in infant formula products, including exempt infant formulas. FSANZ has concluded that it is not possible to consider harmonisation with US food additive permissions.

On this basis, FSANZ will consider aligning the Code to Codex or EU permissions where an evaluation of the evidence supports that such permissions have been appropriately based on a suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and where their use is technologically justified. However, harmonisation with international regulations is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.

4.2.1 Differences in food categories for IFPSDU

Table 5 shows the differences in food categories for IFPSDU across the Code, Codex and EU regulations. As shown several of the relevant food categories in the Code do not directly align with the GSFA or EU regulations i.e. the same numbering applies to different food categories in the different regulations.

Currently the Code only contains an IFPSDU category for protein substitute products. FSANZ notes this food category does not currently capture all IFPSDU. The Codex infant formula standard lists all permissions together and specifies different conditions of use; the GSFA then has an additional food category for formula for special medical purposes intended for infants. The EU takes a similar approach of including products from hydrolysed proteins, peptides or amino acids with infant formula differentiating use conditions through a restriction/exceptions column of the EU list. The EU also lists additional food categories to cover the FSMP for infants and includes various qualifications for use conditions such as different maximum levels and/or different restrictions for different product types with footnotes and a restriction/exceptions column.

Table 5: Comparison of relevant food categories for food additives in the Code, Codex and EU

Food category Section S15—5	Food category name Section S15—5	Codex* GFSA	EU 2016 Regulation (EU) No. 1129/2011
13.1	Infant formula products	(13.1) Infant formulae, follow-up formulae and formulations for special medical purposes for infants <i>Includes product in liquid form, either as a ready-to-eat product, or as reconstituted from a powder.</i>	(13.1) Foods for infants and young children – includes, but not restricted to infant formulae as defined by Directive 2006/141/EC
13.1.1	Soy-based Infant formula	(13.1.1) Infant formulae <i>Includes liquid form, either as ready-to-eat or reconstituted from a powder. Products may be hydrolysed protein and/or amino acid-based or milk based.</i>	(13.1.1) Infant formulae as defined by Commission Directive 2006/141/EC
13.1.2	Liquid formula infant products	(13.1.2) Follow-on formulae – outside scope	(13.1.2) Follow-on formulae – outside scope

Food category Section S15—5	Food category name Section S15—5	Codex* GFSA	EU 2016 Regulation (EU) No. 1129/2011
13.1.3	Infant formula products for special dietary use based on a protein substitute	(13.1.3) Formulae for special medical purposes	(13.1.3) Processed cereal based foods and baby foods – outside scope.
No category	No category	No category	(13.1.5) Dietary foods for infants and young children and infant formulae for special medical purposes (as defined by Commission Directive 1999/21/EC)
No category	No category	No category	(13.1.5.1) Dietary foods for infants for special medical purposes and special formulae for infants <i>Includes dietary foods for infants for special medical purposes, special formulae such as premature infant formulae, hospital discharge formulae, low and very low birthweight formulae, human milk fortifiers.</i>

Notes to table:

*Codex infant formula standard doesn't list permissions by category number

The final hierarchical system of food categories for IFPSDU will depend on the number and arrangement of IFPSDU subcategories in the Standard (refer to section 2.2), however it may be appropriate to consider additional food categories in Section S15—5. For example, if the proposed four IFPSDU subcategories were to proceed, the current food category 13.1.3 in the table to section S15—5 could be revised to represent one subcategory for IFPSDU, or alternatively expanded further into additional subcategories depending on the extent of the use of particular food additives.

Advice is sought from stakeholders on whether all additional food additives or those for use at different levels for IFPSDU could be listed in one category, or whether additional or modified subcategories of food category 13.1 would be needed.

Questions to submitters:

Q19 Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).

4.2.2 Differences in permitted food additives

FSANZ is aware that the formulations of many IFPSDU can be very different to those of general infant formula. It is often necessary to use many individual ingredients rather than relying on the composition of core ingredients to provide macro and micronutrients, which can create technological challenges in manufacturing. Therefore different types of food additives can be required for these products.

4.2.2.1 Previous stakeholder views

Industry noted that non-alignment for food additive permissions would potentially restrict the availability of products that are developed for infants with medical conditions where there are limited options available to manage their dietary needs, particularly those small volume products.

Industry stakeholders highlighted that IFPSDU need to be specially formulated or processed to be suitable for their particular use and can therefore be technologically challenging to produce. For example products designed for tube feeding are required to be highly stable in solution for longer periods of time which requires different emulsifiers and stabilisers than powdered infant formula. Thus industry has requested FSANZ consider permitting a broader range of food additives consistent with EU and Codex regulations to allow for the broader technological needs of IFPSDU.

Specific requests were made for the following food additives currently permitted by the EU and Codex:

- INS 401 Sodium alginate
- INS 415 Xanthan gum
- INS 440 Pectin
- INS 466 Sodium carboxymethylcellulose
- INS 473 Sucrose esters of mono- and di-glycerides
- INS 1450 Starch sodium octenyl succinate
- INS 1422 Acetylated distarch adipate.

4.2.2.2 Comparisons with EU and Codex

Table 6a shows the food additives permitted in Codex or the EU that are not currently in the Code, noting that there are also differences between Codex and the EU. Table 6b shows the food additives permitted in the Code but that have different conditions or use levels in Codex and the EU.

Sodium and potassium phosphates as well as starch sodium octenylsuccinate are permitted in both Codex and the EU. However the ten additives permitted in the EU are specifically for use in 'Dietary foods for infants for special medical purposes and special formulae for infants'. Many of these align with the request from industry for FSANZ to consider as they are currently used in IFPSDU products manufactured overseas. At this stage, FSANZ proposes to consider aligning with these and to apply conditions as noted in Codex or EU regulations (in Table 6a). Industry would be required to provide a justification (safety and technological) to support broader permissions.

For the food additives permitted in the Code but not in either Codex or EU, or where the use conditions and levels differ FSANZ proposes considering amending the Code for consistency.

Table 6a: IFPSDU food additive permissions in EU regulation and Codex that are not in the Code

		Codex					EU		
Food additive name	INS number	Sub-name where relevant	Sub-INS	Food category	MPL (mg/L)	Additional conditions	Food category	MPL (mg/L)	Additional conditions
Calcium carbonates	170				No permission		13.1.5.1	GMP	
Calcium citrates	333				No permission		13.1.5.1	GMP	
Phosphoric acid	338				No permission	-	13.1.1 13.1.5.1	1000	(IFPSDU, for pH adjustment only) Phosphorus expressed as P ₂ O ₅ . Individually or in combination with other phosphates
Sodium phosphates	339	Sodium dihydrogen phosphate	339i	CS 72 (all infant formula) not in GSFA	450	As phosphorus singly or in combination. Plus limits on sodium, potassium and phosphorus in section 3.1.3(e) of CS 72	13.1.5.1	1000	Permission for the different phosphates (sodium, potassium and calcium salts) can be added individually or in combination. Max expressed as P ₂ O ₅ .
		Disodium hydrogen phosphate	339ii						
		Trisodium phosphate	339iii						
Potassium phosphates	340	Potassium dihydrogen phosphate	340i	CS 72 (all IF) not in GSFA	450	As phosphorus singly or in combination. Plus limits on sodium, potassium and phosphorus in section 3.1.3(e) of CS 72	13.1.5.1	1000	Permission for the different phosphates (sodium, potassium and calcium salts) can be added individually or in combination. Max expressed as P ₂ O ₅
		Dipotassium hydrogen phosphate	340ii						
		Tripotassium phosphate	340iii						

		Codex					EU		
Food additive name	INS number	Sub-name where relevant	Sub-INS	Food category	MPL (mg/L)	Additional conditions	Food category	MPL (mg/L)	Additional conditions
Calcium phosphates	341				No permission		13.1.5.1	1000	Permission for the different phosphates (sodium, potassium and calcium salts) can be added individually or in combination. Max expressed as P ₂ O ₅ .
Sodium alginate	401				No permission		13.1.5.1	1000	Adapted composition required for metabolic disorders and for general tube feeding
Xanthan gum	415				No permission	-	13.1.5.1	1200	In products based on amino acids or peptides for use with patients who have problems with impairment of the GI tract, protein mal-absorption or inborn errors of metabolism
Pectins	440				No permission	-	13.1.5.1	10000	In products used in case of GI disorders
Sodium carboxymethylcellulose	466				No permission	-	13.1.5.1	10000	In products for the dietary management of metabolic disorders
Sucrose esters of fatty acids	473				No permission		13.1.1 13.1.5.1	120	Only infant formula products containing hydrolysed proteins, peptides or amino acids. Unity principle applies, with INS 322, 471, 472c and 473
Starch sodium octenylsuccinate	1450			GSFA CS 72	20000	Hydrolysed protein and/or amino acid-based infant formula only	13.1.5.1	20000	

Note: Cells are 'greyed out' where no relevant permission exists

Table 6b: IFPSDU food additive permissions in the Code, Codex and EU regulation

Food additive name	INS number	The Code		Codex			EU		
		Food category	MPL (mg/L) and conditions	Food category	MPL (mg/L)	Additional conditions	Food category	MPL (mg/L)	Additional conditions
Locust bean (carob bean) gum	410	13.1 all infant formula	1000	GSFA CS 72	1000	All IF products	13.1.5.1	10000	For reduction of gastro-oesophageal reflux
Guar gum	412	13.1 all infant formula	1000	GFSA CS 72	1000	In liquid formula containing hydrolysed protein (cat 13.1.3 in GSFA) and CS 72 (in liquid products containing hydrolysed protein) No permission for standard infant formula	13.1.1 13.1.5.1	1000 10000	13.1.1 (only when liquid product contains partially hydrolysed proteins). 13.1.5.1 (In liquid formulae products containing hydrolysed proteins, peptides or amino acids)
Citric and fatty acid esters of glycerol	472c	13.1.3	9000	CS 72-only	9000	Liquid infant formula only (all types)	13.1.1 13.1.5.1	9000	Liquid where product contains partially hydrolysed proteins, peptides or amino acids Unity principle applies, with INS 322, 471, 472c and 473
					7500	Powdered infant formula only (all types)	13.1.1 13.1.5.1	7500	Powder Unity principle applies, with INS 322, 471, 472c and 473
Diacetyltartaric and fatty acid esters of glycerol	472e	13.1.3	400		No permission			No permission	

Note:

Cells are 'greyed out' where no relevant permission exists

4.3 Summary of potential amendments

Table 7 lists proposed amendments to the Code resulting from possible alignment with Codex or EU regulations for IFPSDU. Amendments will be considered following an evaluation of the evidence supporting that such permissions have been appropriately based on a suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and where their use is technologically justified. FSANZ is seeking information to support this consideration.

Note that at this stage the proposed food category in Table 7 is listed as IFPSDU. This however, does not indicate how the food categories may be organised. FSANZ will use information submitted during this consultation to consider which food categories including whether additional subcategories might be warranted.

Table 7: Indicative list of amendments to food additive permissions

Food additive name	INS number	Proposed amendments
Calcium carbonates	170	Add for IFPSDU only at GMP consistent with EU permission.
Calcium citrates	333	Add for IFPSDU only at GMP consistent with EU permission.
Phosphoric acid	338	Add for IFPSDU only at 450 mg/L as phosphorus (equivalent to 1000 mg/L as P ₂ O ₅) consistent with EU permission. This would require an additional explanation of how phosphates are calculated (to be added to subsection 1.3.1—4(6)).
Sodium phosphates	339	Do not make changes specifically for IFPSDU. Changes could be considered for all infant formula consistent with to Codex provisions.
Potassium phosphates	340	Do not make changes specifically for IFPSDU. Changes could be considered for all infant formula consistent with to Codex provisions
Calcium phosphates	341	Do not make changes specifically for IFPSDU. Changes could be considered for all infant formula consistent with to Codex provisions.
Sodium alginate	401	Add at 1000 mg/L for IFPSDU with a qualification statement consistent with the EU regulations
Locust bean (carob bean) gum	410	Add at 10000 mg/L for IFPSDU with a qualification statement consistent with the EU regulations
Guar gum	412	Limit permission for IFPSDU only at 1,000 mg/L, consistent with Codex. Remove permission for general infant formula, since no permissions in Codex and EU.
Xanthan gum	415	Add at 1200 mg/L for IFPSDU only with a qualification statement consistent with EU regulations.
Pectins	440	Add at 10000 mg/L for IFPSDU only with a qualification statement; EU regulations
Sodium carboxymethylcellulose	466	Add at 10000 mg/L for IFPSDU only with a qualification statement; EU regulations
Citric and fatty acid esters of glycerol	472c	Propose new permissions for powder IFPSDU (7500 mg/L) consistent with Codex and EU. Make the current permission for IFPSDU at 9000 mg/L only for liquid product consistent with Codex and EU.

Food additive name	INS number	Proposed amendments
Diacetyltartaric and fatty acid esters of glycerol	472e	Remove permission since not permitted in Codex or EU.
Sucrose esters of fatty acids	473	Add permission for IFPSDU since permitted in EU at 120 mg/L. Not for general infant formula.
Starch sodium octenylsuccinate	1450	Add for IFPSDU at 20000 mg/L consistent with Codex and EU

Questions to submitters:

Q20 Do you support the proposed amendments listed in Table 7 for IFPSDU at the amounts shown?

Q21 Can you provide information on suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and a technological justification for:

- a) Calcium carbonates
- b) Calcium citrates
- c) Phosphoric acid
- d) Sodium alginate
- e) Xanthan gum
- f) Locust bean (carob bean) gum
- g) Pectins
- h) Sodium carboxymethylcellulose
- i) Sucrose esters of fatty acids
- j) Starch sodium octenylsuccinate

Q22 Are there any technologically justified concerns with changing the permissions for citric and fatty acid esters of glycerol (472c) to:

- a) MPL of 9000 mg/L for liquid products
- b) MPL of 7500 mg/L for powdered products?

Q23 What is the technological justification for the use of diacetyltartaric and fatty acid esters of glycerol (472e) in IFPSDU? Are there any technologically justified concerns with the removal of this permission?

5 Safety

5.1 Potential renal solute load

The renal solute load is the amount of metabolic waste products that must be excreted by the kidney. The potential renal solute load (PRSL) refers to the solutes from the diet that would need to be excreted in the urine if not utilised in the synthesis of new tissues or excreted through non-renal routes. To minimise the risk of dehydration and illness from formulas with high protein and electrolyte contents, Standard 2.9.1 specifies a PRSL of no more than 8 mOsm/100kJ for products derived from protein substitutes. An equation to calculate the PRSL is listed in Schedule 29, is based on amounts of sodium, chloride, potassium, available phosphorus and nitrogen in the product.

5.1.1 Previous consideration

Prior to Standard 2.9.1 the osmolality⁶ of infant formula was regulated. However, during Proposal P93, there was a shift to control the PRSL of formula as there was evidence that the solute concentration of a feed was different to the renal solute load of the feed (ANZFA, 1998). Thus PRSL was considered a more suitable parameter of formula to indicate risk to infants for dehydration illness in certain relatively common adverse circumstances to which infants are prone.

5.1.2 Previous stakeholder views

Only one submission commented on the PRSL in relation to IFPSDU that they were not aware of any evidence that the maximum PRSL was ineffective. They also noted that they ensured that the PRSL is appropriate to infants with medical conditions.

Questions to submitters:

Q24 Do you support retaining the current maximum PRSL for any IFPSDU? Please provide your rationale.

5.2 Contaminant MLs

Chemical contaminants may occur at low concentrations in all foods, including infant formula. It is not possible to avoid the presence of very low level contamination in some cases, for example for certain metal contaminants that are ubiquitous in the environment.

The 2016 Consultation paper reviewed the differences between the Code and Codex in relation to Maximum Levels (MLs)⁷ applicable to infant formula. These proposed changes are relevant to IFPSDU. In this section, the current MLs relevant to IFPSDU in the Codex standards and in the EU are discussed.

5.2.1 Current regulation

MLs for contaminants in infant formula products are located in Standard 1.4.1 – Contaminants and Natural Toxicants, Schedule 19 – Maximum levels of contaminants and natural toxicants and Standard 2.9.1. The Code currently includes the following MLs relevant to infant formula: arsenic, aluminium, lead, tin, acrylonitrile and vinyl chloride (refer to table 9). As a general principle, the levels of contaminants and natural toxicants in all foods should be kept As Low As Reasonably Achievable (the ALARA principle).

Where the Code serves an effective risk management function, MLs have been established for some contaminants in infant formula products, including for IFPSDU, consistent with protecting public health and safety. The principles underpinning the approach to MLs in the Code were discussed in the 2016 paper and are summarised below.

⁶ Osmolality refers to the number of osmoles of the particles in a kg of solvent, expressed as milliosmoles (mOsm).

⁷ The Code defines a maximum level (ML) as meaning: *the maximum level of a specified contaminant, or specified natural toxicant, which is permitted to be present in a nominated food expressed, unless otherwise specified, in milligrams of the contaminant or the natural toxicant per kilogram of the food (mg/kg).*

MLs will be specified:

- only for those contaminants that present a significant risk to public health and safety
- only for those foods that significantly contribute to the dietary exposure of the contaminant
- to ensure that levels are as low as reasonably achievable
- consistent with Codex levels, where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.

Both the Codex infant formula standard and the *Codex General Standard for Contaminants and Toxins in Food and Feed* (Codex STAN 193-1995) list Guideline levels (GLs) and MLs for infant formula products. There are no MLs specific to IFPSDU. The Codex principles for establishing MLs note that:

MLs shall only be set for food in which the contaminant may be found in amounts that are significant for the total exposure of the consumer, taking into consideration the Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Section III of the Procedural Manual). The maximum levels shall be set in such a way that the consumer is adequately protected. At the same time the other legitimate factors need to be considered.

Table 8: Current MLs in the Code and Codex standards relevant to infant formula products

Contaminant name	The Code		Codex		Potential amendments to the Code to align with Codex
	Maximum level	Foods applied to	Maximum level	Foods applied to	
Acrylonitrile	0.02 mg/kg	All food	0.02 mg/kg (GL)	Food	Already aligned with Codex - no amendments required.
Aluminium	0.1 mg/100 mL	Soy-based formula	Not applicable		Not amending to align with Codex. Will retain current ML. (in order to keep exposure ALARA), transfer the ML for aluminium from Standard 2.9.1 to Schedule 19
	0.05 mg/100 mL	Infant formula other than soy-based infant formula			
Arsenic	Not applicable		Not applicable		Already aligned with Codex - no amendments required
Melamine	Not applicable		1 mg/kg	Powdered infant formula	FSANZ does not propose to introduce MLs for melamine.
			0.15 mg/kg	Liquid infant formula as consumed	
Lead	0.02 mg/kg	Infant formula products	0.01 mg/kg (lowered from 0.02 mg/kg at 2014 CAC)	Infant Formula (ready to use)	Reduce ML to 0.01 mg/kg to align with Codex.
Tin	250 mg/kg	All canned food	250 mg/kg	Canned foods (other than beverages)	Already aligned with Codex - no amendments required

Contaminant name	The Code		Codex		Potential amendments to the Code to align with Codex
	Maximum level	Foods applied to	Maximum level	Foods applied to	
Vinyl chloride	0.01 mg/kg	All food excluding packaged water	0.01 mg/kg (GL)	Food	Already aligned with Codex - no amendments required.

The EU *Commission Regulation 1881/2006 – Setting maximum levels for certain contaminants in foodstuffs* lists MLs for infant formula, follow-on formulae and dietary foods for special medical purposes intended for infants. As shown in Table 9 below, the regulation includes MLs for cadmium, aflatoxin B1, M1, Ochratoxin A and polycyclic aromatic hydrocarbons (PAHs) relevant to infant formula and FSMP for infants. The preamble text of the EC Regulation 1881/2006 notes that setting MLs ensures:

that food business operators apply measures to prevent and reduce the contamination as far as possible in order to protect public health. It is furthermore appropriate for the health protection of infants and young children, a vulnerable group, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children.

5.2.2 Previous consideration

The 2016 paper considered aligning contaminant MLs with Codex as summarised in Table 8.

5.2.3 Previous stakeholder views

The 2012 Consultation paper sought views on whether full alignment of infant formula contaminant levels with Codex infant formula contaminant levels was appropriate. Several submissions drew attention to the more comprehensive list of MLs (i.e. additional substances) for infant formula in the EU regulations. However, they did not suggest full alignment since the lack of alignment was not creating trade difficulties and there was not an established public health and safety need in Australia and New Zealand. One submission noted that review of contaminant MLs should give consideration to infants more at risk such as those who are premature, unwell or suffer from renal dysfunction.

Some submitters noted that one of the main repercussions of aligning contaminants with Codex will be the removal of the limit for aluminium. There was concern that the aluminium ML may be removed, particularly in relation to the risks to premature infants who have reduced renal function. There was support for retaining the aluminium ML at least for IFPSDU.

Table 9: MLs for dietary foods for special medical purposes intended for infants in the EU (that differ to the Code and Codex)

Contaminant	Food category	Maximum levels	Conditions/Notes
Mycotoxins			
Aflatoxins	Infant formula and follow-on formulae	M1 0.025 µg/kg	<ul style="list-style-type: none"> – The maximum level refers to the products ready to use (marketed as such or after reconstitution as instructed by the manufacturer) – Foodstuffs listed in this category as defined in Commission Directive 2006/141/EC.
	Dietary foods for special medical purposes intended specifically for infants	B1 0.10 µg/kg M1 0.025 µg/kg	<ul style="list-style-type: none"> – Foodstuffs listed in this category as defined in Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes – The ML refers in the case of milk and milk products, to the products ready for use (marketed as such or reconstituted as instructed by the manufacturer) and in the case of products other than milk and milk products, to the dry matter. The dry matter is determined in accordance with Regulation (EC) No 401/2006.
Ochratoxin A	Dietary foods for special medical purposes intended specifically for infants	0.50 µg/kg	<ul style="list-style-type: none"> – Foodstuffs listed in this category as defined in Commission Directive 1999/21/EC of 25 March 1999. – The ML refers in the case of milk and milk products, to the products ready for use (marketed as such or reconstituted as instructed by the manufacturer) and in the case of products other than milk and milk products, to the dry matter. The dry matter is determined in accordance with Regulation (EC) No 401/2006.

Contaminant	Food category	Maximum levels	Conditions/Notes
Cadmium	Infant formula and follow-on formulae: — powdered formula manufactured from cows' milk proteins or protein hydrolysates — liquid formula manufactured from cows' milk proteins or protein hydrolysates — powdered formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins — liquid formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins	0.010 mg/kg wet weight	<ul style="list-style-type: none"> – Foodstuffs listed in this category as defined in Commission Directive 2006/141/EC – The maximum level refers to the product as sold.
		0.005 mg/kg wet weight	
		0.020 mg/kg wet weight	
		0.010 mg/kg wet weight	
Polycyclic aromatic hydrocarbons	Infant formula and follow-on formula	Benzo(a)pyrene 1.0 µg/kg Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene 1.0 µg/kg	<ul style="list-style-type: none"> – Foodstuffs listed in this category as defined in Commission Directive 2006/141/EC – The ML refers to the product as sold. – Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.
	Dietary foods for special medical purposes intended specifically for infants	Benzo(a)pyrene 1.0 µg/kg Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene 1.0 µg/kg	<ul style="list-style-type: none"> – Foodstuffs listed in this category as defined in Commission Directive 1999/21/EC – The maximum level refers to the product as sold.

5.2.3 Consideration of European MLs

As shown in Table 9 the EU specifies MLs for some additional contaminants that are not listed in either the Code or Codex standards. *Commission Regulation 1881/2006* lays down the lowest maximum levels for contaminants reasonably achievable with good manufacturing practices or good agricultural practices (ALARA). As noted in the preamble of the regulation, it is considered an appropriate risk management approach for the health protection of infants, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children.

The following sections discuss the relevance of the European MLs with reference to Appendix 1: Contaminants in infant formula – consideration of health-based guidance values (HBGVs) and the principles for establishing MLs in the Code.

5.2.3.1 Arsenic

Arsenic occurs in various inorganic and organic forms and is found in the environment both from natural occurrence and from anthropogenic activity. The organic forms are of relatively low toxicity while inorganic arsenic has been identified as a human carcinogen from epidemiological studies of populations exposed to inorganic arsenic in drinking water (WHO 2001).

In the 2016 Consultation paper, FSANZ noted that there were limited detections of arsenic in infant formula thus no evidence of a risk to public health and safety from residues of arsenic in infant formula. Therefore, it was considered that there was no specific need to establish an ML for arsenic (inorganic) for infant formula in the Code. This approach was consistent with Codex.

Two submissions to the 2016 paper noted Codex does set an ML for inorganic arsenic in polished rice and is in the process of adopting a limit for husked rice. It was suggested that if rice was used in infant formula (e.g. a non-dairy infant formula), an ML would be appropriate.

FSANZ is aware that international analytical surveys of food, including infant foods have detected the presence of arsenic in rice based foods. However there is little evidence of arsenic being detected in infant formula. In the US FDA summary of results from TDS market baskets from 2006–2013 total arsenic was measured in 32 samples of infant formula (milk based, iron fortified RTF), with no detections. It was also measured in 10 samples of infant formula (milk based, low iron) with no detections. Additionally in September 2013 the USFDA reviewed infant formula in [Analytical Results from Inorganic Arsenic in Rice and Rice Products](#). A total of 10 samples of infant formula were analysed with extremely low levels of arsenic.

FSANZ is aware that rice-based infant formulas are available in both international and the Australia and New Zealand markets. A recent survey of arsenic in rice based products has included rice-based infant formula and the results of these will be available soon for consideration by FSANZ.

FSANZ's preliminary view

At this stage, as there is no evidence of a public health and safety issues for arsenic levels in hydrolysed rice protein-based infant formulas in the Australia and New Zealand market. Therefore, FSANZ concludes there is no need to amend the Code to include a limit for arsenic in IFPSDU. However, FSANZ will consider the need for a ML for inorganic arsenic (for rice that may be used as an ingredient in infant formula) in a separate Proposal at a later time if a sufficient scientific basis for an ML exists.

5.2.3.2 Mycotoxins

Aflatoxins

Aflatoxins are a family of toxins produced by fungi and found on agricultural crops. They are primarily produced by two species of *Aspergillus*: *A. flavus* and *A. parasiticus*. *A. flavus* produces aflatoxins B1 and B2, while *A. parasiticus* produces aflatoxins B1, B2, G1 and G2. Aflatoxin B1 in lactating dairy cattle can be transmitted into milk and milk products as the metabolite aflatoxin M1 (EFSA 2007; JECFA 2016).

Table 10 shows that the EU specifies an ML for M1 in both infant formulae and follow-on formulae and dietary foods for special medical purposes intended specifically for infants and a limit for B1 in dietary foods for special medical purposes intended specifically for infants.

Codex has adopted an ML of 0.5 µg/kg in milk for aflatoxin, but has not established a level in infant formula. Standard 1.4.1 includes MLs for aflatoxins in certain foods. However, no aflatoxin ML has been established for infant formula in the Code.

As noted in Appendix 1, there is limited information on the levels of aflatoxins in infant formula in Australia and New Zealand, in the WHO Global Environment Monitoring System (GEMS) database or in published international studies. However in the 23rd ATDS, aflatoxin M1 was not detected in infant formula samples, and levels of aflatoxins in general foods were low and did not pose a significant health concern to Australian consumers.

As aflatoxins are genotoxic and carcinogenic, human exposure should be minimised to the level that is reasonably practicable. Internationally it is acknowledged that the complete elimination of mycotoxin contaminated commodities is not achievable at this time. However at the Codex Alimentarius several Codes of Practice have been developed, including the following:

- General Code of Practice for the prevention and reduction of mycotoxin contamination in cereals (CAC/RCP 51-2003).
- Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feeding stuffs for Milk Producing Animals (CAC/RCP 45-1997).

FSANZ's preliminary view

In view of these considerations, FSANZ's preliminary view is that introducing new MLs for aflatoxin in infant formula is not necessary. FSANZ considers that the Codex Code of Practice CAC/RCP 45-1997 is a useful risk management tool for manufacturers of IFPSDU products to reduce potential contamination of aflatoxins in infant formula products.

Ochratoxin A

Ochratoxin A is a mycotoxin produced by fungi of the *Aspergillus* and *Penicillium* species. These fungi may grow on stored material under favourable conditions and produce ochratoxin A, which has been found in a wide range of raw commodities and food products including cereals, dried fruit, coffee, wine, beer and grape juice (EFSA 2006).

The EU specifies an ML for dietary foods for special medical purposes intended specifically for infants. Codex only specifies an ML for raw wheat barley and rye. The Codex General Code of Practice CAC/RCP 51-2003 contains two annex relevant to ochratoxin A.

FSANZ's preliminary view

Information on the ochratoxin A content of infant formulas sold in Australia or New Zealand is not available, however in the 23rd ATDS ochratoxin A was not detected in any of the foods for which it was analysed. In addition, available information in WHO GEMS database and overseas assessments have generally found only low levels of ochratoxin A contamination of infant formula. On this basis it is considered unlikely that levels of ochratoxin A in infant formula in Australia are a health concern.

Therefore, at this stage we cannot establish that there is an appropriate scientific basis to harmonise with the EU ML.

5.2.3.3 Polycyclic aromatic hydrocarbons

PAH can be present in raw materials due to environmental contamination from the air by deposition on crops, from contaminated soils and transfer from water to fresh and marine invertebrates.

Commercial and domestic food preparation such as smoking, drying, roasting, baking, barbecuing or frying are recognised as important sources of food contamination. Presence of PAH in vegetable oils can also originate from smoking and drying processes used to dry oil seeds before extracting oil. The major contributors to dietary intakes of PAH are cereals and cereal products (owing to high consumption in the diets) and vegetable fats and oils (owing to higher concentrations of PAH in this food group).

A FSANZ commissioned analytical survey on PAHs in Australian foods, including infant formula, did not identify any health concerns for Australian consumers. This is consistent with the findings of a larger UK Food Standards Agency (UK FSA) survey in which levels of PAHs were below the EU maximum permitted limit.

Exposure to genotoxic and carcinogenic PAHs should be as low as is reasonably practicable. FSANZ notes there is a Codex COP for reducing PAHs from smoking and direct drying (CAC/RCP 68-2009). Although Codex COP CAC/RCP 68-2009 is not specific to reducing PAHs in IFPSDU, FSANZ considers that the COP may help manufacturers reduce PAH levels in ingoing cereals (e.g. rice based) and vegetable fats and oils used in the manufacture of IFPSDU.

FSANZ's preliminary view

FSANZ has no data on levels of PAH in IFPSDU or infant formula more generally. Therefore, at this stage we cannot establish that there is an appropriate scientific basis to harmonise with the EU ML.

5.2.3.4 Cadmium

Cadmium is a naturally occurring metallic element (WHO, 1992). Some forms of cadmium found in soil can be absorbed by plants. Cadmium in water can be taken up by fish, other sea creatures (especially mussels, oysters and crab) and animals (especially in their liver and kidneys). Eating vegetables, plants, seafood or liver or kidneys containing cadmium can be source of cadmium exposure for humans.

The EU has established a number of MLs for cadmium in infant formula based on soy protein isolates and hydrolysed cow's milk proteins (see Table 10). A higher level is set for infant formula manufactured from soy protein isolates, as soy beans can naturally take up cadmium from the soil. There is no Codex ML established cadmium in infant formula. The Code does not include a ML for cadmium in infant formula.

In addition, evidence from Australian and New Zealand total diet studies suggests that levels of cadmium in infant formula are low and generally consistent with those reported internationally. Dietary exposures to cadmium in infant formula are not considered likely to be of health concern.

FSANZ's preliminary view

In view of these considerations, it is FSANZ's preliminary view that introducing new MLs for cadmium in infant formula are not justified. If evidence becomes available indicating levels of cadmium in infant formula may be of health concern, the need to establish a specific ML may be reconsidered.

Summary

FSANZ has no data on levels of cadmium, aflatoxin B1, M1, Ochratoxin A and PAHs in IFPSDU. Therefore, at this stage we cannot establish that there is an appropriate scientific basis to harmonise with the EU MLs for the categories referred to in Table 10.

6 Labelling

In addition to generic labelling requirements in Part 1.2 of the Code, labelling and packaging requirements for infant formula products for general use in Division 5 of Standard 2.9.1 apply to IFPSDU. These include:

- representations about food as an infant formula product (section 2.9.1—16)
- prescribed names (section 2.9.1—17)
- requirement for measuring scoop (section 2.9.1—18)
- warning statements and other directions (section 2.9.1—19)
- legibility requirements for warning statements (section 2.9.1—20)
- declaration of nutrition information (section 2.9.1—21)
- date marking and storage instructions (section 2.9.1—22)
- statements of protein source and dental fluorosis (section 2.9.1—23)
- prohibited representations (section 2.9.1—24).

These requirements were discussed in the 2016 Consultation paper in relation to infant formula (for infants aged 0-<12 months, but not follow-on formula).

Division 4 of the Standard sets out specific labelling requirements for pre-term formula and infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions. These requirements also apply and prevail where there is an inconsistency with a generic labelling requirement or a specific requirement for infant formula intended for general use.

The structure of Standard 2.9.1 was changed during the recent revision of the Code. These structural changes took effect in March 2016 and may address submitter comments made to the 2012 Consultation paper about the operation of generic and specific labelling requirements for IFPSDU in the Standard. The specific requirements for IFPSDU are the focus of this section.

6.1 Pre-term infant formula

Paragraph 2.9.1—13(2)(a) of Standard 2.9.1 requires products formulated for premature or low birthweight infants to be labelled with the warning statement ‘Suitable only for pre-term infants under specialist medical supervision’. This wording is prescribed and must be included on the label to ensure these IFPSDUs are only used for premature and low birthweight infants. The requirement was put in place when Standard 2.9.1 was developed.

The Code requirement for the prescribed name ‘Pre-term Infant Formula’ is discussed under section 2.4 above).

6.1.1 International and overseas regulation

The Codex infant formula standard specifies a prominent statement ‘use under medical supervision’ be used. Similarly, the EU labelling regulations require a statement that the product must be used under medical supervision. US regulations states that the label must include a statement indicating that parents should consult their physicians about the use of infant formulas, such as “Use as directed by a physician” (21 CFR 107.20(f)).

6.1.2 Previous consideration

The requirement in Section 2.9.1—13(2)(a) was considered during development of Standard 2.9.1, under Proposal P93. The P93 assessment noted that there was a potential for pre-term infant formulas to be sold from a retail outlet. Because of this situation, it was considered appropriate to mandate a warning statement to further distinguish the suitability of pre-term formula from other formula (in addition to the words 'pre-term' in the name of the food).

6.1.3 Previous stakeholder views

One submission to the 2012 consultation paper pointed out that certain pre-term infant formula products were available for sale in some Australian pharmacies, and could be purchased without prescription. This submitter noted their concern that the higher protein content of pre-term infant formula (compared to full term infant formula) may be detrimental to infants. For example, pre-term infants and infants classified as small for gestational age could experience rapid weight gain which may be hazardous in the long-term. The submitter believed pre-term infant formula should be used only under medical supervision and not marketed to the general public.

6.1.4 Discussion

FSANZ is aware that pre-term formula is currently available post hospital discharge in Australia and New Zealand. However, this is generally by prescription through the public funded 'Special Authority' government scheme (refer to section 7 – Distribution and access). The warning statement would therefore have less relevance if the pre-term infant formula is not available for general sale.

However, anecdotal evidence from submitters suggests that pre-term infant formula is currently available for general sale in Australia. What is unclear is whether caregivers purchase these pre-term infant formula products without medical specialist advice, and use them in place of an infant formula product for general use (not pre-term), or whether in fact the products can only be sold by prescription.

The EU and the US each require a statement to the effect that pre-term infant formula should be used under medical supervision, or as directed by a physician. Neither regulation requires the wording of these statements to be prescribed. This approach differs from the Code requirement to mandate a specific warning statement with prescribed wording. FSANZ notes that many of the products available in Australia and New Zealand are imported and already comply with EU and US labelling requirements. It would be burdensome for suppliers of the imported products to have to change the labels only because the exact wording of the statement does not align with the Code requirement. FSANZ is also unaware of any difficulties experienced by clinicians or other relevant health professionals in appropriately identifying these products, given that they are primarily used in a clinical setting.

FSANZ notes, however, that the two labelling elements (name of the food and warning statement) are intended to inform that these products are specifically intended for pre-term infants. This may be particularly important given there is anecdotal evidence that these IFPSDU are available for general sale.

FSANZ is seeking information on the use of pre-term infant formula, particularly whether caregivers are able to freely access it or whether it can only be obtained by prescription. Stakeholder views are also being sought on whether it is necessary to require the warning statement to be prescribed, or if the EU and US approach of requiring a similar statement that was not prescribed could be adopted.

Questions to submitters

- Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?
- Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

6.2 Products that are suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions

Paragraph 2.9.1—14(2)(b) of Standard 2.9.1 states that if the label contains a statement that the infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, then for the labelling provisions a statement indicating the following is required in accordance with paragraphs 2.9.1—14(2)(c) – (e):

- that the product is not suitable for general use and should be used under medical supervision; and
- the condition, disease or disorder for which the product has been specially formulated; and
- the nutritional modifications, if any, which have been made to the product.

Information provided in a statement on the label of products for metabolic, immunological, renal, hepatic and malabsorptive conditions that refers to a condition, disease, disorder or nutritional modification is not considered a claim because this information is mandated. This includes products intended for infants with lactose maldigestion that are represented as lactose free or low lactose, and the conditions associated with making such representations.

6.2.1 International and overseas regulation

Codex

Section 9.6 of Codex STAN 72-1981 requires formula for special medical purposes intended for infants to be labelled with the certain information that is also required on FSMPs for older ages (by cross-referencing to the Codex FSMP standard – STAN 180-1991⁸). The information required is:

- a prominent statement “Use under medical supervision”
- a prominent warning statement if the food for special medical purpose poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- a statement that the product is not to be used for parenteral administration.
- the statement “For the dietary management of ...” with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended.
- a statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.

⁸ Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1 and 4.5.5, Codex STAN 180-1991

Codex requires other statements and instructions regulated under Codex STAN 180-1991⁹ to appear on the label or be provided separately:

- a prominent statement indicating that the product is intended as the sole source of nutrition.
- a complete statement concerning the adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.
- a statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.
- feeding instructions, including the method of administration and serving size, if applicable.

European Union

Most of the EU labelling requirements for IFPSDUs are the same as those for FSMPs intended for older ages (IFPSDUs are regulated under the same legislation as other FSMPs). As a result, the EU provides similar provisions to those set by Codex (see above), but with the additional statement that the product is intended for a specific age group, where appropriate.

United States

The US requires that the label of an 'exempt infant formula' be submitted to the US FDA for evaluation before its availability for sale. The regulations for 'exempt infant formula' do not specify any unique labelling statements for these products, however the FDA has the authority under CFR 21 §107.50(d) to impose any specific labelling requirements it considers are necessary for the product to maintain its exempt status.

6.2.2 Previous consideration

FSANZ considered the labelling requirements for products for metabolic, immunological, renal, hepatic and malabsorptive conditions during its Proposal P93 assessment. The approach taken for labelling was consistent with the approach in the draft Codex Standard for infant formula proposed at that time (1999). The draft Codex Standard indicated that a product intended for infants with special nutritional requirements should be labelled to show clearly the special requirements for which the formula is to be used, and the dietary property or properties on which it is based. The draft Codex Standard also indicated that no health claims should be made regarding the dietary properties of the product.

The labelling requirements were developed during Proposal P93 to provide information to caregivers about the medical conditions for which the food has been specially formulated, its nutritional composition and that it should be used under medical supervision.

6.2.3 Previous stakeholder views

Submitters to the 2012 and 2016 Consultation papers raised a variety of issues relating to the labelling requirements for products for metabolic, immunological, renal, hepatic and malabsorptive conditions. Many industry and jurisdiction submitters referred to a lack of clarity regarding the application of certain specific statements (for example, interpretative issues relating to the identification of the condition, disease or disorder). Classification of certain products for metabolic, immunological, renal, hepatic and malabsorptive conditions was considered problematic, with some submitters questioning how these products are being marketed.

⁹ Sections 4.5.2, 4.5.3 and 4.5.6, Codex STAN 180-1991

There was industry support for some or all of the labelling requirements under Standard 2.9.5 to be applied to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (for example, strengthening the non-prescribed statement about how these products should be used under medical supervision to mandatory wording 'only use this product if instructed to do so by a medical professional').

In contrast, there were several industry submitters that opposed any changes to the existing labelling requirements. Several industry and jurisdiction submitters considered that FSMP labelling requirements (Standard 2.9.5) relating to use of the product should apply to IFPSDUs, with some of these submitters citing harmonisation with Codex and EU. The examples provided were a statement to the effect that the food is not for parenteral use; and a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food.

6.2.4 Discussion

FSANZ notes that some of the labelling issues raised by stakeholders relate to how products for metabolic, immunological, renal, hepatic and malabsorptive conditions are defined or categorised. Issues pertaining to product categorisation, definitions and name of the food are being discussed under sections 2.2 – 2.4 in this report.

FSANZ will therefore consider specific labelling issues for these products in a future report for P1028 once the outcomes of the discussion on definitions and name of the food are known. However, a general discussion on how FSMP labelling requirements may apply to any or all IFPSDU subcategories follows.

6.3 Application of FSMP labelling requirements

As noted in section 1.5, FSANZ understands that many IFPSDU are imported into Australia and New Zealand from the EU and the US. Areas of alignment between the labelling requirements in the Code and EU and US labelling regulations should be considered, to ensure imported IFPSDUs are compliant and their supply remains uninterrupted.

FSANZ notes there is overlap between the labelling requirements for products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 2.9.1—14) and the labelling requirements for FMSPs (subsection 2.9.5—10(1)). However, some of the existing FSMP labelling requirements may also be applied to other categories of IFPSDU, or may be relevant to all IFPSDU.

6.3.1 Current FSMP labelling requirements in the Code

Standard 2.9.5 was gazetted in June 2012 and took effect in February 2013. Subsection 2.9.5—10(1) requires FSMP to be labelled with the following advisory or warning statements:

- 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
- a statement to the effect that the food is not for parenteral use (and any addition require statements associated with this requirement).

Subsection 2.9.5—11(1) requires information relating to ingredients to be labelled as:

- a statement of ingredients, 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.

Section 2.9.5—12 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. Infant formula products, including those formulated for special dietary use were specifically excluded from the scope of Standard 2.9.5.

6.3.2 Discussion

Similar to IFPSDU, the majority of FSMP in Australia and New Zealand is imported. Hence the labelling requirements in Standard 2.9.5 for FSMP were developed to be consistent with international requirements where possible. This meant that FSANZ considered EU and US requirements, and Codex specifications.

Under section 6.2.3, FSANZ noted some stakeholder suggestions for certain FSMP labelling provisions to apply to products for metabolic, immunological, renal, hepatic and malabsorptive conditions.

FSANZ is seeking stakeholder views about how the current FSMP labelling requirements could apply to IFPSDUs, including the existing subcategories and those subcategories proposed under section 2.2.

Questions to submitters

Q27 Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?

Q28 Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

6.4 Products for specific dietary use based on a protein substitute

The Code does not contain any specific labelling provisions for products for specific dietary use based on a protein substitute (protein substitute products). In Standard 2.9.1, requirements in Division 5 Labelling and packaging requirements apply, in addition to general labelling requirements in Part 1.2 of the Code.

6.4.1 International and overseas regulation

Codex

As noted in section 2.2.1 above, Section B of the Codex infant formula standard does not specifically list product subcategories. However, Section 9.3 Declaration of Nutritive Value specifies that Formula for Special Medical Purposes Intended for Infants 'shall be labelled with complete nutrition labelling according to Section 4.2 of Standard for the Labelling of and Claims for Foods for Special Medical Purpose' (CODEX STAN 180-1991).

Subsection 4.2.8 of this Codex standard specifies that information on the nature of the animal or plant proteins or protein hydrolysates should be provided.

Subsection 4.2.9 specifies 'Foods for special medical purposes in which the essential characteristic involves a specific modification of the content or the nature of the proteins shall bear a description of this modification and information on the amino acid profile, when necessary'.

European Union

As discussed in section 2.2, FSANZ understands that formula based on protein hydrolysates as a source of protein are currently regulated as infant formula by Commission Directive 2006/141/EC and the incoming Regulation (EU) 2016/127. Neither document sets out specific labelling requirements in relation to protein substitutes.

However, it is possible that the highly specialised protein substitute products (for example, amino acid-based products) imported from the EU are captured under the current Commission Directive 1999/21/EC FMSP regulations and the incoming Regulation (EU) 2016/128. If this is the case they are potentially labelled to meet the EU FSMP labelling requirements. The EU labelling requirements for FSMP are described in section 6.3.1 above.

United States

Labelling requirements for exempt infant formula are outlined in section 2.2.1 above. Labelling of exempt infant formula is permitted to deviate from requirements for formula for general use to ensure the product is appropriately used. There are no specific labelling requirements for protein substitute products.

6.4.2 Previous consideration

There was little consideration of any specific labelling requirements for this category under Proposal P93; the development of a definition of 'protein substitute' the focus of the assessment at that time.

6.4.3 Previous stakeholder views

One issue raised by submitters to the 2012 and 2016 consultation papers was protein substitute products should be required to carry a statement that they are not suitable for use and should be used under medical supervision.

Some submitters made suggestions for new advisory or warning statements relating to the use of protein substitute products (for example, a warning statement that hypoallergenic formulas should not be used in existing allergies and intolerances).

6.4.4 Discussion

Currently in the Code the protein substitute product subcategory captures those products which are partially hydrolysed, extensively hydrolysed and amino acid based. An assessment of possible additional labelling requirements will need to account for how these products are defined and categorised in the Standard and the risk that these different products pose to infants.

FSANZ is aware that highly specialised protein substitute products imported from the EU, such as extensively hydrolysed and amino acid-based products, are carrying FMSP labelling in accordance with EU regulations. In contrast, partially hydrolysed protein substitute products appear to comply with Code labelling requirements. Consideration of labelling requirements for this subcategory will need to consider the international context, given that the most of these products are imported and it is desirable to ensure their uninterrupted supply.

FSANZ notes there is some stakeholder support for extending to protein substitute products the statement that the product is not suitable for general use and should be used under medical supervision. This may be appropriate for certain protein substitute products however FSANZ is unable to make a preliminary assessment at this time.

FSANZ is deferring its consideration of labelling for these products until the approach for product categories (section 2.2) and the issues relating to the definitions and name of the food (sections 2.3 and 2.4, respectively) are finalised.

6.5 Labelling information on safe preparation and use

Subsection 2.9.1—19(3) of Standard 2.9.1 outlines general labelling requirements for preparation and use instructions (including storage and disposal instructions) that apply to all infant formula products. These requirements comprise directions (in words and pictures) for:

- preparing each bottle individually
- storing a bottle of made up formula in the refrigerator prior to use and for it to be used within 24 hours
- using potable, previously boiled water
- using only the enclosed scoop, and
- discarding formula left in a bottle after a feed.

FSANZ is aware that certain IFPSDUs carry additional information to ensure safe preparation and use while other IFPSDUs (for example, ready-to-drink products) do not need to carry one or more of the directions mandated due to the nature of the product.

6.5.1 International and overseas regulation

Specifications in section 9.5 Information for Use of the Codex infant formula standard apply to infant formula for general use and formulas for special medical purposes intended for infants. The EU¹⁰ requires basic instructions for preparation and use of infant formula for special dietary use; these provisions are simpler than the provisions mandated for infant formula and follow-on formula. US requirements¹¹ prohibit exempt infant formulas from complying with general labelling requirements under subpart B – Labelling, because label information, including pictograms and symbols required under subpart B, could lead to inappropriate use of the product.

6.5.2 Previous consideration

During the development of Standard 2.9.1, under Proposal P93, FSANZ did not consider specific labelling requirements for preparation and use of IFPSDU. The generic labelling statements for all infant formula were considered appropriate for IFPSDU.

6.5.3 Previous stakeholder views

FSANZ received some submitter comments to the 2012 and 2016 consultation papers in relation to safe preparation and use instructions for IFPSDU. Some comments related to the application of generic preparation, use and storage instructions, while other comments were made about additional, more specific instructions currently used for certain IFPSDUs.

¹⁰ Article 5, Commission Directive 1999/21/EC on Dietary Foods for Special Medical Purposes and new Commission Delegated Regulation (EU) 2016/128

¹¹ Section 107.50 (d)(4)(iii), US Code of Federal Regulations, Title 21

One industry submitter supported the application of generic preparation and use labelling requirements to IFPSDU, but only if there was flexibility on the wording used for this labelling. They noted that the storage and disposal instructions for IFPSDUs need to be suited to the dietary management of infants with a specific medical condition. Also, many IFPSDU are imported from Europe, which has regulations that provide for multiple languages on packaging, and that in turn limits available space on the product label. Other industry submitters said they were opposed to any additional labelling statements.

Another industry submitter noted that generic labelling preparation and use labelling requirements may not be appropriate for certain IFPSDUs (for example, requirements under paragraph 2.9.1—19(3)(b) is not applicable if a 'ready to drink' formula is viewed as a 'made up' formula).

6.5.4 Discussion

The generic labelling requirements for preparation and use in the Code are intended to apply to all categories of infant formula products, including IFPSDUs. The wording of generic labelling requirements in subsection 2.9.1—(19)(3) is not prescribed, and therefore allows manufacturers to determine the wording that is appropriate for their product. This arrangement accommodates imported IFPSDUs that have to comply with other international regulations.

There are certain specialised IFPSDUs where it may be necessary to provide additional instructions to ensure the safe preparation and use of these products. These additional, more specific instructions are not prohibited by the Code when they are accompanied by mandatory labelling statements. However, FSANZ is interested in whether there are any additional specific labelling requirements for IFPSDU about their safe use and preparation that conflict with, or contradict the general requirements in Section 2.9.1—19(3).

Questions to submitters

Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

6.6 Exemption from 'breast is best' 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'.

6.6.1 International and overseas regulation

In the case of IFPSDU, Codex specifies a statement specifying that 'Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended' (Section 9.6.4 of STAN 72-1981).

The EU does not specify a particular statement on breastfeeding for IFPSDUs. As IFPSDU are proposed to reside in the separate European FSMP regulations, it is expected that the breastfeeding statement intended for infant formula for healthy infants (which refers to the superiority of breast milk and are accompanied by a statement on seeking advice from a health professional) would not apply to European IFPSDU.

The US does not require a statement about breastfeeding on the labels of infant formula products, including IFPSDUs.

6.6.2 Previous consideration

Under Proposal P93, FSANZ considered the statement was not relevant for infants with these conditions because breast milk is not appropriate for infants with medical conditions. The exemption also recognised that IFPMIRHM are used under the supervision of a health professional.

6.6.3 Previous stakeholder views

No specific comments were received about this labelling exemption for IFPSDU in response to the 2012 consultation paper. FSANZ did not seek comments about the exemption for IFPSDU in the 2016 consultation paper, because IFPSDU were out of scope.

6.6.4 Discussion

FSANZ's preliminary view is that it is appropriate for the exemption for IFPSDU to carry the mandatory 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' to remain.

6.7 Exemption from statement about offering foods in addition to infant formula products

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.

6.7.1 International and overseas regulation

Codex STAN 72-1981 Part B does not require any IFPSDU to display a statement about offering foods to infants from 6 months of age. However, it should be noted that Codex applies a number of FSMP labelling requirements to IFPSDUs as discussed in Section 6.3 above, which includes general requirements for feeding instructions and use of the product as a sole source of nutrition.

As European IFPSDUs are regulated under the European FSMP standard, these products are not subject to the general labelling requirements for other infant formula products (unless these requirements are explicitly required in the FSMP standard). As such, there is no requirement for any European IFPSDU to display a statement about offering foods to infants from 6 months of age.

The US does not require a statement on the labels of infant formula products (including IFPSDUs) recommending that infants from the age of 6 months should be offered foods in addition to the infant formula product.

6.7.2 Previous consideration

During Proposal P93, FSANZ introduced requirements specifically for pre-term infant formulas. At this time, it was noted that the nutritional needs of premature infants were significantly different from those of term infants, and that these nutritional requirements continued beyond six months of age.

Therefore, FSANZ considered that it was necessary to exempt pre-term formulas from the statement for offering additional foods to infants beyond six months of age, as this practice may not be in the best interests of a premature infant's health.

6.7.3 Previous stakeholder views

No specific comments were received about this labelling exemption for IFPSDU in response to the 2012 consultation paper.

6.7.4 Discussion

Although there have been developments in the nutritional management of premature infants since Proposal P93, FSANZ notes this group of infants continue to be recognised as having unique nutritional requirements. Pre-term infant formula products are required to display the statement they are to be used under specialist medical supervision, and this medical supervision will ensure that pre-term infants receive additional foods at a time that meets their nutritional and medical needs.

It is FSANZ's preliminary view is that the exemption in subsection 2.9.1—19(5) from the labelling statement in paragraph 2.9.1—19(4)(c) regarding offering other foods to infants from the age of 6 months should remain.

7 Distribution and access

Some IFPSDU are available in supermarkets and standard retail locations, others only through pharmacies and some are only available on prescription in different environments. Some IFPSDUs are provided through very limited pathways to consumers; healthcare professionals (dietitians, doctors), responsible institutions (hospitals, pharmacies) and through home delivery services (initiated by healthcare professional referral).

7.1 Current regulation

There are no particular restrictions on access or sale of IFPSDU in Standard 2.9.1, however many highly specialised products are only available within medical facilities or with prescription.

Exempt infant formula products in the US are grouped by those available at retail level or not as per the description below:

- *Infant formulas generally available at the retail level:* can generally be purchased from retail store shelves that are readily available to the public. Such formulas are also typically represented and labelled for use to provide dietary management for 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 disorders.
- *Infant formulas not generally available at the retail level:* not generally found on retail shelves for consumer purchase. Such formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and state or federal agencies. These formulas are also generally represented and labelled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time.

It is not clear to FSANZ how these products are distributed and accessed in the EU. It appears to be a similar mixture of standard retail locations, only though pharmacies and some are only available on prescription in different environments.

7.2 Previous stakeholder views

Stakeholder views from previous consultation are summarised below.

Summary of issues raised in submissions
Problems with current access
Some stakeholders have concerns that formulas prepared for special purposes may encourage greater use than warranted and sale should be restricted to minimise this use.
Recommend that products that have a valid, special dietary use under the definition for IFPSDU have accompanying medical management provisions and access controls.
There is concern that some of the products for transient type conditions which are available to caregivers in supermarkets and pharmacies present a risk as they 'medicalise' common, normal symptoms in infants and encourage self-diagnosis without the accompanying management and review by health professionals. There is also concern that the ease of access and use of products could also lead to the failure to diagnose and manage true conditions, which could extend the mismanagement beyond infancy to unnecessarily restrictive diets in younger years.
These readily available products could potentially lead to the unnecessary replacement of breastfeeding with formulas that are promoted to manage perceived diarrhoea, hunger or unsettled behaviour.
Current arrangements for the sale of these products in both countries (i.e. some level of restriction) was appropriate
Impact of restriction on sale
Note that there needs to be some caution applied with consideration of the potential impacts of a restriction on sale to the supply and access of these products, particularly as most of these products are imported into Australia and New Zealand.
This limited availability is voluntarily applied by the industry and no market failure exists in this regard. Some conditions of a lesser nature, such as lactose-intolerance, are more widely availability to meet consumer needs.
There are no specific sales channel restrictions in Codex
Other
Consumers would not choose between IFPSDUs. These are recommended by a healthcare professional and used under medical supervision. These products are highly specialised products and must be used after a medical diagnosis is confirmed and only in close, ongoing, conjunction with a team of healthcare professionals; including doctors and dietitians.

7.3 Discussion

As noted above, there are differences in where different types of IFPSDU products are available and how they are accessed, and there are some differences between Australia and New Zealand. Some of the factors which influence how these products are discussed below.

7.3.1 The role of the Pharmaceutical Schedule and PBS schedule

Many IFPSDU are listed on the pharmaceutical schedule in New Zealand and the pharmaceutical benefits scheme in Australia. The New Zealand Pharmaceutical Schedule is a list of the prescription medicines and therapeutic products subsidised by the Government. The Pharmaceutical Management Agency (PHARMAC) is the NZ government agency that decides which pharmaceuticals/special foods to publicly fund in New Zealand (PHARMAC, 2011).

It administers the Pharmaceutical Schedule, which is a list of the approximately 2000 prescription medicines and therapeutic products (including special foods) that are subsidised by the Government. The Schedule is published three times a year and updated monthly.

PHARMAC is also responsible for setting Special Authority restrictions on medicines/special purpose foods to target funded access to the medicine to patients who will benefit the most. For example, PHARMAC sets the Special Authority eligibility criteria for infants to receive subsidised product S-26 Gold Premgro. Doctors or other prescribers (e.g. dietitians can prescribe special foods such as IFPSDU) can apply for Special Authority approval on behalf of their patients. Special Authorities are processed and administered by the Ministry of Health.

The Australian Pharmaceutical Benefits Scheme is a similar system managed by the Department of Health and administered by Department of Human Services. The PBS schedule lists all of the medicines and special purpose foods available to be dispensed to patients at a government-subsidised price (Department of Health, 2017). The Schedule is part of the wider Pharmaceutical Benefits Scheme and aims to subsidise the cost of medicine for most medical conditions.

Most PBS listed medicines are dispensed by pharmacists, used by patients at home and some can only be accessed at specialised medical services, usually hospitals. There is some element of restriction on products that require prescription through the PBS as there are limits on the amounts of PBS-listed medicine and the number of repeat prescriptions (Department of Health, 2017). In addition, many medications on the PBS are subsidised for a specific patient group or indication and fall into three restriction categories:

- unrestricted benefits: no restrictions apply to the therapeutic use
- restricted benefits: can only be prescribed for specific therapeutic uses
- authority required benefits: to prescribe these, doctors need approval from Department of Human Services or the Department of Veterans' Affairs. A doctor must declare the specific conditions and circumstances that justify the use of these medicines.

Given the purpose of both the PHARMAC pharmaceutical schedule and the PBS schedule is to reduce the costs of medical products to consumers, the schedules do include some products that are available in the general retail environment (i.e. without prescription). Thus restrictions from both systems are not easily transferable to this context.

7.3.2 Standard 2.9.5 restrictions

Standard 2.9.5 – Food for Special Medical Purposes does include some restriction on access and sale of FSMP with limits to distribution through section 2.9.5—5, which restrict the persons by whom, and the premises at which FSMP may be sold:

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

- (a) a medical practitioner or dietitian; or
- (b) a medical practice, pharmacy or responsible institution; or
- (c) a majority seller of that food for special medical purposes.

The terms responsible institution and medical practitioner are defined in the standard as:

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

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

or licensing of medical practitioners.

FSMP is required when the dietary management of individuals cannot be easily or completely achieved with other dietary modification including the use of other special purpose foods. These products include formulated products intended for use as the sole source of nutrition, either consumed orally or through an enteral route (e.g. naso-gastric tube), as well as specialised supplementary formulated products. Given the minimal prescribed compositional requirements for these products, a restriction on the sale of FSMP was considered a necessary part of the overall risk management strategy for FSMPs. This approach reduces the potential risks associated with potential unsupervised and inappropriate use of FSMPs. It was also expected to discourage manufacturers or importers from positioning inappropriate products as FSMP in order to take advantage of the less restrictive compositional requirements. The intent of this restriction on sale was to balance the need for consumers to have access to health professional advice about the appropriate use of FSMPs, with the need to ensure the supply chain is maintained and that consumers, particularly those who rely on these products for long periods, can access FSMPs through an appropriate distributor.

7.3.3 Risk associated with IFPSDU

As noted above a restriction on sale and access was introduced in Standard 2.9.5, as there were risks associated with the lack of compositional requirements. The restriction on sale system also aligned with the existing distribution system. For current IFPSDU, the situation differs as the base composition is specified.

The highly specialised products which pose a risk to health and safety if consumed 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 Pharmaceutical schedule and PBS schedule.

The less specialised products which have been more widely available to caregivers through supermarkets and pharmacies for 20+ years do not have the same level of risk associated with their use. The composition is only permitted to be modified as appropriate for the condition, disease or disorder they are intended for. Most do carry labelling to differentiate the product from a general infant formula. Stakeholders have noted that the ease of access to some of the less specialised infant formula products may lead to caregivers selecting to use an IFPSDU product over breastfeeding, based on self-diagnosis. FSANZ is not aware of evidence of a problem with the current distribution channels for IFPSDU.

7.3.4 Labelling restrictions

As discussed in section six of this paper there are a number of labelling requirements already in place to differentiate IFPSDU from general infant formula. These requirements also contribute towards protecting the health and safety of infants through information to inform the appropriate choice of product. Additionally they promote the importance of access to medical or health professional advice on the use of these products. This approach is also used in Standard 2.9.5 for FSMP.

In the EU, the preamble of Commission Delegated Regulation (EU) 2016/128 notes that some products have been placed on the market as FSMP for infants, which are directly marketed to consumers and are more like infant formula. To deal with potential risks related to this, the new regulation is introducing some changes to labelling requirements. To date the requirements in place for infant formula (for healthy infants) have not applied to FSMP for infants. Thus the incoming regulation has subsequently introduced additional restrictions on the labelling, presentation, advertising, and promotional and commercial

practices of FSMP for infants. These changes aim to “*avoid possible abuses linked to the misclassification of products, reduce confusion for consumers on the nature of the different products being offered to them and guarantee conditions of fair competition*”.

7.3.5 Summary

The intent of the current Division for IFPSDU is that most products are recommended by a healthcare professional and used under medical supervision. For the highly specialised products which are provided through very limited pathways to consumers; healthcare professionals (dietitians, doctors), responsible institutions (hospitals, pharmacies) and through home delivery services (initiated by healthcare professional referral), there do not appear to be many concerns about access. These highly specialised products are only accessed after a medical diagnosis is confirmed and only in close, ongoing, conjunction with a team of healthcare professionals; including doctors and dietitians. These distribution channels are managed through the healthcare systems within Australia and New Zealand. FSANZ is seeking input from stakeholders on the evidence of problems with the current distribution and access channels.

Questions to submitters:

Q30 What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

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Attachment A – Questions to stakeholders

- Q1 Are there any other overseas regulations relevant to IFPSDU?
- Q2 What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFPSMP, should pre-term products be included?
- Q3 Do you support inclusion of a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?
- Q4 If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?
- Q5 Are there any issues with the current definition for protein substitutes?
- Q6 Is there a benefit to defining one or more of the following in the Code:
- Hypo-allergenic formula
 - Partially hydrolysed formula
 - Extensively hydrolysed formula
 - Amino acid-based infant formula?
- If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?
- Q7 Are there any issues with the current definition for pre-term products?
- Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?
- Q9 What is the general composition of human milk fortifiers for premature or low birthweight infants?and composition and uses for groups other than premature or low birthweight infants?
- Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?
- Q11 Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?
- Q12 Are any specific compositional requirements (energy/macronutrient etc) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?
- Q13 Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?
- Q14 Are any specific compositional requirements (energy/macronutrient etc) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?
- Q15 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?

- Q16 Are there any issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?
- Q17 Do you have any information to support the inclusion of a minimum and maximum amount of chromium in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?
- Q18 Do you have any information to support the inclusion of a minimum and maximum amount of molybdenum in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?
- Q19 Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).
- Q20 Do you support the proposed amendments listed in Table 7 for IFPSDU at the amounts shown?
- Q21 Can you provide information on suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and a technological justification for:
- a) Calcium carbonates
 - b) Calcium citrates
 - c) Phosphoric acid
 - d) Sodium alginate
 - e) Xanthan gum
 - f) Locust bean (carob bean) gum
 - g) Pectins
 - h) Sodium carboxymethylcellulose
 - i) Sucrose esters of fatty acids
 - j) Starch sodium octenylsuccinate
- Q22 Are there any technologically justified concerns with changing the permissions for citric and fatty acid esters of glycerol (472c) to:
- a) MPL of 9000 mg/L for liquid products
 - b) MPL of 7500 mg/L for powdered products?
- Q23 What is the technological justification for the use of diacyltartaric and fatty acid esters of glycerol (472e) in IFPSDU? Are there any technologically justified concerns with the removal of this permission?
- Q24 Do you support retaining a maximum PRSL for any IFPSDU? Please provide your rationale.
- Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?
- Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.
- Q27 Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?
- Q28 Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

- Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?
- Q30 What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

Appendix 1: Contaminants in infant formula – consideration of health based guidance values

1 Aflatoxins

Aflatoxins are produced primarily by two species of *Aspergillus*, *A. flavus* and *A. parasiticus*. *A. flavus* produces aflatoxins B1 and B2, while *A. parasiticus* produces aflatoxins B1, B2, G1 and G2. Aflatoxin M1 is a major metabolite of aflatoxin B1 in humans and animals and may be present in milk and milk products (EFSA 2007; JECFA 2016).

Hazard information

Aflatoxins are genotoxic and carcinogenic substances, based on studies in test animals and human epidemiological findings. The potency of aflatoxins in inducing liver cancer is substantially higher in individuals infected with the hepatitis B virus. As aflatoxins are genotoxic and carcinogenic it is not possible to establish a HBGV for these substances and exposure levels should be as low as reasonably practicable.

For risk assessment purposes, EFSA (2007) calculated margins of exposure based on lower confidence intervals of benchmark doses (BMDLs) derived from animal or epidemiology studies. EFSA also calculated cancer risks from increased aflatoxin exposure based on cancer potency estimates for aflatoxin B1 calculated by JECFA in 1998. It was assumed that the potency of total aflatoxins is equivalent to that of aflatoxin B1. The values used for risk assessment of aflatoxins by EFSA are shown below.

Reference point	Value
BMDL10 from rat carcinogenicity data (10% extra cancer risk)	170 ng/kg bw/day
BMDL10 from epidemiology data (10% extra cancer risk)	870 ng/kg bw/day
BMDL1 from epidemiology data (1% extra cancer risk)	78 ng/kg bw/day
Cancer potency estimate for hepatitis B virus antigen positive individuals	0.3 cancers/year per 100,000 population per ng aflatoxin B1/kg bw/day
Cancer potency estimate for hepatitis B virus antigen positive individuals	0.01 cancers/year per 100,000 population per ng aflatoxin B1/kg bw/day

JECFA (2016) has recently calculated new cancer potency estimates, but these have not yet been published.

Dietary exposure

Aflatoxin M1 was measured in dairy products, including infant formula and milk based infant dessert as a part of the 23rd ATDS. Aflatoxins B1, B2, G1 and G2 were also analysed in a range of other foods. None of the measured aflatoxins were found at detectable levels in the foods tested. Infant formula was not included in the most recent New Zealand survey of aflatoxins in food (MPI 2011).

The WHO GEMS database only includes reports of aflatoxin B1 analysis for 15 samples of infant formula powder and 3 samples of liquid infant formula. No aflatoxin B1 was detected in these samples. For aflatoxin M1 there are 280 samples of infant formula powder and 44 of liquid formula.

Mean concentrations were 0.2824 and 0.0003 µg/kg, respectively. The value for powder would give an aflatoxin M1 level of 0.035 µg/L for reconstituted formula, which is slightly above the EU limit of 0.025 µg/kg.

A number of studies have reported aflatoxin levels in infant food and formula. In an analysis of 60 fresh milk, baby yogurt, milk powder and milk based infant formula samples purchased in the USA, aflatoxins B1 and B2 were not found in any infant formula samples, while aflatoxin M1 was found in one infant formula sample, at 0.19 µg/kg (Zhang et al 2013). The number of infant formula samples tested was not reported.

Conclusion

There is limited information on the levels of aflatoxins in infant formula in Australia and New Zealand, or in the WHO GEMS database or published international studies. However in the 23rd ATDS, aflatoxin M1 was not detected in infant formula samples, and levels of aflatoxins in general foods were low and did not pose a significant health concern to Australian consumers.

As aflatoxins are genotoxic and carcinogenic, human exposure should be minimised to the level that is reasonably practicable.

2 Ochratoxin A

Ochratoxin A is a mycotoxin produced by fungi of the *Aspergillus* and *Penicillium* species. These fungi may grow on stored material under favourable conditions and produce ochratoxin A, which has been found in a wide range of raw commodities and food products including cereals, dried fruit, coffee, wine, beer and grape juice (EFSA 2006).

Hazard information

JECFA most recently evaluated ochratoxin A in 2007, at which it reconfirmed its previously established provisional tolerable daily intake value (PTWI). The PTWI is based on minimal deterioration in renal function in the pig, observed at a lowest observed effect level (LOEL) of 8 µg/kg bw/day. A safety factor of 500 was applied to the LOEL to derive a PTWI of 112 ng/kg bw/week, rounded to 100 ng/kg bw/week.

Dietary exposure

A wide range of foods were analysed for ochratoxin A in the 20th and 23rd ATDS. The ochratoxin A content of infant formula was not assessed, although infant cereals were tested for this mycotoxin. Ochratoxin A was not detected in any of the foods analysed in either survey. Infant formula was not included in the most recent New Zealand survey of ochratoxin A in food (MPI 2014).

A mean concentration of 0.046 µg/kg was reported for 16 infant formula powder samples in the WHO GEMS database. A survey by the Canadian Food Inspection Agency of 75 samples of milk and soy-based infant formula found that only one sample of soy infant formula had detectable levels of ochratoxin A, at 0.4 µg/kg (CFIA 2014).

In a recent survey of 98 commercially available infant formula (soy and milk based) products purchased in the USA, ochratoxin A was not detected in any of the samples analysed (Cappozzo et al 2017). This paper further noted that the majority of available studies on ochratoxin A in infant formulas have found levels to be below the EU limit (0.5 µg/kg) for ochratoxin A in dietary foods for special medical purposes intended specifically for infants.

An exception was a study on Italian infant formulas which found that 133 of 185 (72%) samples were contaminated with ochratoxin A at levels ranging from below the EU limit to slightly above it (0.035 – 0.69) µg/kg (Meucci et al 2010).

Conclusion

Information on the ochratoxin A content of infant formulas sold in Australia or New Zealand are not available, however in the 23rd ATDS ochratoxin A was not detected in any of the foods for which it was analysed. In addition, available information in WHO GEMS database and overseas assessments have generally found only low levels of ochratoxin A contamination of infant formula. On that basis it is considered unlikely that levels of ochratoxin A in infant formula in Australia are of health concern.

3 Polycyclic aromatic hydrocarbons

PAHs constitute a large class of organic compounds containing two or more fused aromatic rings. A large number of different PAHs may be formed during incomplete combustion or pyrolysis of organic matter, industrial processes and cooking and food processing (JECFA 2006).

Hazard information

In 2005, JECFA reviewed toxicity data on various PAH for the purpose of establishing a health standard for use as a comparator in dietary risk assessments. As 13 of the 33 PAHs assessed were considered to be genotoxic and carcinogenic, a standard threshold approach could not be employed. A margin of exposure approach was taken, using benzo[a]pyrene (BaP) as a marker of exposure to, and effects of, genotoxic and carcinogenic PAHs in food. Based on data from oral carcinogenicity studies in mice with coal tar mixtures a BMDL10 (i.e. for a 10% incidence of tumours) of 100 µg/kg bw/day was established.

Dietary exposure

In a FSANZ commissioned analytical survey of PAHs in Australian foods, PAHs were not detected in a composite sample containing three individual primary samples of infant formula (FSANZ 2004). No information relating to levels of PAHs in infant formula available in New Zealand appears to be available.

No data on the occurrence of PAHs in infant formula are available in the WHO GEMS database. Information in the scientific literature is also relatively limited, although a recent study of infant formula available in Italy found BaP at levels higher than the EU maximum permitted limit of 1 µg/kg (Santonicola et al 2017). In this study levels of PAHs were higher in breast milk than in infant formula samples.

The UK FSA conducted a survey of PAHs in 111 samples of commercial baby foods and 97 samples of infant formula obtained from the UK. No products contained BaP at levels higher than the EU maximum permitted limit, and most were substantially lower (UK FSA 2006).

Conclusion

Exposure to the genotoxic and carcinogenic PAHs should be as low as is reasonably practicable.

A FSANZ commissioned analytical survey on PAHs in Australian foods, including infant formula, did not identify any health concerns for Australian consumers. This is consistent with the findings of a larger UK FSA survey in which levels of PAHs were below the EU maximum permitted limit.

4 Cadmium

Cadmium is a metallic element that occurs naturally at low concentrations in the environment, but at high concentrations in volcanic soils (WHO, 1992). Additional cadmium has entered the environment through industrial processes such as cadmium metal production. Cadmium has also been added to agricultural soils through the use of phosphate fertilisers, and certain organic fertilisers based on sewage sludge (WHO, 1992). Food represents the major source of cadmium exposure, although tobacco smoking adds significantly to the body burden (WHO, 1992).

Hazard information

In 2010 JECFA evaluated a meta-analysis of epidemiological studies measuring the dose–response relationship between urinary beta-2-microglobulin (β 2MG), a biomarker of renal tubule damage, and urinary cadmium excretion. JECFA identified a threshold urinary cadmium concentration below which a steep increase in β 2MG excretion was not observed. Toxicokinetic modelling was used to calculate the dietary cadmium exposure corresponding to the threshold urinary level and a dietary exposure level of 0.8 μ g/kg bw per day was identified. Due to the very long half-life of cadmium (~15 years), the HBGV was expressed as a provisional tolerable monthly intake (PTMI) of 25 μ g/kg bw per month.

Dietary exposure

Levels of cadmium in infant formula were analysed in the 19th, 20th and 23rd and most recently as a part of the ongoing 25th ATDS (FSANZ 2001, 2003, 2011). In general, cadmium levels in infant formula were below the limit of detection (0.5 μ g/kg in the 23rd ATDS). The only detection was in one of four samples in the 23rd ATDS at a concentration of 0.6 μ g/kg¹². In the 2009 New Zealand Total Diet Study (NZTDS) cadmium levels were below the limit of detection (0.2 μ g/kg) in 5 of 8 samples tested. The highest level found in infant formula sold in New Zealand was 0.4 μ g/kg (MPI 2011).

Dietary exposure calculated using the highest cadmium level found (0.6 μ g/kg) and an upper estimate of daily infant formula consumption [200 mL per kg bw; IOM 1991] is 0.12 μ g/kg bw/day, or 3.65 μ g/kg bw/month, which is 15% of the PTMI.

Additional data on cadmium concentrations in infant formula powder and liquid internationally are available in the WHO Global Environment Monitoring System (GEMS) database. The mean concentration of cadmium in infant formula powder was 1.316 μ g/kg based 362 samples, which would equate to a cadmium level of 0.16 μ g/kg in reconstituted formula (based on an assumption of 125 g powder/L water). The mean concentration of cadmium in 108 samples of liquid infant formula was 0.0004 μ g/kg. A survey of infant formula in Canada reported average cadmium levels of 0.23 μ g/kg in ready-to-use milk based formula and 1.18 μ g/kg in soya-based formulae (Dabeka et al 2011). Dietary exposure calculated using the highest cadmium level found in any of the samples tested in this survey (2.95 μ g/kg) and an upper estimate of daily infant formula consumption (200 mL per kg bw) is 0.59 μ g/kg bw/day, or 17.9 μ g/kg bw/month, which is 72% of the PTMI.

12 In the ATDS foods are prepared to a 'table ready' state before analysis, i.e. water would have been added to the infant formula powder before analysis was conducted.

Conclusion

The available evidence from Australian and New Zealand total dietary studies suggests that levels of cadmium in infant formula are low and generally consistent with those reported internationally. Dietary exposures to cadmium in infant formula are not considered likely to be of health concern.

5 Melamine

Melamine is discussed in the Supporting Document 2 Safety & Food Technology – Proposal P1028 Infant formula. As noted in this report, the USFDA derived a TDI of 0.63 mg/kg bw/day in 2007 and subsequently set a TDI of 0.063 mg/kg bw applicable to infants (USFDA 2008). A later expert meeting convened by WHO resulted in the establishment of a higher TDI of 0.2 mg/kg bw which was applicable to the whole population, including infants (WHO 2009). EFSA also set a TDI of 0.2 mg/kg bw/day for melamine in 2010. No new information has been identified that would warrant updating the risk profile.

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