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

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Supporting document 1

Safety and food technology

Proposal P1028 – Infant formula

Executive summary

Food Standards Australia New Zealand (FSANZ) is reviewing regulatory requirements for infant formula products and Special Medical Purpose Products for infants (SMPPi) under Proposal P1028 – Infant formula.

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

The protection of public health and safety is a primary objective for FSANZ in developing or reviewing food standards. Infant formula must be safe for formula-fed infants to consume, and caregivers need to know how to safely prepare, use and store the product.

This Supporting Document (SD) considers permissions for food additives, processing aids, contaminants, L(+) lactic acid producing microorganisms, and labelling requirements for safe preparation and use for infant formula products and SMPPi.

Based on its assessment to date, including consideration of stakeholder views expressed in response to FSANZ's 2021 Consultation Paper 1 – Safety and Food Technology (FSANZ 2021 CP1), as well as previous consultations, FSANZ is proposing a number of regulatory/risk management approaches within this paper. Proposed approaches are made with consideration to the objectives of the proposal, the requirements of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act) and relevant risk management principles.

Food additives

FSANZ has proposed only two food categories in the Code for food additive permissions, being 13.1.1 *Infant formula products* and 13.1.2 *Special Medical Purpose Products for infants*.

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

additive permissions to ensure consistency with European regulations. FSANZ has further sought to ensure consistency of food additive permissions with Codex and European regulations.

FSANZ has developed three principles to guide consideration of the risk management approach for food additives. These principles do not replace the requirements of the FSANZ Act and the assessment criteria prescribed by that Act, but, together with the latter, are intended to guide risk management considerations of food additives in infant formula products. The principles are: (1) the protection of infant health and safety; (2) the number of food additives used in infant formula products should be the least number necessary to achieve the required technological functions; and (3) consideration of harmonisation with international standards. The third principle is of particular relevance to SMPPi, noting that these products are generally not produced in Australia and New Zealand, but mainly imported from Europe. Consistency with European regulations is therefore very important. Following continued assessment using these principles and consideration of submission comments to the FSANZ 2021 CP1, FSANZ proposes the following permissions for food additives, for the different food categories, Maximum Permitted Level (MPL) and any additional conditions, summarised in the table below.

Table 1 Proposed MPL for infant formula products and SMPPi

Food additive	FSANZ proposed MPL (mg/L)	
	Infant Formula Products	SMPPi
Calcium carbonates (INS 170)	NP	GMP (aligns with EU) (13.1.5.1)
Calcium citrates (INS 333)	NP	GMP (aligns with EU) (13.1.5.1)
	Permit as carrier in nutrient preparations, consistent with EU MPL and with condition statement.	
Calcium hydroxide (INS 526)	2000 (aligns with Codex and EU), limits for sodium, potassium and calcium.	
Sodium carbonates (INS 500)	2000 (aligns with Codex) limits for sodium, potassium and calcium.	
Sodium hydroxide (INS 524)	2000 (aligns with Codex), limits for sodium, potassium and calcium. Consequential addition also needed to Schedule 8.	
Potassium carbonates (INS 501)	2000 (align Codex) limits for potassium.	
Potassium hydroxide (INS 525)	2000 (aligns with Codex), limits for potassium. Consequential addition also needed to Schedule 8.	
Phosphoric acid (INS 338)	450 (as phosphorus), (aligns with EU). Additional condition statements on ions.	450 (as phosphorus), (aligns with EU). Only for pH adjustment.
Calcium phosphates (INS 341)	Consistent with EU: Specific permission for tricalcium phosphate (INS 341(iii)) in nutrient preparations added to products (MPL in nutrient preparation 70 mg/L as phosphate).	
Sodium phosphates (INS 339) Potassium phosphates (INS 340)	450 (as phosphorus), (aligns with Codex). Additional condition statements relating to calcium/phosphorous ratio.	
Citric and fatty acid esters of glycerol (CITREM) (INS 472c)	9000 for liquid products, and 7500 for powdered products, (aligns with Codex and EU).	
Starch sodium octenylsuccinate (INS 1450)	NP	20,000 for extensively hydrolysed protein formulas (aligns with Codex and EU), with condition statement.
Locust bean (carob bean) gum (INS 410)	1000, maintain current permission, align Codex.	5000 for gastro-oesophageal formulas (aligns with EU), with condition statement.

Pectins (INS 440)	NP	2000 for extensively hydrolysed protein liquid formulas (aligns with Codex), with condition statement.
		5000 mg/L for gastro-intestinal disorder formulas, (aligns with EU) with condition statement.
Xanthan gum (INS 415)	NP	1000 for extensively hydrolysed protein formulas (aligns with Codex), with condition statement
		1200 for gastrointestinal, protein mal-adsorption, or inborn errors of metabolism formulas (align with EU), with condition statement.
Guar gum (INS 412)	1000 (aligns with the Code, Codex and EU), with condition statement	10,000 for extensively hydrolysed protein formulas (aligns with EU), with condition statement.
Sodium alginate (INS 401)	NP	1000 for metabolic disorders and for general tube-feeding (aligns EU) with condition statement.
Sodium carboxymethylcellulose (INS 466)	Not proposing to permit use of sodium carboxymethylcellulose in any infant formula product. Seeking any information from stakeholders on current use and levels to inform a final decision	
Sucrose esters of fatty acids (INS 473)	NP	120 for extensively hydrolysed protein formulas (aligns with EU) with condition statement.
Diacyltartaric and fatty acid esters of glycerol (INS 472e)	Remove the permission in the Code (aligns Codex and EU).	

NP= Not Permitted
NP= Not Permitted

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

Processing aids

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

Contaminants

Sixteen submissions were received to the FSANZ 2021 CP1 relating to issues of chemical contaminants. FSANZ considered the responses from each submission related to the various contaminants in coming up with its preferred approach. The summary of FSANZ preferred approach to maximum levels (MLs) for the thirteen chemicals or chemical group contaminants is provided in the Table below. No changes are proposed to the current MLs for three contaminants, no MLs are proposed for eight contaminants, and changes for two contaminants consistent with the FSANZ 2021 CP1 options are proposed (for aluminium and lead). A summary of FSANZ preferred approach for contaminants are provided in the table below.

Table 2 Proposed ML for infant formula products and SMPPi

Contaminant	FSANZ preferred approach
Acrylonitrile	No change to the ML of 0.02 mg/L for all foods including infant formula products.
Aluminium	Move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19. Retain single ML of 0.05 mg/100mL for aluminium for IFP including soy-based.
Arsenic	No ML for infant formula products. Monitor and review (for rice that may be used as an ingredient in infant formula).)
Cadmium	No ML to be established.
Lead	Lower ML from 0.02 mg/L to 0.01 mg/L in IFP and apply to infant formula on a ready-to-feed basis.
Melamine	No ML to be established.
Tin & inorganic tin	No change to the ML of 250 mg/L.
Vinyl chloride	No change to the ML of 0.01 mg/L.
Aflatoxins B1 and M1	No ML to be established.
Ochratoxin A	No ML to be established.
Polycyclic aromatic hydrocarbons (PAH)	No ML to be established.
Perchlorate	No ML to be established.
Chloropropanol, glycidol and their esters	No MLs to be established.

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

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

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

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

L(+) lactic acid producing microorganisms

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

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

Labelling

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

Based on submitter comments, consumer evidence and Australian and New Zealand infant feeding guidelines, FSANZ is not proposing changes to most safety-related labelling requirements. These include directions to: prepare bottles individually; instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours; and instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.

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

For the remaining safety-related labelling requirements, FSANZ’s preferred options were also informed (in some cases) by findings of additional microbiological safety assessment. The proposed changes include: a revised direction for water used to reconstitute powdered infant formula (PIF) to include the word ‘cooled’ and for the discard unfinished formula direction to include the text ‘within 2 hours’; for ready-to-drink formula, to not apply directions that each bottle be prepared individually, that made up formula is refrigerated and used within 24 hours prior to use, to use potable, previously boiled water; for concentrated and ready-to-drink formula, to not apply the direction to only use the enclosed scoop.

Other changes being proposed include replacing the existing warning statement to ‘follow instructions exactly’ with: a shorter, prescribed warning statement applicable to all product types; and new directions that instruct not to change proportions of [powder/concentrate], dilute or add other food. FSANZ is also proposing to clarify the source of protein statement to ensure the origin of the protein is declared and that this statement needs to appear in a prominent position just once on the label.

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Abbreviations and Glossary

2012 Consultation paper	Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code: Consultation paper, 26 September 2012
ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
ANZ	Australia and New Zealand
ANZFA	Australia New Zealand Food Authority; the former name for FSANZ
Breast milk	A general term for the human milk provided from the mother's breast and is described as mature milk (to distinguish it from colostrum).
CAC	Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
Codex	Refers to Codex Alimentarius, international food standards setting body
Codex Draft Standard for FuFOI	Refers to the Proposed Draft Revised Standard for Follow-up Formula, Section A: Follow-up Formula for Older Infants (see 22REP/NFSDU Appendix III)
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
EC	European Commission
EU	European
FAO	Food and Agriculture Organization of the United Nations
FSANZ	Food Standards Australia New Zealand
GL	Guideline Level (used in Codex)
GMP	Good Manufacturing Practice
GSFA	Refers to the Codex General Standards for Food Additives
HBGV	Health-based Guidance Value
Infant	A person under the age of 12 months; as defined in Standard 1.1.1 of the Code
Infant formula product (IFP)	A product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants; as defined in Standard 1.1.1 of the Code
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 1.1.1 of the Code
Infant formula products for special dietary use (IFPSDU)	An infant formula product that includes those products listed in Division 4 of Standard 2.9.1. Note that the regulatory framework proposed in the CFS removes this category. Standard 2.9.1 is proposed to cover two categories: Infant formula products and Special medical purpose products for infants

	(SMPPi). The term IFPSDU is used in this paper only in reference to previous consultations and stakeholder comments.
Follow on-formula	An infant formula product that represented as either a breast-milk substitute or replacement for infant formula; and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months; as defined in Standard 1.1.1 of the Code
FSANZ 2021 CP1	FSANZ's 2021 Consultation Paper 1 – Safety and Food Technology
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kJ	Kilojoule
L	Litre
LOAEL	Lowest Observed Adverse Effect Level
ML	Maximum Level
MPL	Maximum Permitted Level
µg	Microgram
mg	Milligram
MoH	Ministry of Health (New Zealand)
MPI	Ministry of Primary Industries (New Zealand)
NHMRC	National Health and Medical Research Council (Australia)
NRV	Nutrient Reference Value established by the NHMRC and NZ MoH (2006)
NZFS	New Zealand Food Safety
Policy Guideline	The Policy Guideline on the *Regulation of Infant Formula Products* notified to FSANZ by the Australia and New Zealand Food Regulation Ministerial Council
PTWI	Provisional Tolerance Weekly Intake
RACP	Royal Australasian College of Physicians
Requirement	Refers to nutritional requirements; the nutrient amount that denotes a concentration or intake level (as established by the NHMRC/MoH, EFSA, IOM, or other expert body) that will support normal growth and development
SD	Supporting Document
Soy-based formula	An infant formula product in which soy protein isolate is the sole source of protein; as defined in Standard 2.9.1
SME	Small to medium enterprise
TDS	Total Diet Survey/Study
The Code	the *Australia New Zealand Food Standards Code*; which ceases to have effect on 1 March 2016
The revised Code	The *Australia New Zealand Food Standards Code;* which takes effect on 1 March 2016. A list of standards and relevant schedules is available at:

	http://www.foodstandards.gov.au/code/Pages/Revised-code-list-of-standards-and-schedules.aspx
US	United States of America
US FDA	US Food and Drug Administration
WHO	World Health Organization
WHO Code	WHO International Code of Marketing of Breast-milk Substitutes [1981]
WHO Guidelines	WHO Safe preparation, storage and handling of powdered infant formula: guidelines (2007)
wt	weight

1 Introduction

All infant formula must be safe for formula-fed infants to consume, and caregivers need to know how to safely prepare, use and store the product. This supporting document covers the assessment of requirements that relate to the safety and food technology for infant formula products.

The specific issues in this paper cover food additives, contaminants, use of lactic acid producing microorganisms, and labelling for the safe preparation and use of IFP. The assessment of these issues included:

- a FSANZ review of existing infant formula requirements in the Code
- risk assessment and reviews of current science
- stakeholder consultation (including, where relevant, submissions to the 2012 Consultation paper on the *Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code* which preceded the raising of Proposal P1028)
- other FSANZ projects
- regulatory and policy activities at a national and international level.

The assessment aimed to determine whether amendments to the Code were needed to apply, or revise current, risk management measures, align requirements with international regulations, and/or improve regulatory clarity. Within each section, FSANZ has provided a proposed option for potential amendments to the Code and the rationale for the option. These options are presented according to section 72 of the FSANZ Act. We are seeking comments from stakeholders on these options to inform FSANZ's decisions on whether to amend the Code and, if so, how.

As presented in the Call for Submissions document, FSANZ's proposed revised regulatory framework will set in place a category of infant formula intended for infants with serious illness or conditions. The category is defined as Special Medical Purpose Products for infants (SMPPi). Products under this category are intended to be restricted from sale to healthy infants (i.e. through pharmacies) and for use under medical supervision (see section 2 in the CFS). Discussion of food additive permissions in this supporting document is presented using this terminology[1]. All labelling issues related to SMPPi is considered separately in Supporting Document 4.

Further background on the regulatory approach to developing or varying food standards, international and overseas regulations, and application of Ministerial policy guidelines was covered in the FSANZ's 2021 Consultation Paper 1 – Safety and Food Technology (FSANZ 2021 CP1) (FSANZ 2021a).

2 Previous consultations

Previous consideration and preliminary views on the topics covered in this supporting document are listed below. This is also summarised in section 1.4 of the CFS paper.

- Consultation paper on infant formula products excluding follow on formula and special infant formulas (FSANZ 2016 CP)
- Consultation paper on Infant formula products for special dietary use (FSANZ 2017 CP)

[1] Standard 2.9.1 currently categorises these products under the heading Infant Formula for Special Dietary Use (IFPSDU). FSANZ's previous consultations for P1028 on IFPSDU products applied other terminology which, for clarity purposes, has not been used in this supporting document.

- Consultation paper covering safety and food technology, addressing submitter comments from the 2016 and 2017 papers (FSANZ 2021 CP1)

This supporting document addresses submitter comments from the FSANZ 2021 CP1 (FSANZ 2021a). There was significant interest from stakeholders on the safety and food technology issues for infant formula products.

Overall, a total of 20 submissions were received to FSANZ 2021 CP1 representing all stakeholder groups: industry and peak bodies (ten submissions), government (six submissions), health professional organisations (three submissions), and public groups (one submission). Of these, 18 commented on issues related to food additives; 16 commented on issues related to chemical contaminants; and 17 commented on labelling issues.

3 Food additives

3.1 Introduction

Food additives have a range of functional properties, some of which are very important for ensuring the safety and quality of infant formula products. A food additive may only be added to infant formula products if permitted in the Code and it complies with a relevant specification. In particular, Standard 1.3.1 – Food additives and Schedule 15 – Substances that may be used as food additives of the Code specifies which food additives are permitted, including maximum permitted levels (MPLs) for use in different food products. For a food additive to be permitted, FSANZ must ensure that it is safe at the permitted level in that particular food and is technologically justified. FSANZ has a general principle that the number of food additives used in infant formula products should be restricted to the minimum necessary to achieve the required technological functions (ANZFA 1999a).

Proposal P1028 is reviewing existing permissions to improve harmonisation with Codex food standards and European regulations to facilitate the importation of infant formula products, especially special infant formulas[2], which generally are not manufactured in Australia and New Zealand. The relevant Codex standards include the infant formula standard (CXS 72-1981) and the General Standard for Food Additives (GSFA) (Codex 1995). The EU regulations of relevance include Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008, which provides a Union list of permitted food additive permissions for different food categories in Annex II, and Commission Regulation (EU) 231/2012, which contains the specifications for food additives listed in Annexes II and III to Regulation (EC) 1333/2008.

For further information regarding Codex standards and EU regulations covering food additive permissions in infant formula products, please refer to the FSANZ 2021 CP1, as several permissions have since been updated (FSANZ 2021a).

This section will address the same following issues relating to reviewing food additive permissions, as covered in FSANZ 2021 CP1:

1. Food class system for food additive permissions
2. Carry-over principle for food additives in infant formula products
3. Harmonisation of food additive permissions
4. Clarifications to the Code.

For most issues, a summary of previous considerations, submitter comments to FSANZ 2021 CP1, a discussion (where relevant), and FSANZ's preferred option for reviewing the Code is

[2] Which fall under the IFPSDU category in the current Standard 2.9.1

presented. For further details regarding previous FSANZ considerations, including the outcomes of FSANZ's risk assessments, please refer to FSANZ 2021 CP1.

3.1.1 Approach to follow-on formula

Following our consideration of submissions to FSANZ 2021 CP1, FSANZ made the decision to include follow-on formula with the scope of P1028 (see section 1.2 of the CFS). Because of the overlap in age ranges for infant formula products (for infants 0-<12 months) and follow-on formula (for infants 6-<12 months), previous considerations on options for food additive permissions are likely to be unaffected by this decision. Under current requirements for follow-on formula in the Code (reviewed in FSANZ 2021a), there is no differentiation between infant formula and follow-on formula for food additives (as they fall under one category in S15),

The Codex Proposed Draft Revised Standard for Follow-up Formula for Older Infants (6 - 12 months) (Codex Draft Standard for FuFOI) revised the age range for these products from 6 - 36 months to 6 - 12 months.[3] The EU regulation for follow-on formula is consistent with this age range. Thus both are better aligned with the Code requirements for follow-on formula which is captured under the food class 13.1 – Infant formula products, with an age limit of 12 months.

FSANZ reiterates that the scope of proposal P1028 does not include products for young children, so-called toddler milks, which are regulated under Standard 2.9.3 - Formulated meal replacements and formulated supplementary foods.

3.1.2 Risk management principles for consideration of food additives

FSANZ has developed three principles to guide consideration of the risk management approach for food additives. These principles do not replace the requirements of the FSANZ Act and the assessment criteria prescribed by that Act, but, together with the latter, are intended to guide risk management considerations of food additives in infant formula products. The risk management principles are: (1) the protection of infant health and safety; (2) the number of food additives used in infant formula products should be the least number necessary to achieve the required technological functions; and (3) consideration of harmonisation with international standards. The latter principle aligns with the FSANZ Act requirements where, in developing or reviewing food standards, FSANZ must have regard to the promotion of consistency between domestic and international food standards.

The third principle is of particular relevance to special infant formulas, noting that these products are generally not produced in Australia and New Zealand. Rather, almost all are imported – mainly from the EU. Overall, adoption of the three principles helps to ensure the continued supply of specialised products as they are essential for the small sub-population of infants who have specific physical or physiological conditions, diseases or disorders.

3.2 Food class system for food additive permissions

3.2.1 Current regulation

Food additive permissions in the Code are organised into a hierarchical food class system where each broad food class is assigned a number, and different types of foods that fall under that broad food class are assigned a 'sub-number'. Food additive permissions for infant formula are listed in the table to section 5 of Schedule 15 of the Code under the broad

[3] The Codex Draft Standard for FuFOI is now held at Step 7, which indicates that it is at the final step prior to being submitted to the Codex Alimentarius Commission for adoption.

food class number 13 – Special purpose foods and, under that, 13.1 – Infant formula products. There are a further three subclasses (13.1.1 – 13.1.3) covering soy-based, liquid, and special infant formula products (see Figure 2.1 in the FSANZ 2021 CP1). Food additive permissions that sit under class 13.1 can be used in any products that sit in the subclasses 13.1.1 – 13.1.3. However, food additive permissions listed under a specific subclass (e.g. 13.1.1) are restricted to that particular subclass.

As mentioned above, follow-on formula is captured under the food class 13.1. As such, food additive permissions listed under food class 13.1 apply to both infant formula and follow-on formula. No separate/additional food additive permissions exist solely for follow-on formula.

3.2.2 Previous consideration

The outcomes of previous consultations had identified a lack of clarity with the current class system, the potential for subclasses not being mutually exclusive, and that not all special infant formulas were captured under the IFPSDU subclasses.

3.2.3 Stakeholder views

FSANZ 2021 CP1 proposed three options for the number of classes of food additives to help address the issues identified by stakeholders as follows:

- Option 1: Retaining the status quo, no change
- Option 2: Creating additional subclasses and/or modifying the current subclasses
- Option 3: Simplifying the approach by reducing the number of subclasses, with condition notes in Schedule 15 to qualify or differentiate permissions.

Eight submitters (five industry, three government) provided comments on this issue, with all supporting Option 3 (simplified class structure) shown in Figure 3.1. It was noted that this option is similar to approaches taken in Codex and the EU and consistent with the three principles of the risk framework being used by FSANZ for P1028. Under this option, the careful drafting of qualification notes and conditions will be important to provide clarity and regulatory certainty, and to meet the second principle of the risk framework (i.e. to limit the number of additives used).

3.2.4 Discussion

In providing their support for Option 3, the following additional comments were made by submitters:

- The subclass name ‘Infant formula products’ should be renamed ‘Infant formula and follow-on formula’.
- The subclass name ‘Infant formula products for special dietary use (IFPSDU)’ should be renamed ‘Infant formula products for special medical purposes (IFPSMP)’ to be consistent with the EU and Codex and to better reflect that these products have been designed for special dietary purposes under medical supervision.

FSANZ is of the view that the existing food class name ‘Infant formula products’ (proposed food class 13.1.1) should not be renamed ‘Infant formula and follow-on formula’, rather, it should remain unchanged, noting that FSANZ is unaware of evidence indicating that the current name is causing confusion for industry or those responsible for enforcing the Code.

As explained in the CFS, the proposed regulatory framework sets a subclass of special infant formula called Special Medical Purpose Products for infants (SMPPi). This is a defined category under the revised regulatory framework (see section 2 of the CFS) (Figure 3.1).

There are some variations on the conditions/qualifications for special infant formulas containing hydrolysed proteins, peptides or amino acid e.g. 'For use in…', 'from birth onwards…'. The suggestion is that these are inconsistent. FSANZ assumes from this comment that the submitter is referring to the proposed conditions for use of food additives as outlined in Table 2.17 in the FSANZ 2021 CP1. FSANZ will ensure that in drafting variations to the Code, the prescribed conditions are consistent with the proposed regulatory framework that categorises high risk infant formula products as SMPPi, will accurately reflect the outcomes of its risk assessment, and take into account permissions in place in Codex and the EU.

3.2.5 Preferred option

Based on previous considerations and stakeholder comments, FSANZ's preferred option is Option 3 – a simplified structure for food classes for food additive permissions applied to infant formula and related products in the table to section 5 of Schedule 15. Under this option, condition statements are proposed to be used to differentiate or qualify specific food additive permissions. Use of condition statements is consistent with international regulations, provides regulatory clarity, and supports the principle of minimal food additives use.

To align with the proposed regulatory framework which separates IFP and SMPPi, the structure of categories within table of Schedule 15 is proposed to be as indicated in Figure 3.1. The category 13.1 Infant formula and related products is comprised of two subcategories IFP (13.1.1) and SMPPi (13.1.2). The name of the category 13.1 is intended to include all products of IFP and SMPPi. Currently there are no food additive permission that would be listed under 13.1 as these would apply to both IFP and SMPPi.

This preferred option aligns with stakeholder views, provides regulatory clarity and avoids re-numbering of Schedule 15 which would have ramifications for food additive permissions across the Code.

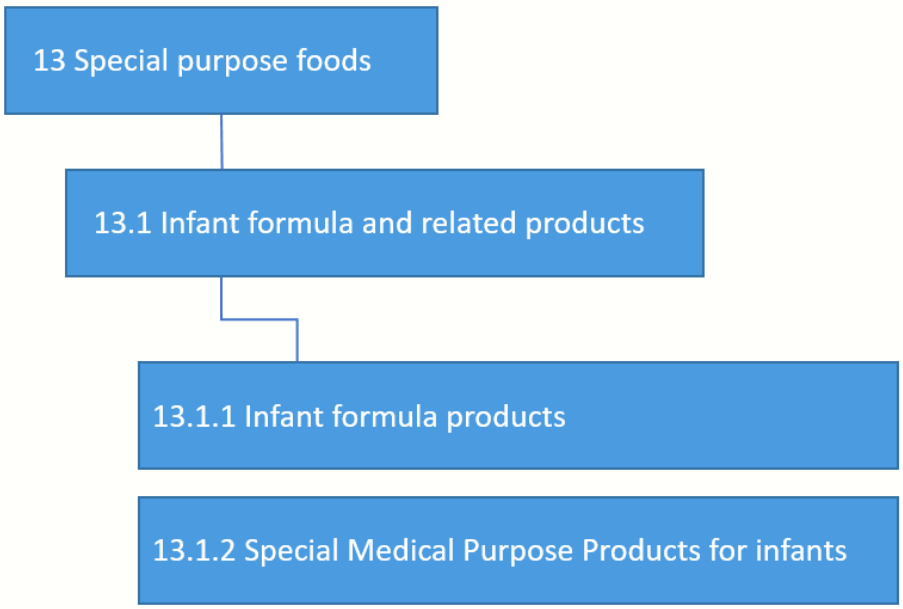

Figure 3.1: Preferred option (option 3) – one IFP and one SMPPi subclass

3.3 Carry-over principle for food additives and infant formula products

3.3.1 Current regulation

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

Currently, subsection 1.3.1—3(2) of the Code allows for the carry-over of food additives for all food classes; there is no exemption for infant formula products.

3.3.2 Previous consideration

FSANZ has proposed to remove carry-over provisions for infant formula products. The outcomes of previous consultations identified a lack of clarity about application of the carry-over principle for infant formula products in the Code compared to international regulations. Submitters were concerned that the removal of carry-over provisions could result in food additive permissions that did not align with Codex provisions and EU regulations, potentially resulting in non-compliant products, trade barriers and disruptions to supply.

3.3.3 Stakeholder views

FSANZ 2021 CP1 reaffirmed that the Code should be as consistent as possible with Codex and the EU and relevant international food additive regulations for infant formula products including special infant formulas (currently the IFPSDU category). As such, the carry-over of food additives should not be permitted unless a specific permission exists for that food additive in the final food. FSANZ noted that the proposed approach is consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population.

In response to FSANZ 2021 CP1, thirteen submissions (nine industry, three government, one health professional) commented on this issue. Government, health professional, and two industry submitters supported FSANZ’s proposed approach; the remaining seven industry submissions were not supportive. However, it would appear from the industry submissions that it is not the proposed changes to carry-over provisions per se that are of most concern, rather, that the changes will not result in complete alignment with Codex and the EU, with gaps in permissions for certain food additives which need to be addressed to prevent impacts on cost and supply. Table 3.3 provides a summary of submitters’ issues.

Table 3.3 Summary of issues raised by submitters regarding the carry-over principle for food additives

Issue	Raised by	FSANZ response
Supportive: The proposed changes best protect infant health and safety, and reflect the principle that the use of food additives should be minimised, per the original intent of the standard. This approach will also support harmonisation with international regulations and, as such, the continued export and import of infant formula products. One submitter noted they have no knowledge of any instance where the carry-over principle has been relied upon for infant formula product marketed in Australia or New Zealand.	6 submissions (3 government, 1 public health, 2 industry)	Noted.
Non-alignment with Codex and EU: The proposed changes will not achieve complete alignment with Codex or EU regulations – which are also not the same. Therefore, if the proposed approach is progressed, further harmonisation with both Codex and EU is required, particularly in regard to permissions for additives added to nutrient preparations and additive preparations. Non-alignment of permissions will have an impact on the cost and supply of IFPSDU in particular, which is most often imported and supplied in small volumes. In the absence of complete harmonisation, the supply of these products into Australia and New Zealand could become commercially non-viable, leaving infants at risk.	7 submissions (7 industry)	Carry-over provisions for food additives used in raw materials and ingredients are to be prohibited unless specific permissions exist for these food additives in the final infant formula product – this is consistent with Codex and EU regulations. Additives that are permitted to be added directly to infant formula products (per S15—5 food class 13.1) are permitted to be added to raw materials and ingredients under the proposed carry-over provisions. To deal with the issues raised related to permissions of food additives in nutrient and food additive preparations alternative approaches are being considered, being conditional permissions. This is not directly related to carry-over. FSANZ will determine permissions based on the principles of international harmonisation and the outcomes of its risk assessment. Additional information from industry in relation to actual/ maximum use levels of certain food additives in infant formula products imported into Australia and New Zealand will be sought where FSANZ's risk assessment conclusions have raised safety concerns.
Complexity and cost: The proposed changes will add complexity to the assessment of compliance, significant costs, and potential trade barriers, due to the need to reformulate and potentially source different ingredients. The impacts of these changes will affect businesses of all sizes, with most of the burden on local manufacturers. It will also depend on the number of product	8 submissions (8 industry)	As noted above, FSANZ will determine permissions based on the outcomes of its risk assessment and with a view to achieving alignment with Codex and EU regulations, so as to minimise any potential trade barriers and the need for product reformulation.

Issue	Raised by	FSANZ response
formulations affected by the proposed changes and the cost of the steps needed in order to comply. Practical steps to ensure compliance will include having to research substitutes, reformulate products and conduct storage stability trials. The number of suppliers of compliant raw materials will reduce and this may also see costs rise.		
Additives in nutrient preparations: There are additives permitted to be added in nutrients for foods for infants that are not listed in S15—5 food class 13.1 or in Schedule 18 as processing aids, hence there was concern that these would no longer be permitted if proposed carry-over provisions come into force. For Codex, these include the five nutrient carriers in CAC/GL 10-1979 – Section D. FSANZ's view is that these can be considered as permitted processing aids, specifically, carriers[4]. One submitter advised that these are used extensively in ingredients and, whilst they will still be clearly permitted, the standard could be amended to clearly state that processing aids are still permitted. Other submitters felt that this issue was ultimately a matter of interpretation which cannot be relied upon in the face of the law. For example, if sodium-L-ascorbate was determined by regulators to be used as an antioxidant (as opposed to 'used as a processing aid' i.e. carrier), then with this interpretation it would not be permitted under the proposed carry-over provisions. This is due to the Code's approach to additives which, if the proposed carry-over provisions are applied to infant formula products, would put an undue emphasis on function, rather than simply level of presence of carry-over additives that are applied by Codex and the EU. For the EU, additives that can be added in nutrients for foods for infants and young children are listed in Regulation (EU) 1130/2011 (amending (EC) 1333/2008, Annex III, part 5, section B). To ensure compliance of products with the proposed carry-over provisions, these additives also need to be	6 submissions (6 industry)	Comments related to interpretation and compliance are out of scope of the review. FSANZ does not have an enforcement or compliance role, rather, this is the responsibility of the relevant enforcement agencies in each Australian state and territory and New Zealand. It is the responsibility of the infant formula product manufacturer to ensure they comply with the requirements of the Code and can justify the technological purpose of any substance that is added to the food. See also Discussion below this table.

[4] Subsection 1.1.2—13(3) states that a substance *used as a processing aid* can be an **additive permitted at GMP.* Additives permitted at GMP are listed in Schedule 16 of the Code.

Issue	Raised by	FSANZ response
authorised by the Code to ensure a reliable supply of imported product. Calcium citrate (INS 333) and tricalcium phosphate (INS 341) are examples.		
Additives in food additive preparations: In response to a specific question raised by FSANZ in CP1 regarding food additive preparations (food class 0 in Schedule 15) used in infant formula products, several submitters advised that certain additives were used in specialised raw materials used in infant formula production. These included ascorbyl palmitate (INS 304) and tocopherols (INS 307, 307b, 308 and 309). One submitter noted that it is difficult to ascertain if these are used in food additive preparations or added directly during production. Only the producers of these raw materials would be privy to this information. Another submitter was of the view that since the technological function for the substances in food class 0 relate to their function in additives, rather than their function in the actual infant formula product, it is not necessary to review or re-evaluate their appropriateness as part of this consultation.	4 submissions (4 industry)	FSANZ notes that both ascorbyl palmitate (INS 304) and tocopherols concentrate, mixed (INS 307b) currently have permissions in food class 13.1 within Schedule 15, and these permissions will be maintained. See Discussion below this table.
Permissions for nutrient compounds that can also serve an additive function: The Codex standard for infant formula (CXS 72-1981) makes specific reference to advisory lists of nutrient compounds in CAC/GL 10-1979, with regards to permitting their presence as a result of carry-over[5]. However, there is no such equivalent in the Code, leaving a gap between Code and Codex carry-over permissions. If a nutrient form is not listed in S15—5 food class 13.1, then it would not be permitted to be carried over as an additive, even if directly permitted as a nutrient. With respect to the safety of the end products, it is irrelevant if these are added to the raw material for a technological or nutritive function. This has not been identified in the proposal put forward in the FSANZ 2021 CP1. A proposed solution is to include a new food additive section to Standard 2.9.1 of the Code (suggested wording reflects that in the footnote and is	3 submissions (3 industry)	It is the responsibility of the infant formula product manufacturers to ensure they comply with the requirements of the Code and can justify the technological purpose of any substance that is added to the food. See also Discussion below this table.

[5] *'Only the food additives listed in this Section or in the* Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) *may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:[…]'*

Issue	Raised by	FSANZ response
provided in the discussion below).		
Suggested changes to S15—5: A definition of 'carry-over' and a list of prohibited food additives for infant formula could be included in section S15—5 of the Code to provide added clarity.	1 submissions (1 industry)	'Carry-over of food additive' is defined in section 1.3.1—3 of the Code. FSANZ has considered CMA's suggestion to include a list of prohibited food additives in S15—5 of the Code, and has decided against this proposal. FSANZ notes that S15—5 comprises a table of permissions for food additives, which is consistent with comparable international regulations, which also list permitted food additives only, and is also consistent with how the Code operates, including how food additive permissions are regulated.
Processing aids: There was support for processing aids not falling within the proposed carry-over provisions, and submitters were of the view that this should be made very clear in the Standard should the proposed provisions proceed.	3 submissions (3 industry)	Section 1.3.1—3(2) of the Code refers specifically to 'carry-over of food additive' and, as such, further clarification in other standards in the Code is considered unnecessary.

3.3.4 Discussion

Additives in nutrient preparations

The Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979) contains an advisory list of food additives for special nutrient forms at Section D. This list comprises five food additives for 'special nutrient forms' that are permitted for use as 'nutrient carriers' to convert some vitamins and other nutrients into suitable preparations. These include gum arabic (gum acacia) (INS 414), silicon dioxide (INS 551), mannitol (for vitamin B12 dry rubbing, 0.1% only) (INS 421), starch sodium octenyl succinate (INS 1450), sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids) (INS 301).

In the EU, Commission Regulation (EU) No 1130/2011 (amending Annex III to Regulation (EC) No 1333/2008) outlines the Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrient preparations. Annex III, Part 5, Section B lists those food additives added in nutrient preparations intended to be used in foodstuffs for infants and young children. The list is more extensive than that of Codex, and includes the five nutrient carriers listed in Codex. Similar to Codex, the food additives have a technological function in nutrients or nutrient preparations e.g. as carriers, stabilisers or coatings for the nutrients within the preparation.

FSANZ notes the concerns raised by submitters that the five nutrient carriers listed in Codex CAC/GL 10-1979 – Section D are not listed in S15—5 food class 13.1 or in Schedule 18 as processing aids and, as such, may no longer be permitted if the proposed changes to carry-over provisions come into force. It is argued this would be a source of inconsistency between the Code, and Codex and EU regulations. Submitters made specific mention of sodium-L-ascorbate in this regard.

However, FSANZ reaffirms that the five nutrient carriers are all additives permitted at GMP in the Code and, as such, can be considered as processing aids under the Code (as stated in the earlier consultation documents). Subsection 1.1.2—13(3) of the Code states that a substance *used as* an **additive permitted at GMP* can be used as a processing aid. Therefore, these substances can be used as processing aids (i.e. carriers) in nutrient preparations for infant formula products. No changes to the Code are required to permit their continued use and the proposed changes to carry-over provisions will not impact their use (as generally permitted processing aids, which can include the technological purpose of carrier).

FSANZ also notes submitters' concerns that, to ensure compliance of products with the proposed carry-over provisions, additives that can be added in nutrients for infant formula products as listed in Regulation (EU) 1130/2011 (amending (EC) 1333/2008, Annex III, part 5, section B) also need to be authorised by the Code to ensure a reliable supply of imported product. Submitters made specific mention of calcium citrate (INS 333) and tricalcium phosphate (INS 341).

FSANZ proposes to establish additional permissions for other food additives, where appropriate to do so. Permissions may be established via the harmonisation of food additive permissions, as discussed in the next section, which includes a consideration of calcium citrate and tricalcium phosphate at Section 2.4.1 and Table 2.5.13 below.

In certain cases, permissions may be conditional on their use being only in nutrient preparations added to infant formula products. This approach would be consistent with that taken by Codex and the EU.

Additives in food additive preparations

As stated in CP1, the use of food additives used in food additive preparations (table to S15—5, food class 0) in infant formula and current IFPSDU products has not been specifically considered. This is because permissions under the Table to S15—5, food class 0 apply for all food classes – with no exceptions for infant formula products. In addition, proposed changes to the carry-over provisions apply to additives added to 'a raw material or an ingredient' and, as such, are not applicable to additives added to preparations of food additives. Submitters were supportive of maintaining the status quo for food additives used in food additive preparations.

In response to a specific question raised by FSANZ regarding food additive preparations used in infant formula products, industry identified ascorbyl palmitate (INS 304), which is a fat-soluble form of ascorbic acid (vitamin C) used as an antioxidant to protect lipids from peroxidation, thus increasing the shelf life of a product. Also identified were tocopherols (INS 307, 307b, 308 and 309), which can also act as antioxidants and preservatives, to inhibit lipid oxidation. All of these are listed in the Table to S15—5, food class 0 and provisions covering their use will not change if the proposed changes to the carry-over provisions come into effect. Importantly, INS 304 and 307b are also listed in food class 13.1 of Schedule 15.

Permissions for nutrient compounds that can also serve an additive function

Industry submitters were concerned about a possible barrier to compliance relating to the carry-over of nutrient compounds that also perform an additive function. In the Codex standard for infant formula (CXS 72-1981), there is an explicit reference to the advisory lists of nutrient compounds in CAC/GL 10-1979, permitting their presence as a result of carry-over:

'Only the food additives listed in this Section or in the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) *may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions: [...]'.*

Submitters were concerned that there is no equivalent provision in the Code, leaving a potential gap between the Code and Codex carry-over permissions for infant formula. Specifically, where a nutrient form is not a permitted additive in S15—5 food class 13.1, then, under FSANZ's proposed approach, that nutrient form would not be permitted to be carried over into infant formula products as an additive, even when it is directly permitted in infant formula as a nutrient[6]. Submitters suggested that this issue could be resolved by adding a new food additive section in Standard 2.9.1 of the Code to aid clarity if proposed changes to carry-over provisions are pursued, which will help with international alignment. This new section should include the express permission to carry over substances listed in S29—7[7] into infant formula products, providing the end products comply with the specified maximums for nutrients concerned. The suggested wording reflects that currently in CXS 72-1981, as follows:

> *'Only the food additives listed in the sub-food categories 13 of Schedule 15 or substances listed in Schedule 29—7[1] may be present in the foods described in Standard 2.9.1—3 as a result of carry-over from a raw material or other ingredient*

[6] FSANZ notes submitters' comments regarding the use of sodium ascorbate providing an antioxidant function and carried over from the oil that constitutes one of the ingredients in infant formula.
[7] Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

(including food additive) used to produce the food.'

[1] *Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes.*

FSANZ does not support what has been suggested. It does not support altering the structure of how food additives are regulated in the Code as it maintains they should continue to be listed within Schedule 15, and not split off into Schedule 29. What FSANZ is proposing is to ensure consistency with international regulations but via permissions using condition statements in Schedule 15 as explained earlier.

3.3.5 Preferred option

Based on previous considerations and stakeholder comments, FSANZ's preferred option remains unchanged. That is, the carry-over of food additives should not be permitted unless a specific permission exists for that food additive in the final food.

A clear and simple explanation of the proposed carry-over provisions is provided below (as copied from an earlier submission received from the New Zealand Ministry for Primary Industries (NZ MPI):

> *Carry-over (from raw materials and ingredients to the final food)* ***is not*** *permitted when there is no specific provision for the food additive in the standard.*
>
> *Carry-over (from raw materials and ingredients to the final food)* ***is*** *permitted when there is a specific provision for the food additive in the standard.*

It is important to emphasise that any additives permitted to be added directly to infant formula products (per S15—5 food class 13.1) are permitted to be added to raw materials and ingredients.

The proposed approach will help ensure the safety of infant formula products which are used as the primary nutrition source for infants who are a vulnerable population. It is vital that food additives added to infant formula products have been assessed as safe and that their use is technologically justified. These issues have been raised in submissions from jurisdictions and the health professional organisation. The proposed approach also addresses the principle of minimal food additive use in infant formula products. Importantly, the proposed approach will ensure alignment with Codex, EU and relevant international food additive regulations for infant formula products.

FSANZ notes industry's concerns particularly in relation to special infant formulas (current IFPSDU), which is typically imported, in that these products may no longer be compliant if the carry-over of food additives was no longer allowed. The supply of such products into Australia and New Zealand could become commercially non-viable. However, given that the proposed approach is consistent with Codex and EU regulations, it is likely that the industry is already familiar with, and able to comply with, the proposed changes to provisions, when it comes to imported product.

FSANZ will aim to ensure consistency of food additive permissions with Codex and EU Regulations so that carry-over and compliance is not of concern for infant formula products (see next section). FSANZ will also propose an appropriate transitional period that ensure continuous supply of these products. The transitional period will be considered and proposed in the 2nd CFS related to this proposal, when drafting is released for public comment.

3.4 Harmonisation of food additive permissions

3.4.1 Overview

Section 3.1.2 of this paper outlines the three risk management principles guiding FSANZ's consideration of food additive permissions. Further details regarding how FSANZ applied these principles to its consideration of harmonisation of food additive permissions was provided in Section 2.4.1 of CP1.

For each food additive of interest, FSANZ has considered the differences in permissions (including the maximum use levels) between the Code, Codex and EU regulations. In line with its risk management principles and, based on the outcomes of a safety assessment and the stated technological justification, FSANZ has determined the most appropriate approach to harmonise individual permissions.

Note that where food additive permissions for infant formula products in the Code are currently consistent with food additive provisions in Codex standards (essentially CXS 72-1981), these have not been considered in this paper but will be included in the proposed drafting.

3.4.2 Current regulation

Paragraph 1.1.1—10(6)(a) of the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a food additive, unless expressly permitted by the Code. Standard 1.3.1 Food additives contains the relevant permissions. Paragraph 1.3.1—3(1)(a) states that a substance may be used as a food additive in relation to a food if permitted for that food by Schedule 15.

In Schedule 15, food additive permissions for infant formula are listed in the table to section S15—5. As described in Section 2.2 of this paper, this table uses a hierarchical food class system for food additive permissions and infant formula products are listed in the class 13 Special purpose foods. Schedule 3 Identity and Purity of the Code lists the appropriate specifications for food additives. A permitted food additive must also comply with an appropriate specification.

3.4.3 Previous consideration

FSANZ 2016 CP considered additives permitted in Codex standards (as the global reference point) only. The consultation paper released in 2017 included a consideration of the European regulations as well, noting that most highly specialised IFPSDU products are imported into Australia and New Zealand from the EU. Both papers listed the differences and sought information and data on safety and technological need, to inform FSANZ's assessment.

3.4.4 Stakeholder views and discussion

FSAZN 2021 CP1 drew together information provided in submissions up until that point on the safety and technological need for additives, together with the outcomes of FSANZ's risk assessments of particular food additives, to propose an approach for harmonising permissions and associated risk management options.

In response to FSANZ 2021 CP1, 18 submissions (10 industry, 6 government, 2 health professional) commented on this issue. In general, submitters supported amending the Code to align with Codex and EU food additive permissions. Several government submissions were supportive subject to FSANZ's risk management principles being met, in particular, the

protection of infant health and safety, and justification of need. This was particularly relevant to special infant formulas (current IFPSDU), many of which are imported into Australia and New Zealand from the EU. One government submitter advocated a cautious and conservative approach to the use of food additives in infant formula products as persons less than 12 months old represent the most vulnerable consumer demographic in the Australia New Zealand population. Another commented that the redrafting of Standard 2.9.1 must make clear that pre-market assessment must occur for all new substances, in line with the Policy Guideline for the regulation of infant formula and the original intention of this standard.

In response to Question 4 of FSANZ 2021 CP1 regarding any cases where a lack of alignment with EU regulations had caused a delay in important formula reaching vulnerable infants, one health professional organisation responded that they were unaware of any case where a vulnerable New Zealand infant under dietetic care was experiencing delays in accessing the special formula that they needed. The other submitter had consulted with paediatric dietitians in major paediatric hospitals across Australia and also advised that no infant formulas were identified as desired but delayed or blocked from import.

In response to Question 6 regarding practical barriers to complying with new permissions and limits, one heath professional organisation was of the understanding that several smaller firms use contract manufacturers so costs may not be as large as anticipated, as they would be shared by each of the companies contracting that manufacturer.

Industry submissions recommended that food additives that contribute essential nutrients not have levels specified, provided that there is no exceedance of nutrient compositional limits. Submissions reasoned that safe use is determined by the level present, not whether it is added as a nutrient or food additive. There was a strong recommendation to harmonise with relevant EU regulations on foods for special medical purposes and, as such, the food class system for food additive permissions should also align with European regulation. In particular, the Codex standard and EU regulations do not have sub-divisions of IFPSDU and, if any such sub-divisions were to be retained by FSANZ, they should not be contrary to the additive permissions of Codex or EU (see Section 3.2 of this paper).

In response to Question 7 in FSANZ 2021 CP1 regarding what (if any) practical barriers may have to be overcome on production costs per product lines, industry submitters indicated that the reformulation of individual products and product lines could be required, and that there could be significant costs for businesses associated with reformulation, depending on the number of products concerned, and particularly for small to medium enterprises (SMEs). There was concern that special infant formulas (current IFPSDU) manufactured globally may no longer be commercially viable to be supplied to Australia and New Zealand, due to having to manufacture a formulation specifically for these countries in very small quantities. One submitter provided an estimate of costs of reformulation, as a Commercial in Confidence attachment to their submission.

In response to Question 8 regarding the relative impacts of non-alignment of permissions on smaller versus larger businesses, one submitter responded that businesses of all sizes potentially could be impacted, with another submitter indicating that significant costs could be unevenly spread across the market, but primarily the burden would be on local manufacturers.

3.4.5 Preferred option

The preferred option is to harmonise food additive permissions in line with the considerations discussed in section 3.4.1. The following sections provide a summary of submitters' views for harmonisation of permissions for individual food additives that were reviewed in FSANZ 2021 CP1, together with a discussion (where relevant), and FSANZ's preferred option. FSANZ's

preferred options are also summarised in Table 3.5.13.

FSANZ notes that there are still some risk assessment concerns related to granting permissions for some of these food additives, especially with regards to high MPLs. Therefore, in several cases, FSANZ is again seeking advice from stakeholders regarding evidence of safety at proposed levels, actual use levels, and justification for use at the requested MPL, before making a final determination.

Per FSANZ 2021 CP1, food additives that are acidity regulators are considered as a group (Section 3.5.1 below). The other ten food additives are considered individually as they have a number of technological purposes such as emulsifiers, stabilisers and thickeners (Sections 3.5.2 – 3.5.12 of this paper). For a detailed comparison of infant formula product food additive permissions in the Code, Codex, and European regulations, see Tables 2.7 – 2.8 of FSANZ 2021 CP1.

3.5 Food additive permissions by type or substance

Following the FSANZ 2021 CP1, the regulatory framework and definitions for infant formula products and IFPSDU were reviewed and redefined. As a result of this, extensively hydrolysed protein infant formula is now proposed to be included within the SMPPi category, instead of infant formula products (see CFS). Further to this, the SMPPi category includes highly specialised medical products, including those that may pose a risk to healthy infants. The framework allows these products to differ from general requirements set for infant formula products where needed to meet the intended medical purpose of the product. As such, these products must be used under medical supervision and have mandatory labelling requirements to state the medical condition, disease or disorder they are to be used for.

Based on the above, food additive permissions noted in Codex and the EU that relate to extensively hydrolysed protein infant formula would be permitted only within the SMPPi category instead of infant formula products. The food additives that are affected by the proposed approach are starch sodium octenylsuccinate (section 3.5.4), pectins (section 3.5.6), xanthan gum (section 3.5.7), guar gum (section 3.5.8), sodium alginate (section 3.5.9) and sucrose esters of fatty acids (section 3.5.11).

FSANZ seeks additional information from health professionals and manufacturers on the safety, justification and appropriateness of adopting Codex and EU MPLs for hydrolysed protein formulas within the SMPPi category. FSANZ may revise its preferred option based on the outcomes of international assessments or any additional information received.

3.5.1 Acidity regulators

Previous consideration

FSANZ 2016 CP sought information on the technological justification and need of acidity regulators for use in infant formula in Codex (CXS 72-1981). In 2017 (addressing IFPSDU products), FSANZ also considered acidity regulator permissions for relevant food categories 13.1.1 and 13.1.5.1 in Annex II of Commission Regulation (EU) No 1129/2011. The detailed comparison of permissions in the Code, Codex, and European regulations for acidity regulators is provided in Table 2.7 of FSANZ 2021 CP1.

Stakeholder views and discussion

Six submissions (four industry, two government) provided general comments on the use of acidity regulators. Submitters were supportive of FSANZ's approach to aligning with permitted levels in Codex and the EU. Both government and industry suggested that

condition statements be applied to calcium, sodium, potassium and phosphorus salts to ensure conformity with maximum limits and ratios listed in the table to S29—9 of the Code (which lists the required vitamins, minerals and electrolytes in infant formula and follow-on formula), and to be consistent with Codex and the EU. FSANZ is aware of the need to ensure conformity with cation limits in relation to those substances that are permitted forms of nutrients in the Code, Codex and the EU, noting that in some cases, these limits may be of more significance than the MPLs for the food additive in question. FSANZ agrees with the approach suggested by submitters, which is to apply condition statements for calcium, sodium, potassium and phosphorus salts, where appropriate to do so.

One industry submitter was of the view that, for those acidity regulators that are permitted forms of nutrients, there would be a redundant additional compliance check for maximum levels as maximum amounts for composition already exist. Whilst FSANZ acknowledges this concern, the proposed approach is consistent with how the Code operates, including how food additive permissions are regulated and it is the responsibility of infant formula product manufacturers to ensure compliance with the Code and that they can justify the technological purpose of any substance that is added to the food.

The INC noted that it appeared that FSANZ had not taken into account density (assumed to be of the liquid IFP); this would need to be considered if the proposals are to proceed. FSANZ assumes INC is referring to the difference in providing MPLs for liquid IFP compared to powders. It is important to note that unless otherwise stated in the Code that MPLs apply to infant formula product preparations made up for consumption (subsection 1.3.1—4(4)). Therefore the units of the MPL in the Code are in mg/L, which is comparable to Codex and the EU. FSANZ notes that it did make errors in using the units mg/kg rather than mg/L in CP1. This has been amended in this document.

Preferred option

The preferred options for permitting the use of each acidity regulator is provided in Table 3.5.13.

3.5.2 General considerations on thickeners, emulsifiers and stabilisers

Previous consideration

Consultation papers released in 2016 and 2017 sought information on a range of food additives used as thickeners, emulsifiers and stabilisers in infant formula products, including international safety assessments, history of safe use and technological justification for their use. The detailed comparison of permissions in the Code, Codex, and European regulations for these food additives has been provided in Table 2.8 of FSANZ 2021 CP1.

Stakeholder views and discussion

Two submissions (one government, one health professional organisation) provided general comments on the use of thickeners in infant formulas. The health professional organisation was of the view that further investigation into the efficacy and safety of thickeners in infant formulas marketed as ‘anti-reflux’ is required. There is insufficient evidence to support thickeners as effective to prevent or reduce the impacts of infant reflux – this was also noted by one government submitter. Exposure of infants to food additives which have no demonstrated benefit is unnecessary. Further, the availability of such infant formulas may discourage breastfeeding in an effort to reduce infant reflux and reduce the associated stress. The government submitter was of the view that FSANZ should justify the need for permissions for the gum-based thickeners, in the context of risk management principle 2 and also in light of case reports for necrotising enterocolitis (NEC) in premature infants (noting a

clear causal link yet to be determined).

FSANZ reviewed the case reports suggesting an association between the use of gum-based thickeners and gastrointestinal disorders in infants, including necrotising enterocolitis (NEC) and other relevant information in the scientific literature. Based on the available data it is not possible to determine if there is a causal association between NEC in infants and xanthan gum, carob bean gum or other thickeners. JECFA and the US FDA have reached similar conclusions. FSANZ considers that best clinical practice should be followed in feeding premature infants and/or infants with gastro-oesophageal reflux disease or other medical conditions, and that such infants should be under medical supervision.

In addition to the above, several industry submitters provided advice that CXS 72-1981 (amended 2020) had been updated to permit the use of several thickeners i.e. pectins and xanthan gum in some infant formula products. These have been updated in the relevant section of this supporting document.

Preferred option

Comments made by submitters in relation to individual food additives, together with FSANZ's response (including the preferred options for permitting the use of each food additive) have been provided in the sections that follow and summarised further in Table 3.5.13.

3.5.3 Citric and fatty acid esters of glycerol (CITREM) (INS 472c)

Previous consideration

FSANZ 2021 CP1 proposed to align with Codex and EU by introducing a lower MPL of 7500 mg/kg for powdered products and to retain the 9000 mg/kg for liquid products. FSANZ 2016 sought information on:

(i) the technological need for extending the use of this food additive (currently at 9000 mg/L in food class 13.1.3 *Infant formula products for specific dietary use based on a protein substitute*) to all types of infant formula
(ii) any technologically justified concerns with changing the permissions for this food additive to 9000 mg/L for liquid products and 7500 mg/L for powdered products, per the EU and Codex.

Stakeholder view

Five submissions (three industry, two government) provided general comments on the use of this food additive, expressing their support for the 2021 proposed approach.

Preferred option

Based on the previous consideration and stakeholder support, FSANZ's preferred option is to progress with the CP1 approach, which is to permit use of this food additive in infant formula products to harmonise with Codex and EU, with MPLs of 9000 mg/L for liquid products and 7500 mg/L for powdered products. These conditions will be noted in drafting of the Schedule.

3.5.4 Starch sodium octenylsuccinate (INS 1450)

Previous consideration

Based on the previous consideration and stakeholder support, FSANZ 2021 CP3 proposed approach was to permit use of this food additive in infant formula products to harmonise with Codex and EU, with MPLs of 9000 mg/L for liquid products and 7500 mg/L for powdered

products.

Stakeholder views

Six submissions (four industry, two government) provided comments on FSANZ's proposed approach to permit the use of this food additive in certain IFPSDU (i.e. products based on hydrolysed protein and/or amino acids) at an MPL of 20,000 mg/L. Submitters were supportive of including permissions in the Code for use of this food additive. One government submitter noted that as permissions would be limited to IFPSDUs containing hydrolysed protein, this would be in line with safety principles to minimise the use of food additives and the principle of harmonisation with overseas regulations.

However, industry submitters were of the view that use should not be restricted to IFPSDU containing hydrolysed protein and/or amino acids. Instead, its use in all IFPSDUs should be permitted, to better align with the EU regulations, which are wider than proposed by FSANZ. As a result, they did not support the restriction to IFPSDU containing hydrolysed protein and/or amino acids.

Industry also pointed out that starch sodium octenylsuccinate is permitted as a food additive for addition to nutrient preparations intended to be used in infant formula in the EU. This should be taken into consideration if FSANZ amends the carry-over principles.

Preferred option

Based on the previous consideration and stakeholder support, FSANZ's preferred option is to progress with FSANZ 2021 CP1 approach, which is to permit use of this food additive in certain IFPSDU only (i.e. products based on extensively hydrolysed protein and/or amino acids) at an MPL of 20,000 mg/L. This will apply to the new category SMPPi. FSANZ considers the restriction of only being used for products containing extensively hydrolysed protein and/or amino acids is appropriate, consistent with the food additive principles, whilst still ensuring better alignment with the relevant international regulations.

FSANZ notes that this food additive is included in Section D of CAC/GL 10-1979 (as one of five nutrient carriers) and Commission Regulation (EU) No 1130/2011 (amending Annex III to Regulation (EC) No 1333/2008), permitting its addition to nutrient preparations (MPL of 100 mg/kg). As explained in the discussion section of Section 2.3 of this paper, no changes to the Code are required to permit its continued use for this purpose.

3.5.5 Locust bean (carob bean) gum (INS 410)

Previous consideration

This additive is currently permitted in the Code for use in all infant formula products (up to 1000 mg/L), consistent with Codex. In the EU, permission is limited to food category 13.1.5.1 – Dietary *foods for infants for special medical purpose and special formulae for infants* (up to 10,000 mg/L) only for products for the reduction of gastro-oesophageal reflux. FSANZ 2017 CP proposed to harmonise with the EU and sought views on this approach, together with supporting information.

Stakeholder views

Nine submissions (five industry, three government, one health professional organisation) provided comments on FSANZ's proposed approach to maintain this food additive's use in infant formula consistent with Codex (MPL 1000 mg/L) and to permit its use in certain

IFPSDU to align with EU (MPL 10,000 mg/L), specifically for use from birth onwards in products for reduction of gastro-oesophageal reflux.

In general, government submissions were not supportive of the proposed approach stating there was no clear rationale for its addition in general infant formulas and the approach was not consistent with risk management principles 2 and 3. To this end, more information from industry on the need for this food additive in standard infant formula would be helpful.

Government submitters noted that this additive is permitted for use in special infant formulas in the EU only for the management of gastro-oesophageal reflux. There was concern that safety data is not available for use of this additive at the higher levels proposed. This view was shared by the health professional organisation. They noted there are safety concerns regarding use for very young infants and safety and tolerance above 6,000 mg/L has to be demonstrated. It was noted that EFSA is seeking toxicological data for the re-evaluation of this substance in foods for infants below 16 weeks of age. In line with principle 1, FSANZ should consider the outcomes of the re-evaluation when making a final recommendation.

Some industry submissions were supportive of FSANZ's proposed approaches, however one submitter provided literature references indicating levels up to 5,000 mg/kg (L) are safe and technologically justified to thicken infant formula to alleviate gastro-esophageal reflux in infants. Levels of addition need not exceed 5,000 mg/L, nor is there justification for higher levels.

Preferred option

Based on the previous consideration and stakeholder comments, FSANZ's preferred option for infant formula products is to progress with the FSANZ 2021 CP1 approach, which is to maintain the current permission to align with Codex (MPL 1000 mg/kg). FSANZ's risk assessment concluded that use of locust bean (carob bean) gum at the current MPL is unlikely to be of toxicological concern, and this approach is consistent with risk management principle 3.

FSANZ's preferred option for SMPPi at this stage is to progress with an amended approach, which is to permit in SMPPi at a lower MPL of 5,000 mg/L as noted by an industry submitter which is the upper level required for the technological purpose. This would be on the condition that it is used from birth onwards in products for reduction of gastro-oesophageal reflux. FSANZ seeks additional information from industry on justification and use at this proposed level. It notes that this is lower than the MPL in the EU (10,000 mg/L), but FSANZ risk assessment notes there are no clinical studies or studies in neonatal animals supporting safety at this higher level. In addition, FSANZ will consider the outcomes of the EFSA evaluation (if available), before making its final recommendation in the 2nd CFS.

3.5.6 Pectins (INS 440)

Previous consideration

The Code does not permit pectins in infant formula products. In the EU, permission is limited to food category 13.1.5.1 (up to 10,000 mg/L) in products from birth onwards for infants with gastrointestinal disorders. In 2017 FSANZ proposed to align with the EU permission only for use in special infant formulas for gastrointestinal disorders. Views on this approach as well as information on safety and technological justification were requested.

The proposed approach was revised in CP1 to include a permission for use in infant formula at an MPL of 2000 mg/L, to be consistent with JECFA. Specifically, risk assessments by

JECFA and FSANZ had concluded that there was no safety concern with permitting the additive for infant formula products up to 2000 mg/L.

FSANZ 2021 CP1 noted EFSA's 2021 conclusion that the current EU MPL of 10,000 mg/L (mg/kg) should be reduced. The EFSA report also indicated that industry use levels for food category 13.1.5.1 were in the range of 3466 mg/L (mean) to 4170 mg/L (maximum). As such, the permission proposed in FSANZ 2021 CP1 for use of pectins in IFPSDU was changed to an MPL of 5000 mg/L (mg/kg). FSANZ considered this would not restrict access to imports of specific types of IFPSDU, but sought information from health professionals and industry on justification and use.

Subsequent to the release of the FSANZ 2021 CP1, a 2020 amendment to CXS 72-1981 permitted the food additive at a maximum level of 0.2 g in 100 ml (e.g. 2000 mg/L) of the product ready for consumption in liquid hydrolysed protein infant formula only. This permission has not yet been incorporated into the GFSA but will occur as an outcome of the CCFA52 meeting in September 2021.

Stakeholder views and discussion

Ten submissions (five industry, four government, one health professional organisation) provided comments on FSANZ's proposed approach for use of pectins in infant formula products and certain IFPSDU.

Government and health professional submissions were not supportive of the proposal to permit the additive in IFPSDU, based on principle 1. Submitters noted that EFSA had concerns about safety at higher levels, and that JECFA conclusions indicated exposure at 5000 mg/L was of concern. There had also been reports of delayed gastric emptying in animals. More evidence of safety and efficacy for human infants at levels over 2000 mg/L would be desirable and submitters recommended additional clinical trials to assess safety in IFPSDU.

FSANZ's risk assessment, which concluded that use up to 2000 mg/L does not raise safety concerns, was based on a comparison of the estimated exposure and the no observed adverse effect level (NOAEL) in a study in neonatal piglets. Delayed gastric emptying was observed at higher doses but not at the NOAEL, so is not of concern at a proposed use level of 2,000 mg/L.

In contrast, industry were supportive of FSANZ aligning with EU for special infant formulas (at an MPL of 5000 mg/L or 10,000 mg/kg) so as to not restrict access to specific types of imported special infant formulas from Europe.

An industry submitter provided a number of published studies suggesting there were no safety concerns with the use of formulas containing a fibre complex (including pectin) at a level of 0.5 g/100 mL (i.e. 5,000 mg/L). These studies do not report any serious adverse events considered to be treatment related, and provide some supporting information of tolerability and growth at pectin concentrations up to approximately 4000 mg/L. However, the majority have limitations such as absence of a control group, small sample sizes, and little information provided in relation to safety. Given these limitations, these studies were not considered sufficient to alter FSANZ's approach that it is appropriate to maintain JECFA's conclusions that consumption of infant formula containing pectin at concentrations ≥ 5000 mg/L is of concern.

The FSANZ's Risk Assessment did not specifically address or assess SMPPi (FSANZ 2021b).

Preferred option

Based on the above discussion, FSANZ's preferred option is to prescribe the following two permissions for pectins within SMPPi:

- 2000 mg/L MPL for hydrolysed protein liquid formulas
- 5000 mg/L MPL for gastro-intestinal disorder formulas

Formulas for gastro-intestinal disorders (the second SMPPi product and higher MPL) will include a condition statement noting use from birth onwards in products used in case of gastro-intestinal disorders.

However, FSANZ continues to seek further information from industry on justification and use at the higher level of 5000 mg/L. In addition FSANZ will consider the outcomes of the EFSA evaluation (if available), before making its final recommendation within the 2nd CFS.

3.5.7 Xanthan gum (INS 415)

Previous consideration

Xanthan gum is not permitted in the Code for infant formula products. The EU permits its use in food category 13.1.5.1 at levels up to 1200 mg/L only in products based on amino acids or peptides for use with patients who have problems with impairment of the gastrointestinal tract, protein malabsorption or inborn errors of metabolism. In 2017, FSANZ proposed alignment with the EU to enable continued supply of special infant formulas for these infants. Information was requested to support further consideration.

The proposed approach was revised in FSANZ 2021 CP1, noting that JECFA had concluded that, based on the available data, the consumption of xanthan gum in all infant formula products at a proposed maximum level of 1000 mg/L does not raise safety concerns. New studies published since the JECFA evaluation did not indicate any need to revise JECFA's conclusions. Also in FSANZ 2021 CP1, FSANZ sought information from health professionals on the need for the higher MPL for xanthan gum of 1200 mg/L.

Subsequent to the release of FSANZ 2021 CP1, a 2020 amendment to the Codex standard (CXS 72-1981) permitted the food additive at a maximum level of 1000 mg/L for products ready for consumption in powdered hydrolysed protein and/or amino acid based infant formula only. This permission has not yet been incorporated into the GFSA but will occur as an outcome of the CCFA52 meeting in September 2021.

Stakeholder views

Eight submissions (three industry, four government, one health professional organisation) provided comments on FSANZ's proposed approach for use of xanthan gum in infant formula and certain IFPSDU.

In general, government submitters did not support the proposed approach, but were supportive of a permission for IFPSDU only at 1000 mg/L, as a level assessed by JECFA and shown to present no health and safety concerns. Submitters noted that this was the level requested by industry for consideration.

One submitter referred back to the 2017 RACP submission. It advised that carob bean gum and xanthan gum appear to have been the main thickening agents mentioned in the literature that have been associated with gastrointestinal disorders. As such, removal of guar gum as being a permissible thickening agent to infant formula could not be supported.

To meet Risk Management principles 1 and 2, additional information would be desirable on the safety of the additive at the higher MPL, use levels in the EU, and any potential impacts on imports of IFPSDU, if the lower level of 1000 mg/L was implemented.

The health professional organisation recommended FSANZ consider the strength of evidence on safety in human research. Animal studies and limited observational human studies indicate xanthan gum may be safe for vulnerable infants, however 22 case reports have potentially linked xanthan gum with NEC. As such, a conservative approach to protect infant safety was advocated.

In contrast, industry were supportive of this additive's use up to 1200 mg/L. Submitters noted that this limit is shown to have a safe history of use, would align with the EU, and would ensure importation of IFPSDU. Several submitters suggested that, in light of the recent Codex permission and, in terms of achieving minimum efficient regulation, this be permitted in all IFPSDU (including powdered hydrolysed protein and/or amino acid based infant formula) to align with Codex. One submitter advised they could support permitting at 1000 mg/L to align with JECFA's risk assessment.

Preferred option

Based on the previous consideration and stakeholder comments, FSANZ's preferred option is to vary the FSANZ 2021 CP1 approach for infant formula and permit use of this additive in powdered hydrolysed protein and/or amino acid based infant formula for SMPPi products due to use of hydrolysed protein and/or amino acid ingredients only (MPL 1000 mg/L) to be consistent with Codex (2020 amendment). This approach addresses the three risk management principles and, in particular, maintains alignment with recent Codex permissions.

For additional SMPPi products, FSANZ's preferred option at this stage is to progress with the FSANZ 2021 CP1 approach, which is to permit the use of xanthan gum in certain SMPPi at an MPL of 1200 mg/L, to align with the EU. Use is from birth onwards in products based on amino acids or peptides for patients with gastrointestinal tract problems, protein mal-adsorption, or inborn errors of metabolism. However, FSANZ continues to seek information from stakeholders on the safety of the additive at the higher MPL, use levels in the EU, and potential impacts on imports if the lower level of 1000 mg/L is implemented, which will assist FSANZ in making its final recommendation. Industry advice is further sought on FSANZ's preferred approach to include two permissions for SMPPi products, with different MPLs and condition statements, but not for general IFP.

3.5.8 Guar gum (INS 412)

Previous consideration

The Code currently permits the use of guar gum in all infant formula products at 1000 mg/L (noting that it is listed in food class 13.1). Codex provisions in both the GSFA and CXS 72-1981 limit use to liquid infant formula containing hydrolysed protein up to 1000 mg/L. The EU permits its use in food category 13.1.1 at 1000 mg/L for liquid product containing partially hydrolysed proteins; and in food category 13.1.5.1 at 10,000 mg/L in liquid products containing hydrolysed proteins, peptides or amino acids.

In 2017, FSANZ proposed to amend the permission by restricting permission for use in specific IFPSDU, namely, liquid products containing hydrolysed proteins, peptides or amino acids. The rationale was that this would be consistent with Codex provisions and EU regulations and align with the minimal use principle. FSANZ 2021 CP1 proposed maintaining the current permission in infant formula products (MPL 1000 mg/L) and sought further

information justifying the need for a 10-fold higher MPL for certain IFPSDU (per the EU category 13.1.5.1).

Stakeholder views and discussion

Five submissions (three industry, two government) provided comments on FSANZ's proposed approach for use of guar gum in infant formula and certain IFPSDU.

Government submitters noted that EFSA is conducting a re-evaluation and has called for toxicological data to assess safety in infants under 16 weeks. As such, FSANZ should await the outcomes of this assessment before setting an MPL and seek information on the need for a higher MPL of 10,000 mg/L in IFPSDU. Alternatively, it was proposed that FSANZ restrict permissions to IFPSDU only, noting that this is consistent with principles 2 and 3.

Industry submitters were supportive of the permission for IFPSDU from birth onwards at an MPL of 10,000 mg/L in liquid products containing hydrolysed proteins, peptides or amino acids. INC advised they had sought information from their EU contacts which they would provide to FSANZ if and when received. One industry submitter sought to clarify whether the current permission with a limit of 1000 mg/L would be retained.

As presented in the CFS, the regulatory framework and definitions for infant formula products and special infant formulas were reviewed and redefined. As a result, it is proposed that extensively hydrolysed protein is only permitted in SMPPi, whereas partially hydrolysed protein is permitted in IFP. .

Preferred option

Based on the above discussion, FSANZ's preferred approach is to retain the current permission in the Code which permits guar gum in infant formula products at 1000 mg/L. For SMPPi, FSANZ's preferred option is to progress with the FSANZ 2021 CP1 approach, which is to permit the use of guar gum in certain SMPPi at an MPL of 10,000 mg/L, to align with the EU. Use is from birth onwards in products containing extensively hydrolysed proteins, peptides or amino acids.

However, FSANZ continues to seek further information from industry on justification and use at the higher level. In addition FSANZ will consider the outcomes of the EFSA evaluation (if available), before making its final recommendation within the 2nd CFS.

3.5.9 Sodium alginate (INS 401)

Previous consideration

Sodium alginate is not permitted in the Code for infant formula products, nor is it permitted for use in infant formula by Codex. FSANZ 2017 CP noted that it was permitted in the EU for special medical purpose products. In 2017, and again in the FSANZ 2021 CP1, FSANZ proposed to align with the EU regulations and permit sodium alginate in the Code for IFPSDU at a MPL of 1000 mg/L, specifically for products suitable for infants from four months onward in special food products with adapted composition, required for metabolic disorders and for general tube-feeding. However, noting the limited evidence of current use identified in the EU (EFSA 2017), in the 2021 CP1 FSANZ sought data from industry on the current use levels to inform the final decision.

Stakeholder views

Six submissions (three industry, two government, one health professional organisation) provided comments on FSANZ's proposed approach for use of sodium alginate in certain IFPSDU.

The government and health professional organisations did not support the proposed approach of adding sodium alginate to IFPSDU (MPL of 1000 mg/L) to align with the EU without clear evidence on safety and justification. Submitters were of the view that there are other additives on the market that can perform the same functions and a greater understanding of the impact of not permitting its use would be required before this proposed approach could be supported.

In contrast, industry supported the proposal to align with the EU, specifically for the group of vulnerable infants identified. Submitters noted that the requirement to state "from 4 months" does not align with the mandatory statement for all infant formula "suitable from birth". In addition, clarification was sought regarding information presented in Section 2.4.9 compared with Table 2.17 the FSANZ 2021 CP1 (FSANZ 2021a), as to whether or not FSANZ proposes uses in general tube-feeding.

Preferred option

Based on the previous consideration and stakeholder comments, FSANZ's preferred option at this stage is to progress with the FSANZ 2021 CP1 approach. Under the proposed regulatory framework, only certain SMPPi will be permitted to use sodium alginate to an MPL of 1000 mg/L. This is to ensure access to these products for infants that require them and to ensure harmonisation with the EU. However, FSANZ continues to seek additional information from industry on use levels in the EU and the potential impact on imports of not permitting its use to assist in making a final recommendation, noting the concerns of some stakeholders.

The proposed conditions of use will be from 4 months onwards in products for dietary management of metabolic disorders and for general tube-feeding.

3.5.10 Sodium carboxymethylcellulose (INS 466)

Previous consideration

Sodium carboxymethylcellulose is not permitted in the Code or Codex for use in infant formula products. In 2017 FSANZ proposed to permit this food additive up to 10,000 mg/L in IFPSDU, specifically in products for dietary management of metabolic disorders, to align with the EU and so to minimise potential interruptions to trade.

FSANZ 2021 CP1 noted that data on safety and use levels were lacking and sought information from stakeholders on current use levels to assist in making a final decision. As noted by some submitters FSANZ provided inconsistent advice within the FSANZ 2021 CP1. In section 2.4.10 FSANZ concluded:

> *'No information on current use was provided to FSANZ in 2017, based on this FSANZ is not proposing to permit use of sodium carboxymethylcellulose in any infant formula product. We are seeking any information from stakeholders on current use and levels to inform a final decision.'*

Unfortunately FSANZ stated in its summary table, Table 2.17 of FSANZ 2021 CP1 to 'permit in certain IFPSDU to align with EU' (at 10,000 mg/L) with the EU condition statement. This was not a correct summary of our review at that time.

Stakeholder views

Six submissions (three industry, two government, one health professional organisation) provided comments on FSANZ's proposed approach for use of sodium carboxymethylcellulose in certain IFPSDU.

The government and health professional organisation were of the view that FSANZ should not permit the use of this food additive in the absence of adequate safety data for young infants or a technological need.

In contrast, industry was supportive of a permission for use at levels up to 10,000 mg/L, to align with the EU limits and conditions. Industry commented that it was likely this addition would be for liquid products only.

Preferred option

Based on the previous consideration and stakeholder comments, FSANZ's preferred option at this stage is to progress with the FSANZ 2021 CP1 approach, which is to not permit the use of sodium carboxymethylcellulose in any infant formula product or SMPPi.

FSANZ continues to call for additional information from stakeholders on current use and usage levels and may revise its preferred option based on the outcomes of international assessments or any additional information received.

3.5.11 Sucrose esters of fatty acids (INS 473)

Previous consideration

Sucrose esters of fatty acids are not permitted for use in infant formula products in the Code or Codex. They are permitted in EU regulations for the food categories 13.1.1 and 13.1.5.1 in products containing hydrolysed proteins, peptides and amino acids up to 120 mg/L.

In 2017, FSANZ proposed to add a permission for use of the additive in IFPSDU to be consistent with the EU to ensure trade harmonisation and minimise the risk of potential barriers for specialised products needed for infants who have specific physical or physiological conditions, diseases or disorders. At that time, industry requested that FSANZ consider permitting the food additive for all infant formula products.

The FSANZ 2021 CP1 noted the lack of safety assessments for infants less than 16 weeks, and proposed to limit the permission to IFPSDU containing hydrolysed proteins, peptides and amino acids up to 120 mg/L. This approach would not restrict access to specific types of IFPSDU sourced from Europe. However, recognising the lack of studies in international risk assessments conducted on infants below 12 or 16 weeks of age, FSANZ sought additional information from health professionals and manufacturers about the need for, and use of sucrose esters of fatty acids in IFPSDU in Australia and New Zealand.

Stakeholder views

Seven submissions (three industry, three government, one health professional organisation) provided comments on FSANZ's proposed approach for use of sucrose esters of fatty acids in certain IFPSDU.

In general, the government and health professional organisation did not support FSANZ's proposed approach without additional data on safety and justification. It was noted that this additive may have a role in specialised infant formula but concern was expressed around the

lack of data on the safety for infants aged less than 12 weeks. Submitters noted that infants under 12 weeks of age were not included in a 2018 EFSA exposure assessment but that EFSA is currently undertaking a risk assessment for infants below 16 weeks of age (EFSA 2018). Submitters also noted JECFA had requested refined dietary exposure estimates for these substances because current, conservative dietary exposure estimates for some age groups exceeded the Acceptable Daily Intake (ADI) (WHO/FAO 2020). Submitters noted the potential of these additives to induce laxative effects in adult volunteers at doses > 30 mg/kg bw per day (WHO 1999). Therefore the determination of a proposed approach should wait until the outcomes of work being done internationally and information sought from health professionals is available.

Industry supported FSANZ's proposed approach noting that it would prevent restriction of access to specific IFPSDU which may be solely sourced from Europe into the Australian and New Zealand markets. Notwithstanding the above, one submitter advised that they were not aware of any current use.

Preferred option

Based on the previous consideration and stakeholder comments, FSANZ's preferred option at this stage is to progress with the FSANZ 2021 CP1 approach, which is to permit sucrose esters of fatty acids to an MPL of 120 mg/L for certain special infant formulas (SMPPi under the revised regulatory framework) to align with EU. The proposed conditions of use are for products containing hydrolysed proteins, peptides or amino acids.

FSANZ continues to call for additional information from health professionals on safety and justification, and information from manufacturers about industry use of sucrose esters of fatty acids in SMPPi for the Australian and New Zealand markets. FSANZ may revise its preferred option based on the outcomes of international assessments or any additional information received.

3.5.12 Diacyltartaric and fatty acid esters of glycerol (INS 472e)

Previous consideration

Diacyltartaric and fatty acid esters of glycerol are currently permitted in the Code for infant formula products for specific dietary use based on a protein substitute (food class 13.1.3) with an MPL of 400 mg/L. This food additive is not permitted by Codex or the EU in any infant formula.

In 2017 FSANZ proposed to remove permission on the basis that there are no equivalent permissions in Codex or the EU. CP1 noted that justification of use provided in industry submissions was not sufficiently strong to maintain its permission. Further, no evidence of its current use had been provided. Therefore, FSANZ proposed to remove the permission in the Code.

Stakeholder views

Six submissions (three industry, three government) provided comments on FSANZ's proposed approach for diacyltartaric and fatty acid esters of glycerol, which was to remove existing permissions in the Code, for food class 13.1.3.

Government supported FSANZ's proposed approach to remove the permission based on FSANZ's assessment and the principle to minimise use of food additives in these products.

In contrast, industry was not supportive, noting the removal of the permission in the absence of any safety concerns may be unsuitable, as it would result in the unnecessary and costly reformulation of products containing the substance. Several industry submissions noted that the additive is authorised for general use in food, e.g., the US under 21 CFR 184.1101 that allows its use in some infant products. The submitters also noted that as there was no identified risk in relation to this additive, and that products containing it have been present in the market globally for decades, any decision to remove the permission should be based on a risk assessment.

Preferred option

Based on the previous consideration and stakeholder comment, FSANZ's preferred option is to progress with the FSANZ 2021 CP1 approach, which is to remove the permission in the Code. FSANZ notes that despite the further consultation that occurred as part of FSANZ 2021 CP1, insufficient evidence was provided in relation to its current use to justify maintaining the permission.

As noted in FSANZ 2021 CP1, FSANZ reiterates that if there is a technological need for such a permission then a future application seeking such a permission could be made, noting that evidence of safety and technological need and justification will be required.

3.5.13 Summary: preferred options for food additive permissions

Table 3.5.13 Summary table of proposed food additive permissions for IFP and SMPPi

Food additive	FSANZ proposed MPL (mg/L)	
	IFP	SMPPi
Calcium carbonates (INS 170)	NP	GMP to align with EU (13.1.5.1)
Calcium citrates (INS 333)	Permit as carrier in nutrient preparations, consistent with EU MPL and with condition statement	
Calcium hydroxide (INS 526)	2000 align Codex and EU, limits for sodium, potassium and calcium	
Sodium carbonates (INS 500)	2000 to align Codex, limits for sodium, potassium and calcium.	
Sodium hydroxide (INS 524)	2000 to align Codex, limits for sodium, potassium and calcium. Consequential addition also needed to Schedule 8.	
Potassium carbonates (INS 501)	2000 to align Codex, limits for sodium, potassium and calcium.	
Potassium hydroxide (INS 525)	2000 to align Codex, limits for sodium, potassium and calcium. Consequential addition also needed to Schedule 8.	
Phosphoric acid (INS 338)	450 (as phosphorus), align EU. Additional condition statements relating to calcium/phosphorous ratio, and total levels of sodium, potassium, calcium and phosphorus, needing to meet other Code requirements	450 mg/L (as phosphorus), consistent with EU. Only for pH adjustment.
Calcium phosphates (INS 341)	Consistent with EU: Specific permission for tricalcium phosphate (INS 341(iii)) is permitted in nutrient preparations added to products (MPL in nutrient preparation 70 mg/L as phosphate).	

Sodium phosphates (INS 339) Potassium phosphates (INS 340)	450 (as phosphorus), align Codex. Additional condition statements relating to calcium/phosphorous ratio	
Citric and fatty acid esters of glycerol (CITREM) (INS 472c)	9000 for liquid products, and 7500 for powdered products, align Codex and EU.	
Starch sodium octenylsuccinate (INS 1450)	NP	20,000, align Codex and EU. Condition statement for use in products based on hydrolysed protein and/or amino acids.
Locust bean (carob bean) gum (INS 410)	1000, maintain current permission, align Codex.	5000 to achieve technological purpose, altered. Include a condition statement: for use from birth onwards in products for reduction of gastro-oesophageal reflux, align EU
Pectins (INS 440)	NP	2000 with condition statement: for hydrolysed protein liquid formulas, align Codex 5000 for gastro-intestinal disorder formulas, amended. Condition statement: for use from birth onwards in products used in case of gastro-intestinal disorders, align EU.
Xanthan gum (INS 415)	NP	1000, align Codex, but condition statement: in powdered infant formula products that contain hydrolysed protein and/or amino acid based infant formula only. 1200, align EU, with condition statement: for use from birth onwards in products based on amino acids or peptides for patients with gastrointestinal tract problems, protein mal-adsorption, or inborn errors of metabolism.
Guar gum (INS 412)	NP	1000, maintain current permission, align Codex and EU but with condition statement: in liquid infant formula containing hydrolysed protein only. 10,000, align EU, with condition statement: for use from birth onwards in products containing hydrolysed proteins, peptides or amino acids.
Sodium alginate (INS 401)	NP	1000, align EU, with condition statement: from 4 months onwards in products for dietary management of metabolic disorders and for general tube-feeding.
Sodium carboxymethylcellulose	Not proposing to permit use of sodium carboxymethylcellulose in any infant formula product.	

(INS 466)	Seeking any information from stakeholders on current use and levels to inform a final decision	
Sucrose esters of fatty acids (INS 473)	NP	120, align EU, condition statement: only products containing hydrolysed proteins, peptides or amino acids
Diacyltartaric and fatty acid esters of glycerol (INS 472e)	Remove the permission in the Code, align Codex and EU.	

NP= Not Permitted

3.6 Clarifications to the Code

3.6.1 Previous consideration

FSANZ 2021 CP1 sought stakeholders' comments on the following points of clarification to the Code:

1. Hydroxypropyl starch – FSANZ proposed to amend the MPL for hydroxypropyl starch for soy-based infant formula to correct what is generally understood by all stakeholders to be an error. The proposal was to reduce the MPL of 25,000 mg/L to 5000 mg/L to be consistent with the original intent of Proposal P93 and Codex.

2. Carrageenan – FSANZ noted that there was a permission for carrageenan in the Code for liquid infant formula (sub-class 13.1.2), but that there was no permission for its use in soy-based infant formula (sub-class 13.1.1), potentially resulting in a lack of clarity regarding permission for use in liquid, soy-based infant formula. FSANZ investigated the original drafting intent and considered information provided by submitters on the technological function for carrageenan in liquid infant formula (both soy-based and milk-based). On this basis, FSANZ proposed to clarify permissions in the Code for carrageenan such that it is clear that it may be used in all liquid infant formula, including soy-based liquid infant formula.

3. Starches (INS 1413, 1414 and 1450) – FSANZ proposed to remove the condition statement 'Section 1.3.1—6 applies' next to these three starches within food classes 13.1.1 and 13.1.3. Section 1.3.1—6 (Food additives performing the same purpose) is sometimes known as the 'unity principle'[8]. The condition statement is not required since section 1.3.1—6 applies to all food classes and food additives and there is no need to make a special case for infant formula.

For further details on the earlier consideration of these issues and stakeholder views, refer to FSANZ 2021 CP1.

3.6.2 Stakeholder views

Four submitters (two government, two industry) provided comments, expressing support for FSANZ's proposed approaches to dealing with each of these three issues.

[8] Section 1.3.1—6 (Food additives performing the same purpose) states: 'If a food contains a mixture of substances that are **used as food additives* to perform the same technological purpose, the sum of the proportions of these substances in the food must not be more than 1.'

3.6.3 Preferred option

Based on previous considerations and stakeholder comments, FSANZ's preferred options are to:

1. Hydroxypropyl starch – reduce the MPL for hydroxypropyl starch for soy-based infant formula to 5000 mg/L.

2. Carrageenan – clarify permissions in the Code for carrageenan such that it is clear that it may be used in all liquid infant formula, including soy-based liquid infant formula.

3. Starches (INS 1413, 1414 and 1440) – remove the condition statement 'Section 1.3.1—6 applies' next to these three starches within food classes 13.1.1 and 13.1.3.

3.7 Updates to nomenclature and INS numbers

3.7.1 Previous consideration

FSANZ noted that there are some inconsistencies in nomenclature and INS numbers used in the Code and Codex. However, correcting these inconsistencies in the Code to better align with Codex would have flow-on consequences for other food classes. As such, FSANZ advised that this issue would not be considered further as part of this proposal, a decision that was supported by stakeholders responding to FSANZ 2016 CP.

3.7.2 Stakeholder views

Five submitters (two government, three industry) provided comments, expressing support for FSANZ's proposed approach to retain the current nomenclature and INS numbers. This was in noting that such changes will have impacts on all other food classes with labelling and cost impacts, which have not been consulted on with industry. Any major changes would need to be part of a dedicated proposal and widely consulted upon.

3.7.3 Preferred option

Based on previous considerations and stakeholder comments, FSANZ's preferred option is to refrain from making changes to nomenclature and INS numbers as part of this proposal.

4 Processing aids

4.1 Previous consideration

Processing aids were covered in FSANZ 2016 CP (FSANZ 2016) including a comparison between Codex and the Code for processing aids. Codex does not have a processing aid standard. The conclusion of the FSANZ 2016 CP was we were unaware of issues relating to permissions for processing aids. The Code does not specify processing aids that can only be used in the manufacture of infant formula products and no changes to current approaches were proposed. FSANZ 2021 CP1 noted that two submitters to the FSANZ 2016 CP supported this approach. We therefore concluded that processing aids used in the manufacture of infant formula would not be considered further.

4.2 EU regulations for hydrolysed protein

EU regulations in 2006 set a specification for the use of enzyme processing aids for dairy processing and preparation of hydrolysed protein used in infant formula products. (COMMISSION REGULATION (EC) No 1609/2006[9]) In 2021, new EU regulations for enzyme processing aids were adopted. The main change from 2006 was that new enzyme processing aids could be used if assessed through a pre-market approval process by a national authority for safety and stability (COMMISSION IMPLEMENTING REGULATION (EU) 2020/1823 of 2 December 2020[10] and guidance[11]).

In Australia and New Zealand, there is a general prohibition on the use of processing aids in food unless expressly permitted in S18. Guideline 3.3.2 in the Application Handbook lists requirements for the pre-market assessment of enzyme processing aids. This includes a requirement that applicants provide a list of foods or food groups that is likely to contain the processing aid or its metabolites, and the list should be based on the food classification system used in S15-5 (infant formula products is 13.1.1). If an application included the infant formula category, then a "budget method calculation" would be undertaken for the relevant population group.

4.3 Preferred option

The Code already includes a standard for processing aids that covers enzyme processing aids used in dairy processing. Therefore, FSANZ proposes no changes to the current standards for enzyme processing aids.

5 Contaminants

5.1 Introduction

Chemical contaminants can be naturally occurring components of foods, found naturally in the environment, produced by microorganisms, or produced through industrial activities. It is not always possible to completely eliminate the presence of very low levels of contamination in foods, however risk management measures can help minimise human exposure.

Standard 1.4.1 – Contaminants and natural toxicants and Schedule 19 – Maximum levels of contaminants and natural toxicants as well as Standard 2.9.1 – Infant Formula specify the maximum levels (MLs) of a number of contaminants for infant formula products. Previous consultations for P1028 outlined the principles that underpin the approach to setting MLs in the Code (FSANZ 2016, FSANZ 2012). Comparison between the requirements in the Code and international regulations and standards were also reviewed. Therefore, please refer to FSANZ 2021 CP1 for further details.

[9] COMMISSION REGULATION (EC) No 1609/2006 of 27 October 2006 authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cow's milk protein for a two-year period https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1609&from=HR

[10] Commission Implementing Regulation (EU) 2020/1823 of 2 December 2020 amending Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1823&from=EN

[11] Scientific Guidance for the submission of dossiers on Food Enzymes EFSA Journal 2021;19(10):6851https://www.efsa.europa.eu/en/efsajournal/pub/6851

MLs will be specified in the Code:

– only for those contaminants that present a significant risk to public health and safety
– only for those foods that are major contributors to total dietary exposure of the contaminant
– where those MLs are practically achievable
– to be 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.

In the absence of a prescribed ML for a food-contaminant combination, the concentration of all contaminants in food should be kept to as low as reasonably achievable (ALARA).

The FSANZ 2021 CP1 presented proposed approaches on three issues:

1. Maximum levels for contaminants
2. MLs for infant formula in the dry powder form or as consumed
3. Contaminant definition.

As per Section 3 of this paper on food additives, for most issues, a summary of previous considerations, submitter comments to FSANZ 2021 CP1, a discussion (where relevant), and FSANZ's preferred option for reviewing the Code is presented. For further details regarding previous FSANZ considerations, including the outcomes of FSANZ's risk assessments, please refer to the 2021 Consultation paper.

5.2 Maximum levels for contaminants

5.2.1 Stakeholder views

Of the 20 submissions received in response to FSANZ 2021 CP1, 16 commented on issues related to chemical contaminants, including FSANZ's proposed approaches.

The government and health professional organisation supported an approach to establishing MLs that protect infants' health and safety, noting the preamble to EU Commission Regulation 1881/2006 – Setting maximum levels for certain contaminants in foodstuffs. Infants are a vulnerable population group and for this reason there is a greater level of risk that needs to be managed. MLs should be set at a level that is practically achievable based on a contemporary risk assessments.

Harmonisation with EU and/or Codex contaminants where safe and appropriate was supported, noting that this would ensure both imported and Australian infant formula contaminant levels remain low. Whilst one government submitter sought more information on what, if any, are the potential risks of not harmonising with more stringent international MLs for trade, another government submitter noted that aligning MLs would help avoid a situation where products that exceed contaminant levels overseas are able to be sold in Australia.

In general, industry supported FSANZ's risk-based approach for establishing MLs, and indicated general support for FSANZ's proposals. One industry submitter expressed concern that with any changes to current MLs, industry may have to potentially retest ingredients and/or finished goods for contaminants. Sourcing compliant replacement ingredients may impose a trade barrier and, as a result, reformulations of current products may be necessary.

Table 4.2 provides a summary of submitters' views regarding the harmonisation of MLs for a number of specific contaminants as identified in previous consultation papers, together with a discussion (where relevant) and FSANZ's preferred option for reviewing the Code. For some contaminants, a more detailed discussion is also provided in Sections 5.2.1 – 5.2.6 under the table.

For a comparison of Code, Codex and EU MLs for infant formula contaminants see Table 3.1 of the FSANZ 2021 CP1.

Table 4.2 Summary of submitter comments to proposed approach in CP1 for contaminant MLs, FSANZ response and preferred option

Issue and proposed approach from FSANZ 2021 CP1	Raised by	FSANZ response and preferred option
Acrylonitrile (No change to the ML of 0.02 mg/L for all foods including infant formula products.)	5 submissions (4 industry, 1 government). All supportive of FSANZ's proposed approach. Submitters noted that this ML is listed in S19—5 for all foods including infant formula products. The ML aligns with Codex; the EU has no ML.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no change to the ML of 0.02 mg/L for all foods including infant formula products.
Aluminium (Move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19.)	4 submissions (3 industry, 1 government). All supportive of moving the ML for aluminium from Standard 2.9.1 to Standard 1.4.1 and Schedule 19.	Preferred option is to proceed with CP1 approach: move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19.
Aluminium (Retain single ML of 0.05 mg/100mL for IFP, including soy based infant formula.)	5 submissions. (4 industry, 1 government). Industry was not supportive of the FSANZ 2021 CP1 approach of a single ML for all infant formula. Rather, there was support for the status quo, or else for alignment with Codex and international regulations (which do not have MLs for aluminium in infant formula). Government supported the FSANZ 2021 CP1 approach suggesting that retaining the ML will keep exposure as low as reasonably achievable. See also Discussion section below.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: retain single ML of 0.05 mg/100mL for aluminium for IFP including soy-based. See Discussion section below.
Arsenic (No ML for arsenic (inorganic) or 'arsenic, total' for infant formula products, consistent with Codex. Monitor and review (for rice that may be used as an ingredient in infant formula)	6 submissions (4 industry, 1 government, 1 health professional). All supportive noting: - MLs have not been established by international regulatory agencies - Recent surveys show low/no detected levels - Continued monitoring should be undertaken noting the increasing popularity of rice-based formula.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no ML for infant formula products.
Cadmium 2 options for consideration: • Do not establish an ML	12 submissions (7 industry, 4 government, 1 health professional). In general, industry supported option 1 noting that dietary exposures are not considered likely to be of health concern and there is no data available for soy-based formula. If the option of establishing an ML is pursued, then FSANZ should use a risk-based approach rather than simply aligning with the EU. Government and health professionals supported option 2 noting	Preferred option is to proceed with option 1: no ML to be established. See also Discussion section below.

Issue and proposed approach from FSANZ 2021 CP1	Raised by	FSANZ response and preferred option
• Harmonise with EU MLs noting that soya protein can contain higher cadmium levels due to the plant's uptake from the soil.)	that harmonising with the EU is appropriate for both safety and trade. See also Discussion section below.	
Lead (Reduce the ML for lead from 0.02 mg/L to 0.01 mg/L in IFP and apply this level on a ready-to-feed basis. Align with Codex CXS 193-1995.)	6 submissions (4 industry, 2 government). All supportive of FSANZ's proposed approach. Two submissions noted that updated lead levels in food additives used in infant formulas, as set by JECFA, would also apply, as JECFA monographs are referenced in Schedule S3-2 of the Code.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: reduced ML from 0.02 mg/L to 0.01 mg/L in IFP and apply to infant formula on a ready-to-feed basis.
Melamine (Do not establish an ML, despite ML in place for Codex.)	6 submissions (4 industry, 2 government). All supportive of FSANZ's proposed approach, with one submitter noting that an ML should not be included in the Code for a substance that should not be present in infant formula products.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no ML to be established.
Tin & inorganic tin (No change to ML of 250 mg/L which would also apply to infant formula products. Approach is consistent with Codex.)	5 submissions (4 industry, 1 government). Industry supported FSANZ's proposed approach. One submitter suggested that a definition for canned foods be provided. Government raised the concern that FSANZ had not considered the EU ML for inorganic tin of 50 mg/L. See also Discussion section below.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: retain current ML of 250 mg/L. See also Discussion section below.
Vinyl chloride (No change to the ML of 0.01 mg/L)	4 submissions (3 industry, 1 government). All supportive of FSANZ's proposed approach, which aligns with Codex.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no change to the ML of 0.01 mg/L.
Aflatoxins B1 and M1 (Do not establish MLs. The Codex Code of Practice CAC/RCP 45-1997 is a useful risk management tool.)	6 submissions (4 industry, 2 government). Industry supports the FSANZ 2021 CP1 approach noting CAC/RCP 45-1997 is a useful tool. Government does not support the FSANZ 2021 CP1 approach, noting that harmonisation with the EU will prevent the export of products to Australia that do not meet EU MLs. See also Discussion section below.	Preferred option is to proceed with CP1 approach: no ML to be established. See Discussion section below.
Ochratoxin A (Do not establish MLs.)	6 submissions (4 industry, 2 government). Industry supports the FSANZ 2021 CP1 approach. Government does not support the FSANZ 2021 CP1 approach for reason given above for aflatoxins. Submitters also noted that possible mycotoxin contamination in plant-based ingredients had not been investigated.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no ML to be established. See Discussion section below.

Issue and proposed approach from FSANZ 2021 CP1	Raised by	FSANZ response and preferred option
	See also Discussion section below.	
Polycyclic aromatic hydrocarbons (PAH) (Do not establish an ML.)	7 submissions (4 industry, 3 government). Industry supports the FSANZ 2021 CP1 approach, with one submitter noting that it is considered unlikely that levels in infant formula in Australia are a health concern. Government does not support the FSANZ 2021 CP1 approach for reasons given above for mycotoxins. Submitters also noted that harmonising with the EU ML should be achievable and will protect infant health and safety. See also Discussion section below.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no ML to be established. See Discussion section below.
Perchlorate (Do not establish an ML.)	7 submissions (4 industry, 3 government). Industry supports the FSANZ 2021 CP1 approach. Government does not support the FSANZ 2021 CP1 approach for reasons given above for mycotoxins. See also Discussion section below.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: no ML to be established. See Discussion section below.
Chloropropanol, glycidol and their esters (Do not establish an ML. Continue to work with international agencies, sharing data and information with a view to identifying further mitigation measures.)	7 submissions (4 industry, 3 government). Industry supports the FSANZ 2021 CP1 approach to not establish MLs, based on the outcomes of the preliminary assessment. Government does not support the FSANZ 2021 CP1 approach for the same reasons given for mycotoxins. Rather, there was support for aligning with the EU ML and also doing a review of international data. See also Discussion section below.	Preferred option is to proceed with the FSANZ 2021 CP1 approach: **no MLs** to be established. See Discussion section below.

5.2.2 Acrylonitrile, arsenic, lead, melamine, vinyl chloride

Since all submitters agreed with the approach proposed in FSANZ 2021 CP1 for these contaminants, these were not considered further and the preferred option is to progress with the FSANZ 2021 CP1 approach (Table 4.2).

5.2.3 Aluminium

Previous consideration

Paragraph 2.9.1—8(c) includes MLs for aluminium in soy based and all other infant formula of no more than 0.1 mg/100mL and of 0.05 mg/100mL, respectively. The less restrictive ML for aluminium in soy-based formula was set noting that there was evidence to indicate that the lower ML may not be achievable for soy protein isolate (ANZFA 1999b).

In 2016 FSANZ proposed to retain an ML for aluminium despite there being no ML in the Codex CXS 193-1995, and sought information from stakeholders on achievability and cost and trade implications of setting a single ML of 0.05 mg/100 mL for infant formula (including soy-based).

Stakeholder views

Five submissions (four industry, one government) provided comments on FSANZ's proposed approach to MLs for aluminium. Industry submitters did not support the FSANZ 2021 CP1 proposed approach of a single ML of 0.05 mg/100 mL for infant formula, including soy-based. Submitters supported the status quo: MLs of 0.1 mg/100 mL in soy based formula and 0.05 mg/100mL in all other infant formula, or else supported the view that the Code should align with Codex and international regulations (which do not include MLs for aluminium in infant formula).

Other arguments supporting their opposition to the proposed approach were:

1. It was not clear how FSANZ had calculated the ML of 0.05 mg/100 mL from the JECFA (2011) or EU (2017) HBGV. It was noted that dietary exposures (as measured in the most recent Australian Total Diet Surveys in 2011 and 2014) did not come close to any toxicological limits.

2. Dietary intake information provide to support the ML suggested that older infants' (9 months) exposure to aluminium came from baked goods (e.g. muffins, scones, cakes and slices) and not infant formulas. Baked goods are irrelevant to the dietary intake of 0-6 month olds where infant formula is their sole source of nutrition. Any assessment of risk would need to take this into consideration.

In light of these comments, industry requested further information that helps demonstrate what (if any) public health benefit the ML achieves.

In contrast, government supported the FSANZ 2021 CP1 approach, citing evidence from the 23rd and 24th ATDS that concentrations approached the ML of 0.05 mg/100 mL. As such, retaining the ML would help keep exposure within safe levels of dietary exposure.

Discussion

In response to submitters' query regarding how the ML of 0.05 mg/100 mL was calculated, this ML was set as part of Proposal P93 – Review of Infant Formula, following a toxicological

assessment of the data available at that time, including from Australian Market Basket surveys and industry (ANZFA 1999b). In the FSANZ 2021 CP1, this level was put forward as the preferred option noting that it is more protective and there is no indication that this level cannot be met by manufacturers.

As part of the FSANZ 2016 CP, FSANZ's conducted a risk profile of aluminium based on the Provisional Tolerable Weekly Intake (PTWI) of 2 mg/kg bodyweight (bw) established by JECFA and using occurrence data from the 23rd and 24th ATDS. In response to submitters' comments at dot point 2 above, it should be noted that dietary exposure to aluminium from infant formula alone was calculated. It was found to be well below the aluminium PTWI, using an upper estimate of infant formula consumption and the highest aluminium level found in the ATDS (0.53 mg/kg). Dietary exposure calculated using the highest ML in Standard 2.9.1 (1 mg/L for soy-based formula) and the same consumption amount was 70% of the PTWI. The 2016 risk profile concluded that aluminium limits in Standard 2.9.1 were considered to be health protective. Aluminium has not been analysed in any subsequent ATDS.

FSANZ 2021 CP1 made reference to the findings of the 2016 New Zealand Total Diet Study (NZTDS), regarding infants' dietary exposures to aluminium, which exceeded the PTWI. Again in response to submitters' comments at dot point 2 above, FSANZ acknowledges that infants in this study were aged from 6-12 months, and that the higher levels of exposure were mostly from baked goods and possibly from flour containing aluminium based raising agents, not infant formula. The report did not include separate exposure estimates for infant formula as the sole source of nutrition. It should be noted that the limit of reporting for infant formula was 1 mg/kg = 0.1 mg/100g, which is equivalent to the ML for soy-based formula and higher than the ML for other infant formula. Results were at, or below, the limit of reporting. As such, an accurate picture of actual levels cannot be ascertained from this survey and aluminium had not previously been analysed for in the NZTDS, so no earlier data is available, nor trend analysis possible.

FSANZ is of the view that, in the absence of any new data or information, the rationale presented in FSANZ 2016 CP and FSANZ 2021 CP1 is still valid. Specifically:

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

Notably, FSANZ is unaware of any new data for aluminium in infant formula subsequent to the 24th ATDS. The 2016 NZTDS remains the most current published New Zealand study, however, it did not include data for soy-based infant formula. FSANZ is of the view that in the absence of contemporary data to inform aluminium MLs, it should apply a conservative approach to protect this vulnerable population. In this context, Note 4 to Standard 1.4.1 – Contaminants and natural toxicants[12] remains valid.

[12] Limits have been set under this Standard when it has been determined that there is a potential risk to public health and safety if the prescribed limits are exceeded, that should be managed by a standard. This Standard is to be read in the context of the requirements imposed in the application Acts that food must be safe and suitable for human consumption. For example, the concentration of contaminants and natural toxicants should be kept as low as reasonably achievable.

FSANZ notes that submitters have previously argued that the implications of retaining an ML in the Code in the absence of equivalent international regulations could result in a situation where additional quality assurance procedures are imposed on manufacturers of formula destined for sale in Australia and New Zealand, including compliance testing of aluminium levels for each batch of infant formula. FSANZ notes that as there are already MLs for aluminium in the Code, its preferred approach is unlikely to have an impact on existing quality assurance procedures.

Preferred option

Based on submitters' comments and FSANZ's assessment, FSANZ's preferred option is to progress with the FSANZ 2021 CP1 approach, which is to retain a single ML of 0.05 mg/100 mL for infant formula products including soy-based formula.

5.2.3 Cadmium

Previous consideration

There is no Codex or Code ML for cadmium in infant formula, however the EU has established MLs based on cow's milk proteins or protein hydrolysates, and soya protein isolates alone or in a mixture with cow's milk proteins Commission Regulation (EU) 2021/1323 (10 August 2021) amending Regulation (EC) No 1881/2006. It was considered that infant formula products manufactured from soy protein isolates (alone or in a mixture with cow's milk proteins), can contain higher cadmium levels than milk-based products since soy beans naturally take up cadmium from the soil. Higher MLs were set for soya-based products.

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. However, soy-based infant formula has not been analysed for cadmium in any ATDS from the 19th ATDS (2001) onwards, nor was it analysed in the last three NZTDSs of 2003-04, 2009 or 2016, hence there is no relevant data available for this product.

FSANZ 2021 CP1 proposed two options for cadmium MLs and sought comments on the impacts of each option:

1. Do not establish an ML for infant formula in the Code on the basis that dietary exposures to cadmium in infant formula are considered unlikely to be of health concern, noting that no data is available for soy-based infant formula.

2. Harmonise with the EU MLs on the basis that soy protein isolates, alone or in a mixture with cow's milk proteins, can contain higher cadmium levels than milk-based products since soy beans naturally take up cadmium from the soil.

Stakeholder views

Twelve submissions (seven industry, four government, one health professional) provided comments on FSANZ's proposed approach to MLs for cadmium. In general, industry submitters supported option 1 noting that dietary exposures are not considered likely to be of health concern and there is no data available for soy-based formula. If the option of establishing MLs is pursued, then FSANZ should use a risk-based approach rather than simply aligning with the EU. This is in noting that the EU MLs for powder are only 2 times the liquid values – hence, in effect, the MLs for powdered products are much stricter. Therefore simply adopting the EU limits may not align with limits FSANZ would otherwise adopt using a

risk-based process. Infant formula powder is typically reconstituted using an ~7X ratio and setting a single limit (as-fed) would still serve to control cadmium levels in both liquid and powder products. It should also be noted that cadmium MLs are being reviewed in the EU with MLs for formula made from plant protein isolates other than soya likely to be introduced in the near future. These are equivalent to those that exist for soya-based formula (0.02 mg/kg and 0.01 mg/kg for powdered and liquid infant formula, respectively).

The government and health professional organisation supported option 2 noting that harmonising with the EU is appropriate for both safety and trade. In addition, harmonisation would prevent the export of products to Australia that do not meet the EU MLs. Including an ML will provide a clear threshold of protection for infants rather than relying on 'unsuitable' food provisions in state Food Acts.

Discussion

Evidence from Australian and New Zealand total diet studies indicates that levels of cadmium in infant formula (non soy-based) are low and generally consistent with those reported internationally. Concerns have been raised by industry regarding the MLs set for the powder and liquid, whereby the MLs for the powder are effectively much stricter. The preferred approach would be for FSANZ to set MLs using a risk-based approach, noting that setting a single limit for the product ready for consumption would be sufficient for controlling cadmium levels. There is no Australian or New Zealand data available for cadmium in soy-based formula to inform the establishment of an appropriate ML.

FSANZ has noted the comments made by the government and health professional organisation that harmonisation with the EU should occur to avoid the export of products to Australia that do not meet the EU MLs. As these comments reflect those made for the contaminants under Section 5.2.5 below, please see FSANZ's response under the Discussion heading of that section.

Preferred option

Based on submitters' comments and FSANZ's assessment, the preferred option is Option 1 – to not establish cadmium MLs.

5.2.4 Tin & inorganic tin compounds

Previous consideration

Schedule 19 – Maximum levels of contaminants and natural toxicants of the Code includes an ML of 250 mg/kg for tin in all canned foods. Codex has set an ML of 250 mg/kg for 'Canned foods (other than beverages), and the EU has an ML of 50 mg/kg for tin (inorganic) for 'Canned infant formulae and follow-on formulae (including infant milk and follow-on milk), excluding dried and powdered products'.

As tin is used to cover the inside of food containers (ANZFA, 1999b), and most powdered infant formula is packaged as a food in a can, FSANZ considered that the Code ML captures infant formula. Therefore, CP1 proposed no change to the ML of 250 mg/kg.

Stakeholder views

Five submissions (four industry, one government) provided comments on FSANZ's proposed approach to the ML for tin. Industry submitters supported FSANZ's approach. One submitter noted that there is no definition of canned foods in the Code; the inclusion of a statement addressing this in Standard 2.9.1 would assist in clarifying this requirement.

The government submitter raised the concern that FSANZ had not assessed whether the EU ML for inorganic tin of 50 mg/kg for liquid infant formula products should be adopted in the Code. Given the reliance on imported special infant formula from the EU, which includes liquid formulas, and the potential for an increasing market in ready-to-feed liquid formula, harmonising with EU MLs for these products should be considered, to future proof the Standard and protect infants.

Discussion

As part of the FSANZ 2016 CP, FSANZ's conducted a risk profile (Attachment A2.4 of 2016 SD2, being a summarised risk assessment) of tin and inorganic tin compounds based on a PTWI for inorganic tin of 14 mg/kg bw set by JECFA in 1989 (WHO 1989). There were minimal data on the levels of inorganic tin in infant formula. In the 19th ATDS, there were no detections of tin in 9 infant formula samples using a method with an LOR of 0.02 mg/kg (ANZFA 2001). Assuming a tin concentration in infant formula at this LOR and an upper estimate of daily infant formula consumption (200 mL per kg bw), FSANZ calculated the dietary exposure to tin to be approximately 0.03 mg/kg bw/week or 0.2% of the PTWI.

Analytical tests for tin in infant formula have not been undertaken in any subsequent ATDS. However, tin was analysed in the 2016 NZTDS. In this study, none of the samples had concentrations above the LOR of 0.05 mg/kg.

Although limited, Australian and New Zealand data indicate low levels of tin in infant formula. FSANZ's 2016 risk profile determined that dietary exposure to tin from infant formula products is very low relative to the PTWI, and is not considered to pose a health risk. As such, FSANZ is of the view that an additional ML for inorganic tin for a subset of products is unlikely to have any practical impact on the existing level of health protection. Therefore, FSANZ is proposing to proceed with the FSANZ 2021 CP1 approach, which involves no changes to the current ML of 250 mg/kg in the Code for all canned foods.

FSANZ notes the industry submitter's comment to include a statement in Standard 2.9.1 clarifying that the ML for tin for canned foods is also applicable to infant formula. FSANZ considered the suggestion but it does not believe such a statement is required or needed to be added into the Code, or specifically Standard 2.9.1. Infant formula manufacturers need to ensure they comply with all relevant requirements of the Code, like all food manufacturers.

Preferred option

Based on submitters' comments and FSANZ's assessment, FSANZ's preferred option is to proceed with the FSANZ 2021 CP1 approach, which is to retain the current ML of 250 mg/kg.

5.2.5 Aflatoxins B1 and M1, Ochratoxin A, Polycyclic aromatic hydrocarbons, Perchlorate

Previous consideration

Aflatoxins B1 and M1

Schedule 19 of the Code includes MLs for aflatoxins in peanuts and tree nuts only. Similarly, Codex has not established an ML for infant formula. In contrast, the EU specifies an ML for M1 in infant formula and follow-on formula, and MLs for both M1 and B1 in dietary foods for special medical purposes intended specifically for infants.

FSANZ 2021 CP1 noted that there was limited information on the levels of aflatoxins in infant

formula in Australia and New Zealand, and internationally. In the 23rd ATDS, aflatoxin M1 was not detected in infant formula samples, and levels in general foods were low.

Codex has developed several Codes of Practice that relate to the prevention/ reduction of mycotoxins, including the Code of Practice (COP) for the Reduction of aflatoxin B1 in raw materials and supplemental feeding stuffs for milk producing animals (CAC/RCP 45-1997). FSANZ considers this a useful risk management tool for manufacturers of infant formula products. In view of these considerations, together with previous stakeholder support for not establishing MLs for aflatoxins, CP1 proposed not to establish MLs for these substances.

Ochratoxin A

No MLs have been set for ochratoxin A in Schedule 19 of the Code. The EU includes an ML for dietary foods for special medical purposes intended specifically for infants. Codex specifies an ML for raw wheat, barley and rye. The Codex General Code of Practice for the prevention and reduction of mycotoxin contamination in cereals (CAC/RCP 51-2003) contains an annex on the prevention and reduction of contamination by ochratoxin in cereal grains (Annex 3).

FSANZ 2021 CP1 noted that there was limited information on ochratoxin A in infant formula sold in Australia and New Zealand. In the 23rd ATDS ochratoxin A was not detected in any of the foods for which it was analysed. Internationally, only low levels of ochratoxin A contamination of infant formula had been reported. On this basis, FSANZ considered it unlikely that levels of ochratoxin A in infant formula in Australia and New Zealand would be a health concern. In view of these considerations, together with previous stakeholder support for not establishing an ML for ochratoxin A, CP1 proposed not to establish an ML for this substance.

Polycyclic aromatic hydrocarbons (PAH)

No MLs have been set for PAH in Schedule 19 of the Code or by Codex. The EU includes an ML for infant formulae and follow-on formulae, including infant milk and follow-on milk of 1.0 µg/kg.

There is a Codex Code of Practice for reducing PAHs from smoking and direct drying (CAC/RCP 68-2009). Whilst it is not specific to the reduction of PAHs in infant formula productions, CP1 stated that the COP could assist manufacturers to reduce PAH levels in raw materials used in the production of infant formula, for example, cereals and vegetable fats and oils.

FSANZ 2021 CP1 noted that FSANZ held no data on PAH levels in infant formula products. An analytical survey on PAHs in Australian foods published in 2010 found no detectable PAH above the LOD in infant formula (FSANZ, 2010). Therefore, FSANZ determined that there was no appropriate scientific basis to support harmonising with the EU ML for PAHs.

Perchlorate

There are no Code or Codex MLs for perchlorate, however, in July 2020, the EU amended Regulation (EC) No 1881/2006 to include an ML for perchlorate of 0.01 mg/kg for infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula[13].

FSANZ 2021 CP1 noted FSANZ held no data on perchlorate levels in infant formula

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0685&rid=3

products. Therefore, it was not possible to establish an appropriate scientific basis to establish an ML for perchlorate to harmonise with the EU ML.

Stakeholder views

There were seven submissions that provided comments on FSANZ's proposed approach, which was to not establish MLs for Aflatoxins B1 and M1, Ochratoxin A, PAHs and perchlorate. These included 4 from industry and 3 from government.

Industry submitters supported the FSANZ 2021 CP1 approach. For Aflatoxins B1 and M1, they concurred that CAC/RCP 45-1997 was a useful risk management tool. For PAH, one industry submitter noted that it was unlikely that levels in infant formula in Australia are a health concern.

In contrast, government submitters did not support the FSANZ 2021 CP1 approach for these substances. Views were similar to those expressed for cadmium. It is important to align with EU MLs given that many special infant formulas (current categorised as IFPSDU) that are available in Australia and New Zealand are imported from the EU. Aligning with the EU would help prevent the potential import of rejected EU product.

In addition, for ochratoxin A, a government submitter noted that industry innovation is resulting in new plant-based ingredients such as pea protein and that previous analyses of milk-based formula may not adequately reflect mycotoxin contamination that can occur in plant-based ingredients. For PAH, submitters suggested harmonising with the EU ML of 1.0 µg/kg in IFPSDU to protect infant health and safety, noting local products should have no problems achieving this based on FSANZ's assessment.

Discussion

FSANZ has considered the comments made by government supporting the establishment of MLs to align with those in the EU, so as to avoid the export of products to Australia that do not meet EU MLs. However, FSANZ's proposed approach remains unchanged from the FSANZ 2021 CP1, which is to not establish MLs for aflatoxins B1 and M1, ochratoxin A, PAH and perchlorate.

FSANZ acknowledges that one of the primary goals of P1028 is to undertake a review of existing provisions in the Code to improve harmonisation with Codex food standards and European regulations to facilitate the importation of infant formula products, especially special infant formulas, which generally are not manufactured in Australia and New Zealand. However, in making determinations regarding MLs for contaminants in infant formula, there are several other principles underpinning the establishment of MLs (as outlined in Section 5.1 of this paper) that FSANZ must take into account.

One notable example in this paper where alignment with international regulations was not the primary consideration involves FSANZ's review of aluminium MLs. Government submitters supported the proposed approach to retain a single ML, noting that it would keep exposure to within safe levels. This was despite there being no Codex or EU ML at this time.

FSANZ is of the view that the four contaminants under consideration do not meet these guiding principles for setting MLs. The limited available data in both Australia and internationally does not give rise to any public health and safety concerns. In addition, when considering the levels analysed in the 23rd ATDS (for mycotoxins) and the PAH analytical survey, there is no basis on which to set MLs for the purposes of keeping levels to ALARA. Further, there are several Codex COPs in place, which are useful risk management tools for infant formula manufacturers. It is also worth noting that the current situation whereby there

are EU MLs but no equivalent Code MLs has been in place for some time, and FSANZ has not received any advice from the relevant enforcement agencies indicating that the import of rejected EU product is occurring. In all, FSANZ reiterates that it cannot establish an appropriate scientific basis for setting MLs to harmonise with those of the EU for these four contaminants.

FSANZ has noted the comment made by a government submitter regarding the potential mycotoxin contamination of alternative plant-based ingredients e.g. pea protein, which is not reflected in the existing analytical data for milk-based formula. In response to this comment, FSANZ advises that CP3 proposes to define the protein source, where any new protein source (including plant-based protein sources) would require a pre-market approval before the product could be legally sold within Australia and New Zealand. This would include a consideration of potential contaminants.

Preferred option

Based on submitters' comments and FSANZ's assessment, FSANZ's preferred option is to proceed with the FSANZ 2021 CP1 approach, which is to not establish MLs for aflatoxins B1 and M1, ochratoxin A, PAH and perchlorate.

5.2.6 Chloropropanol, glycidol and their esters

Previous consideration

These contaminants were not considered in the 2016 or 2017 discussion papers. Whilst there are no Codex MLs, CP1 noted that a Codex Code of Practice for reducing 3-MCPD esters and glycidyl esters in refined oils and products made with refined oils (including infant formula) had been developed and adopted in 2019 (CXC 79-2019).

The EU has set a regulatory limit for glycidyl esters (as glycidol) in liquid infant formula (i.e. ready-to-consume) of 6.0 µg/kg (Commission regulation (EU) 2018/290). In September 2020 the EU also set MLs for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) in liquid infant formula of 15 µg/kg (Commission regulation (EU) 2020/1322). This ML is to be reviewed in view of lowering within two years from the date of application.

FSANZ 2021 CP1 noted that New Zealand Food Safety (NZFS), with the input of FSANZ, had coordinated an analytical survey of 3-MCPD and glycidyl esters in cooking oils and infant formula, the results of which were published in March 2020. Using the survey findings, FSANZ undertook a preliminary risk assessment of dietary exposure to 3 month old infants, to identify any potential health and safety risks. Estimated dietary exposures to 3-MCPD esters indicated that there were no public health concerns at current exposure levels. For glycidyl esters, based on the exposure estimates, it was noted that the margin of exposures were within the range considered to be of possible concern by JECFA (WHO 2017). However, FSANZ determined that the preliminary nature of the survey limited the potential to draw any firm conclusions.

There are currently a range of measures in place to support a continued reduction of levels in edible oils (and, as such, foods made with edible oils including infant formula). In addition to the Codex COP, an Industry Toolbox (BLL and Food Drink Europe) has been developed, which includes a number of mitigation tools to assist industry to continue to reduce levels of 3-MCPD esters and glycidyl esters in food to ALARA.

Based on the outcomes of the preliminary risk assessment, and in light of the measures already in place to assist manufacturers in preventing or reducing levels levels of 3-MCPD esters and glycidyl esters in food, CP1 proposed to not set any MLs for these contaminants.

FSANZ would continue to collaborate with international agencies, sharing data and information, with a view to identifying further mitigation measures.

Stakeholder views

Seven submissions (four industry, three government) provided comments on FSANZ's proposed approach to MLs for 3-MCPD esters and glycidyl esters. Industry submitters supported the proposal to not establish MLs, based on the outcomes of the preliminary assessment.

In contrast, government submitters did not support FSANZ's proposed approach, for the same reasons given for the contaminants discussed in Section 4.2.5 above and cadmium, i.e., FSANZ should align with the EU to help prevent the potential import of rejected EU product. In particular, there was support for aligning with the EU ML for liquid formula and for FSANZ to consider appropriate MLs for powdered products for glycidyl esters based on FSANZ's analytical findings. One submitter suggested a further review of data from international jurisdictions be undertaken before concluding that an ML is not needed.

Discussion

FSANZ has considered the comments made by government submitters regarding establishing MLs to align with the EU or else undertaking a further review of international data before concluding that an ML is not needed. However, FSANZ's preferred option remains unchanged from the FSANZ 2021 CP1. The preliminary nature of the NZFS analytical survey, with non-representative sampling of infant formula and limited data points, limits the potential to draw any firm conclusions regarding the presence of any public health and safety issues arising from the presence of these contaminants in infant formula. The guiding principles for setting MLs, as discussed in Section 4.2.5 above, are also of relevance in this regard.

In addition, FSANZ is of the view that it is important to give the industry adequate time to fully implement the mitigation measures outlined in the Codex COP adopted in 2019. It is anticipated that as the industry takes full advantage of the mitigation approaches readily available to them, contaminant levels in infant formula products will continue to decrease to ALARA, without the requirement to set an ML. As mentioned above, FSANZ will continue to collaborate with its international counterparts to share the most contemporary data and information and will review its preferred approach in light of any new findings, as appropriate.

Preferred option

Based on FSANZ's assessment, FSANZ's preferred option is to proceed with the FSANZ 2021 CP1 approach, which is to not establish MLs for 3-MCPD esters and glycidyl esters.

5.3 MLs for infant formula in dry powder form or as consumed

5.3.1 Previous consideration

The default unit for all contaminant MLs in Schedule 19 is mg/kg unless specified otherwise. As such, the ML for lead, which is the only contaminant currently in Schedule 19 with an ML that is specific to infant formula, is in mg/kg.

Subsection 2.9.1—4(2) specifies that the compositional requirements of Standard 2.9.1 apply to the powdered or concentrated form that has been reconstituted as per directions or in ready to drink form. Thus, the ML for aluminium currently included in Standard 2.9.1 is expressed in terms of mg/100 mL (as consumed).

In the FSANZ 2021 CP1, FSANZ proposed approach was to apply MLs that are established for infant formula to an ‘as consumed’ form in mg/kg. A number of reasons for this approach were provided, including that it would ensure consistency with international requirements.

5.3.2 Stakeholders views

Six submissions (five industry, one government) provided comments on FSANZ’s proposed approach to express MLs in an ‘as consumed’ form in mg/kg. Four industry submitters indicated a preference for MLs to be stated on a powder basis. It was noted that this would be more practical for implementation. However, they could accept MLs to be stated for the product ‘as consumed’ (mg/kg), aligning with Codex, if other stakeholders had strong opposing views.

One industry and the government submitter were of the view that MLs for infant formula apply to the ‘as consumed’ form in mg/kg. Government supported this approach for the reasons outlined by FSANZ in CP1, including that it is consistent with international requirements.

5.3.3 Preferred option

Based on submitters’ comments and FSANZ’s assessment, FSANZ’s preferred option is to proceed with the FSANZ 2021 CP1 approach, which is to apply MLs that are established for infant formula to an ‘as consumed’ form in mg/kg.

5.4 Contaminant definition

5.4.1 Previous consideration

MLs in the Code do not usually specify a contaminant definition[14] because the identity of the toxicologically relevant contaminant to which the ML applies is clear. It was noted that for clarity, inclusion of a contaminant definition could be useful for some of the metals relevant to infant formula. Despite this, previous consultations and the FSANZ 2021 CP1 did not propose to change the definition of analytes which are common to both infant formula and other foods, rather, this issue could be addressed as part of a possible future review of Standard 1.4.1.

5.4.2 Stakeholders views

Three submissions from industry provided comments on this issue, with all three supporting FSANZ’s proposed approach.

5.4.3 Preferred option

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

5.5 Other issues raised by submitters

Table 4.5 Summary of issues raised by submitters

[14] The term ‘Contaminant definition’ is one that refers to the form of the analyte to which the ML applies or which may or should be analysed in commodities (as noted in the Explanatory Notes for Codex CXS 193 1995).

Issue	Raised by	FSANZ response
New sources of plant-based proteins for infant formula, such as pea, potato and rice, create the potential for presence of contaminants not previously found in milk-based formula. To ensure infant formula regulations are fit for purpose into the future, consideration should be given to potential contaminants in these new plant-based ingredients.	1 submission (1 government)	FSANZ 2021 CP1 proposes to define the protein source, where any new protein source (including plant-based protein sources) would require a pre-market approval before the product could be legally sold in Australia and New Zealand. This would include a consideration of potential contaminants.
The submitter expressed support for the development of a food packaging information guide to provide a consolidated and comprehensive information source for industry including information on safety issues and obligations of food businesses to use safe packaging materials.	1 submission (1 industry)	Comment in response to Section 3.6 of FSANZ 2021 CP1. Noted.

6 Lactic acid producing microorganisms

6.1 Previous consideration

There is currently a voluntary permission in Standard 2.9.1 that states:

> *L(+) lactic acid producing microorganisms may be added to infant formula product.*

FSANZ assessed the risk to the health and safety of infants—healthy, as well as preterm, low birth weight and immunocompromised—from the addition to infant formula products of any L(+) lactic acid producing microorganisms (FSANZ 2021b). FSANZ concluded that that the use of non-toxigenic L(+) lactic acid producing microorganisms in the production of fermented infant formula—where no viable bacteria are present in the final product—does not present a risk to public health and safety. On this basis, FSANZ proposed that the Standard should be clarified to ensure that only non-pathogenic L(+) lactic acid producing microorganisms are added to infant formula products. FSANZ also asked submitters the following questions:

> *Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic. Do these need to be explicitly excluded or is the base 'safe and suitable' requirement considered sufficient to manage this risk?*

6.2 Stakeholder views

Twenty submitters responded to the FSANZ 2021 CP1 on this matter. Government submitters did not support the current unrestricted permission for addition of L(+) lactic acid producing microorganisms to infant formula products. Industry submitters supported retaining the current permission. Several also commented that they did not support addition of L(+) lactic acid producing microorganisms for purposes other than acidification and, if added for any other purpose, full pre-market assessment would be needed. Views on the inclusion of the requirement for "non-pathogenic" and/or "non-toxigenic" were also divergent, with some opposing the inclusion of this requirement due to the overarching requirement for food to be safe and suitable. Some specific comments in response to 2021 submissions are listed in

Table 5.2

Table 5.2 Summary of stakeholder views on lactic acid producing microorganisms

Issue	Raised by	FSANZ response
Does not support L(+) lactic acid producing microorganisms used for purposes (e.g. probiotics) other than acidification. Use for other purposes (such as fermented infant formulas) should be subject to full risk analysis with regard to Policy Guideline principles. Disagrees with FSANZ view there are no potential public health and safety risks associated with fermented infant formulas—wants a more detailed risk assessment. Consider the regulatory status of added microorganisms into the future, given their purpose of addition may no longer be technological.	Government	Addition of L(+) lactic acid producing microorganisms during IF production employs a fermentation of lactose to lactic acid which lowers pH and prevents growth of pathogenic bacteria. It does not result in a fermented milk product per se, as regulated under Standard 2.5.3 – Fermented milk products of the Code. A fermented infant formula product would require pre-market assessment.
Supports retaining the current permission for L(+) lactic acid producing microorganisms, which is consistent with Codex.	Industry	FSANZ notes that the Codex Draft Standard for FuFOI clarifies the purpose of using L(+) lactic acid producing microorganisms for acidification.
There should not be internal inconsistencies within the Code, for example with permissions for use of microorganisms in Standard 2.5.3.	Industry	Standard 2.5.3 regulates fermented milk products. Permission for a fermented infant formula product (i.e. containing live microorganisms) requires an application to amend Standard 2.9.1.
Considers a regularly-updated list of either permitted or prohibited microorganisms could provide greater clarity for industry.	Industry	Out of scope for P1028; would have implications for other standards in the Code.
FSANZ should undertake further work on whether the addition of microorganisms to food should explicitly be prohibited unless permitted by the Code (without reliance on Standard 1.5.1 Novel foods); microorganisms only permitted to be added to infant formula if a safety assessment has concluded it is safe for the intended purpose and set any necessary conditions for its safe use.	Government	This is already the case (assuming proposed clarification of existing permission to be used for acidification). Microorganisms, including probiotics, are already a category of novel foods in Standard 1.5.1 that require pre-market assessment.
Given lack of data of safety of L(+) lactic acid producing microorganisms in pre-term infants, a warning should be applied to infant formulas that contain this microorganisms.	Medical professionals	SMPPi are specifically formulated to address a disease, disorder or medical condition, supported by generally accepted scientific data, and the composition of SMPPi can only deviate from the essential composition of infant formula products to address the product's special medical purpose. As SMPPi are subject to a restriction on sale, are generally supplied via prescription, and used under medical supervision, FSANZ considers a warning statement is not required.

Issue	Raised by	FSANZ response
No discussion on the permissions for L(+) lactic acid producing microorganisms in infant formula in the FSANZ 2016 CP; suggests additional consideration , on safety and efficacy of microorganisms in infant formula product.	Industry	FSANZ is proposing clarification to this permission (see discussion). Any other purpose for adding L(+) lactic-acid producing microorganisms to infant formula would require a pre-market assessment which covers both safety and efficacy.
Stated the use of the word 'live' (on infant formula product label in the context of live cultures) is misleading and false as infant formula powder is 'dead' unless *Cronobacter* is present. Considered this information to be marketing.	Consumer group	FSANZ notes the example provided related to a statement about reconstituting powdered formula with water that has cooled to body temperature. Water at higher temperatures may adversely affect heat sensitive ingredients such as live cultures. Consumer protection legislation must also be taken into account: information about 'live cultures' must not be false or misleading.

6.3 Discussion

The origins of the current unrestricted permission for addition of L(+) lactic acid producing microorganisms in Standard 2.9.1 goes back to the regulations in place prior to the development of joint Australia New Zealand Food Standards Code in the late 1990's.

At that time, the Australian Food Standards Code included a permission for the addition of "lactic acid" for acidification purposes (ANZFA 1999a). The *New Zealand Food Regulations 1984* (NZFR 1984) included permissions for "lactic acid" and "lactic acid producing cultures" to be added for acidification. The latter part of this permission (for acidification) was lost in the drafting of the new joint standard, Standard 2.9.1.

The addition of L(+) lactic acid producing microorganisms for acidification purposes aligns with the permission in draft Codex standard for follow up formula and the EU regulation.

Addition of L(+) lactic acid producing microorganisms is a long standing practice in manufacturing of milk products, including infant formula. Lactic acid is produced during the fermentation of lactose and allows the pH to be controlled during production and preventing growth of pathogenic bacteria (Speer 1998). Potentially L(+) lactic acid producing microorganisms can be added to an infant formula product to produce a fermented milk product (i.e. containing live organism) or for a probiotic purpose. There is significant interest in the addition of microorganisms to infant formula for probiotic purposes. Under existing requirements in the Code, such a permission would require full pre-market assessment and a new permission would fall within Standard 1.5.1 *Novel foods.* FSANZ considers that clarifying the current permission in Standard 2.9.1 to indicate the purpose of use (for acidification) would align with the original intent of the permission and would provide regulatory certainty around the addition of microorganisms for both industry and enforcement agencies.

There was a preference from some submitters, and no strong opposition from other submitters, to clarify the current permission such that only non-pathogenic L(+) lactic acid producing microorganisms may be added. FSANZ notes that Standard 1.6.1 sets microbiological limits in food (listed in Schedule 27-4, including infant formula products) and the *Compendium of Microbiological Criteria for Food* (FSANZ 2018) also sets process hygiene criteria and microbiological specifications for infant formula products. However, the Compendium microbiological limits exclude infant formula containing lactic acid producing

microorganisms. Furthermore, the Compendium provides industry guidance - it is not a legislative instrument. The risk of pathogenic L(+) lactic acid producing microorganisms being added to infant formula products may be managed to some degree by requirements in State and Territory and New Zealand food acts for food to be safe and suitable. However a specific requirement that added L(+) lactic acid producing microorganisms must be non-pathogenic could add clarity, strengthen requirements and minimises risk.

6.4 Preferred option

The preferred option is to retain the existing permission but clarify that L(+) lactic acid producing microorganisms may be added *for acidification purposes*. We also propose to clarify the permission that only non-pathogenic or non-toxigenic microorganisms may be used.

Microorganisms added to infant formula products for a probiotic purpose require premarket assessment as a novel food prior to use in infant formula.

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

7 Gene technology

Paragraphs 1.1.1—10(5)(c) and (6)(g) of Standard 1.1.1 require that, unless expressly permitted, a food for sale must not be a *food produced using gene technology*, or have as an ingredient or component of a *food produced using gene technology*. This requirement is applied to all infant formula products and Special Medical Purpose Products for Infants (SMPPi). Any food, ingredient or component produced using gene technology must be assessed for safety through FSANZ pre-market assessment before it can be sold in Australia and New Zealand. Further to this, the addition of any food, ingredient or component *produced using gene technology* to infant formula products or SMPPi must be assessed for the use specifically within infants.

The Code currently holds two permissions for *food produced using gene technology*, within infant formula products. This includes:

- voluntary addition of 2′-O-fucosyllactose (2′-FL), either alone or in combination with Lacto-N-neotetraose (LNnT) to infant formula products, and
- voluntary addition of ‘2′-fucosyllactose’ (2′-FL) produced via microbial fermentation of new genetically modified (GM) *Escherichia coli* (*E.coli*) BL21 production strains in infant formula products.

Requirements to label ingredients in IFP and SMPPi as ‘genetically modified’ are discussed in SD3 and SD4, respectively.

8 Labelling

8.1 Introduction

Division 5 of Standard 2.9.1 includes specific labelling requirements for safety, including requirements for directions for preparation and use, date marking, warning statements, prescribed names, certain age-related statements and protein source information. These provisions are necessary to ensure caregivers have sufficient information to choose an appropriate formula for their infants and prepare and use them in a safe manner.

FSANZ consulted stakeholders through FSANZ 2016 CP and FSANZ 2021 CP1 on these provisions. In the latter consultation paper, FSANZ drew on submitter comments, additional microbiological safety risk assessment and consumer evidence in its consideration of the labelling elements relating to safety. FSANZ proposed some revisions to: certain directions for preparation and use; one of the warning statements; and clarifications relating to the protein source statement.

Seventeen of the 20 submitters to FSANZ 2021 CP1 commented on labelling matters discussed below.

As noted in Section 1.2 of the CFS, the scope of P1028 has been extended to include follow-on formula. Most labelling requirements apply to both infant formula and follow-on formula. Those requirements that differ include prescribed names (section 8.9) and the statement that follow-on formula should not be used for infants aged under the age of 6 months (section 8.11).

8.2 Directions for preparation and use

8.2.1 Current regulation

Standard 1.2.6 – Information requirements – directions for use and storage outlines generic requirements for all foods (including infant formula products).

Subsection 2.9.1—19(3) requires the label on a package of an infant formula product to include directions (in words and pictures) for the preparation and use, which instruct that:

(a) each bottle should be prepared individually; and
(b) if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and
(c) potable, previously boiled water should be used; and
(d) if a package contains a measuring scoop—only the enclosed scoop should be used; and
(e) formula left in the bottle after a feed must be discarded.

While both words and pictures are required to provide clear and unambiguous directions for preparation and use (subsection 2.9.1—19(3)), the exact wording is not specified.

8.2.2 Previous consideration

Based on the assessment in section 5.3.1 of FSANZ 2021 CP1, FSANZ's proposed approach was to:

- maintain without change the mandatory requirement for directions:
  - to prepare bottles individually (paragraph 2.9.1—19(3)(a)), and
  - instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—19(3)(b)).
  - Instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used (paragraph 2.9.1—19(3)(d)).

- revise the direction for water used to reconstitute powdered formula to include the word 'cooled' (paragraph 2.9.1—19(3)(c)).

- revise the direction instructing to discard unfinished formula to include the text 'within 2 hours' (paragraph 2.9.1—19(3)(e)).

- not apply the following directions to ready-to-drink formula:

  - for each bottle to be prepared individually (paragraph 2.9.1—19(3)(a))
  - to refrigerate formula and use within 24 hours if it is made up and stored prior to use (paragraph 2.9.1—19(3)(b))
  - to use potable, previously boiled water (paragraph 2.9.1—19(3)(c)).

- to not to apply the direction to only use the enclosed scoop to concentrated and ready-to-drink formula.

8.2.3 Stakeholder views

Seventeen submitters (8 industry, 6 government, 3 health professionals) commented on FSANZ's proposed approach.

All submitters supported maintaining without change the mandatory directions to prepare bottles individually, the direction to refrigerate and use made up formula within 24 hours, and the direction instructing that only the enclosed scoop be used.

All submitters except one health professional supported the proposed approach to include a qualifier (e.g. 'cooled') about the water temperature used to reconstitute powdered formula, although there were comments about terminology.

Similarly, all submitters except one health professional supported the inclusion of a time period in the direction instructing to discard unfinished formula. However, there were differing views about the specific time proposed.

There was full support from all submitters to not apply directions to ready-to-drink formula for preparing bottles individually, storage of made up formula and use of potable previously boiled water; and to not apply the enclosed scoop direction to concentrated and ready-to-drink formula.

Responses to issues raised by stakeholders are provided in Table 8.2.3.

Table 8.2.3 Responses to submitter issues relating to directions for preparation and use

Issue	Raised by	FSANZ response
Storage of made up formula		
Suggest the direction specifies 'it must be *prepared*, refrigerated and used within 24 hours'. This would help to dispel consumers' misconception that the 'make up per bottle' relates to not being able to make up formula ahead of time.	Government (1)	FSANZ has no evidence to indicate caregivers are confused between the directions 'prepare each bottle individually' and 'refrigerate made up formula prior to use'.
Water used to reconstitute powdered formula		
Sought flexibility to use other synonyms for 'cooled' (e.g. 'room temperature' or 'lukewarm' for the following reasons: • they are currently used on labels • these synonyms reflect infant feeding guidance • they are helpful when considering the impact of water temperature on specific heat sensitive ingredients and the solubility of the powder.	Industry (4)	FSANZ is not proposing to prescribe the use of the word 'cooled'. See section 8.2.4.
Concerned that terms such as 'refrigerated' and 'chilled' may not be appropriate due to possible increased difficulty dissolving and dispersing powdered infant formula in chilled water and issues of practicality when formula is being prepared for immediate use.	Government (1)	FSANZ considers there is no safety issue. See section 8.2.4. FSANZ also notes the synonyms 'refrigerated' and 'chilled' are not currently used.
FSANZ's consumer evidence indicates some caregivers are confused. Some elements of the directions should be prescribed for consistency where there is a safety risk. These include the word 'cooled' to prevent the use of 'lukewarm' water being used to reconstitute powdered formula, and the discard time.	Government (2)	FSANZ's assessment indicates there is no safety risk regarding the use of synonyms for the temperature of the water used to reconstitute powdered formula. See section 8.2.4. Further, there is no evidence the proposed wording to discard unfinished feeds 'within 2 hours' is a microbiological risk to infants.
Measuring scoop		
Noted the consumer evidence in SD4 to FSANZ 2021 CP1 indicated a significant proportion of caregivers believed any scoop could be used. Suggestions included: prescribing the exact wording, reconsidering the existing wording or the placement of this direction.	Government (2)	FSANZ has observed the majority of products either use the exact wording or use similar wording to make it clear to only use the provided scoop, and locate the direction within the step-by-step directions. This suggests there may be other reasons why some caregivers are not using the enclosed scoop. FSANZ considers caregiver awareness and self-reported behaviour would unlikely be improved by prescribing the wording or location of this direction.
Discarding leftover formula		

Sought flexibility to use other terms such as 'within one hour' or 'immediately after a feed' for consistency with Australia infant feeding guidelines. A health professional submitter considered the wording should be consistent with Australian infant feeding guidelines.	Industry (3), Health professional (1)	Given the duration is shorter than the proposed maximum of 'within 2 hours', the use of these terms does not pose a risk to infants. FSANZ's approach to not prescribe the words of the statement aligns with the approach taken for the direction to store unused made up formula for use within 24 hours.
Considers increasing from 1 hour to 2 hours should be supported by a microbiological risk assessment.	Government (1)	The findings of additional risk assessment supported increasing to 2 hours. See section 8.2.4.
Clarity is needed on the start time for this period e.g. 'within X hours of the formula being made'	Government (1)	FSANZ notes the NHMRC infant feeding guidelines recommend formula that has been at room temperature for less than one hour (and not offered to the infant) may be stored in a refrigerator for up to 24 hours. However, there is no evidence that caregivers leave feeds at ambient temperatures before use. FSANZ has also observed most products include labelling information advising preparation just prior to feeding or using immediately after preparing.

8.2.4 Discussion

Water used to reconstitute powdered formula

Current industry practice indicates use of either the term 'cooled' or the synonyms 'room temperature' or 'lukewarm'. FSANZ has also observed some formula labels specify the water temperature at 37ºC or 40ºC.

The Australian Infant Feeding Guidelines recommend using lukewarm water to reconstitute powdered formula and the reconstituted formula should feel 'just warm' when tested on the inside of the wrist (NHMRC 2012). FSANZ understands that warmer water will more easily dissolve the formula powder, and cooler water (at room temperature or lower) would preserve the integrity of any heat sensitive ingredients.

Recently updated New Zealand Infant Feeding Guidelines recommend using cooled boiled water and shaking or swirling the bottle until the formula is mixed well (Ministry of Health 2021). FSANZ notes a recent New Zealand risk assessment recommended using water cooled to room temperature (Soboleva 2021). The New Zealand Infant Feeding Guidelines also recommend how to warm stored feeds and the formula temperature should feel just warm to the touch, which is similar to the Australian guideline.

FSANZ's previous safety assessment indicated there was no increased risk if 37ºC water is used for reconstitution in a scenario that included a total of 45 minutes preparation plus warming/cooling time, followed by a 30 minute feeding period.

Noting comments from some submitters to FSANZ 2021 CP1 about potential safety concerns if certain synonyms were used (e.g. 'lukewarm', 'room temperature'), FSANZ re-ran the risk assessment model to test the effect of using boiled water that has been cooled to lukewarm

(20-42ºC) to reconstitute powdered infant formula that is then held at ambient temperatures (up to 32ºC) for immediate feeding over a period of 1 hour or 2 hours. When compared to the previous scenario, the combination of these variables (including the water temperature) did not increase the relative risk of illness (refer to Attachment 1 to this SD).

FSANZ considers the use of synonyms for 'cooled' do not pose a risk and may be helpful to caregivers. The proposed revision to include the word 'cooled' in the Standard therefore remains appropriate. Further, the wording of the direction will not be prescribed, enabling flexibility by industry to use other terms such as 'room temperature' or 'lukewarm'.

Discarding leftover formula

Some submitters to FSANZ 2021 CP1 commented that FSANZ's proposed approach to include the text 'within 2 hours' was inconsistent with Australian Infant Feeding Guidelines which recommend to discard any unfinished formula left at room temperature for longer than one hour. One government submitter suggested further risk assessment was needed to support a change from the Australian Infant Feeding guideline of 1 hour to 2 hours.

The findings of the risk assessment modelling re-run by FSANZ indicated no change in risk after two hours at a greater ambient temperature (up to 32ºC), compared to 75 minutes at a lower ambient temperature (up to 25 ºC) in the baseline scenario in the FSANZ 2021 CP1 (see Attachment 1 to this SD). These findings support the previous assessment in FSANZ 2021 CP1.

As noted above, the wording of the direction will not be prescribed. Labels that currently refer to 'within one hour' or discard 'immediately after a feed' will still be able to do so, as there is no change in risk. This approach is similar to the approach taken for the direction to use made up formula within 24 hours when it is stored before use.

8.2.5 Preferred option

FSANZ's preferred option is to:

- maintain without change the mandatory requirement for directions:
  - to prepare bottles individually (paragraph 2.9.1—19(3)(a)), and
  - instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—19(3)(b)).
  - instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used (paragraph 2.9.1—19(3)(d)).

- revise the directions:
  - for water used to reconstitute powdered formula to include the word 'cooled' (paragraph 2.9.1—19(3)(c)).
  - instructing to discard unfinished formula to include the text 'within 2 hours' (paragraph 2.9.1—19(3)(e)).

- to not apply the following directions to ready-to-drink formula:
  - that each bottle to be prepared individually (paragraph 2.9.1—19(3)(a))
  - to refrigerate formula and use within 24 hours if it is made up and stored prior to use (paragraph 2.9.1—19(3)(b))
  - to use potable, previously boiled water (paragraph 2.9.1—19(3)(c)).

- to not apply the direction to only use the enclosed scoop to concentrated and ready-to-drink formula.

8.3 Standardised wording or pictures for directions for preparation and use

8.3.1 Current regulation

Standard 2.9.1 does require the wording and pictures for directions for preparation and use to be standardised.

8.3.2 Previous consideration

Based on the assessment in section 5.3.2 of FSANZ 2021 CP1, FSANZ proposed to maintain the current approach to not prescribe or standardise the exact wording or pictures to be used for the required directions of use and preparation on infant formula products.

8.3.3 Stakeholder views

Seventeen submitters (eight industry, six government, three health professionals) who commented were generally supportive of FSANZ's proposed approach. Industry submitters supported the status quo for reasons of flexibility and consistency with Codex CXS 72-1981. Two health professional submitters supported the proposed approach, however one health professional was opposed to it. Government submitters held diverging views. A summary of issues raised in submissions is included in the Table 8.3.3 below.

Table 8.3.3 Responses to submitter issues relating to standardised wording or pictures for directions for preparation and use

Issue	Raised by	FSANZ response
Noted some directions include the word 'must' and suggest clarity is needed that the exact wording is not prescribed.	Industry (3)	Noted. FSANZ will consider whether the current drafting requires clarification, noting that the words for preparation and use are not prescribed.
Strongly supported standardised words and pictures to align with NHMRC Infant Feeding Guidelines and images and language similar to the WHO guide on preparing powdered infant formula (PIF).	Health professional (1)	FSANZ notes this would not be possible given there are inconsistencies between the Australian and the New Zealand Infant Feeding Guidelines and also the WHO PIF guidelines (WHO 2007).
Suggest the wording of the direction for only using the enclosed scoop should be prescribed.	Government (1)	FSANZ has observed the majority of labels either use the exact wording or use similar wording to make it clear to only use the provided scoop. This suggests there may be other reasons why some caregivers are not using the enclosed scoop. FSANZ considers caregiver awareness and self-reported behaviour would unlikely be improved by prescribing the wording of this direction.
Suggest a new requirement to prohibit text or images idealising the use of infant formula.	Government (1)	FSANZ considers a new requirement is unnecessary given there is existing provisions in subsection 2.9.1—24(1) Prohibited representations relating to text and pictures.

8.3.4 Discussion

FSANZ found little evidence that caregivers find the lack of standardisation for directions for preparation and use confusing or whether there would be any benefit of prescribing standardised text and pictures. The current approach affords industry flexibility to word the required directions appropriately for their particular product and is consistent with Codex specifications.

8.3.5 Preferred option

FSANZ's preferred option is to maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions for preparation and use on infant formula products.

8.4 Date marking

8.4.1 Current regulation

Generic date marking requirements in Standard 1.2.5 (Information requirements – date marking of food for sale) apply to infant formula products (there are no specific date marking requirements for infant formula products in Standard 2.9.1) i.e. a best-before date or use-by date is required on the package of all infant formula products.

The onus is on the food business to determine whether to label with a best-before date or a use-by date. To ensure product integrity for use by infants, the exemption from date marking in subsection 1.2.5—3(2) where a best-before date is 2 years or more does not apply to infant formula products.

8.4.2 Previous consideration

Based on the assessment in section 5.4.1 of the FSANZ 2021 CP1, FSANZ's proposed approach was to maintain existing date marking requirements for infant formula products.

8.4.3 Stakeholder views

All 17 submitters (eight industry, six government, three health professionals) who commented on this issue supported FSANZ's proposed approach.

8.4.4 Preferred option

FSANZ's preferred option is to maintain existing date marking requirements for infant formula products.

8.5 Storage instructions

8.5.1 Current regulation

Standard 1.2.6 (Information requirements – directions for use and storage) requires the following information be declared:

- if specific storage conditions are required to ensure that a food will keep until the use-by or best-before date, a statement of those conditions is provided (paragraph 1.2.6—2(a))
- if the food must be used or stored in accordance with certain directions for health or safety reasons – those directions (paragraph 1.2.6—2(b)).

These requirements apply generally to all foods including infant formula products.

Section 2.9.1—22 requires the storage instructions on the package of infant formula products to cover the period after the package is opened.

8.5.2 Previous consideration

Based on the assessment in FSANZ 2021 CP1 (section 5.4.2), FSANZ's proposed approach was to maintain the existing requirements for storage instructions including the specific requirement for infant formula products, to cover the period after the package is opened.

8.5.3 Stakeholder views

All 17 submitters who commented on this issue supported FSANZ's proposed approach.

8.5.4 Preferred option

FSANZ's preferred option is to maintain:
- existing generic requirements for storage instructions
- the specific requirement for infant formula products, to cover the period after the package is opened.

8.6 Legibility requirements for warning statements

8.6.1 Current regulation

Infant formula products are subject to general legibility requirements in Division 6 of Standard 1.2.1. Section 1.2.1—24 states a word, statement, expression or design required by the Code to be contained, written or set out on a label, must be legible, be prominent so as to contrast distinctly with the background of the label and be in English. Section 1.2.1—25 mandates general requirements for the size of type for warning statements, based on the surface area of the package.

Specific legibility requirements in section 2.9.1—20 apply to print and package size for the warning statements required by subsections 2.9.1—19(1) and 2.9.1—13(2). Packages of infant formula products with a net weight of more than 500 g must display the required warning statements in size of type of at least 3 mm. Packages with a net weight of 500 g or less must display the same required warning statements in size of type of at least 1.5 mm. These specific requirements override the general requirements in section 1.2.1—25.

8.6.2 Previous consideration

Based on the assessment in section 5.5.1 of FSANZ 2021 CP1, FSANZ proposed to maintain the existing legibility requirements for generic and specific warning statements on infant formula product labels.

8.6.3 Stakeholder views

All 17 submitters who commented on this issue (eight industry, six government, three health professionals) supported FSANZ's proposed approach. One health professional suggested an additional formatting requirement.

Table 8.6.3 Response to submitter issue relating to legibility requirements for warning statements

Issue	Raised by	FSANZ response
Considered some statements are not sufficiently prominent on labels. Suggest all warning statements are presented in separate boxes with background colour contrasting with surrounding colour.	Health professional (1)	FSANZ has observed the majority of products co-locate, capitalise and/or use bold font for the warning statements 'breast milk is best' and to 'follow instructions exactly'. Some products also voluntarily display the warning statements within a box or with a contrasting background colour. FSANZ considers existing legibility requirements are appropriate.

8.6.4 Preferred option

FSANZ's preferred option is to maintain existing legibility requirements for generic or specific warning statements on infant formula product labels.

8.7 Warning statements about following instructions exactly

8.7.1 Current regulation

Paragraph 2.9.1—19(1)(a) requires the label on a package of powdered infant formula product to include the warning statement: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill.* The warning statement for concentrated infant formula product is the same (paragraph 2.9.1—19(1)(b)), except the word 'concentrate' is used in place of 'powder'.

Paragraph 2.9.1—19(1)(c) requires the label on a package of 'ready to drink' infant formula product to include the warning statement: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready to drink' formula except on medical advice. Incorrect preparation can make your baby very ill.*

8.7.2 Previous consideration

Based on the assessment in section 5.5.2 of FSANZ 2021 CP1, FSANZ proposed to:

- maintain the existing requirement for a warning statement on ready-to-drink infant formula product labels about following instructions exactly (paragraph 2.9.1—19(1)(c)).

- amend the warning statements for powdered infant formula products (paragraph 2.9.1—19(1)(a) and concentrated infant formula products (paragraph 2.9.1—(1)(b) to include the additional text 'or add anything to this formula'. The proposed full warning statement was:

  Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of [powder/concentrate] or add anything to this formula except on medical advice. Incorrect preparation can make your baby very ill.

8.7.3 Stakeholder views

Of the 17 submitters who commented on this issue, all industry submitters (8) did not support the proposed extension to the warning statements for powdered and concentrated infant formula products. Six industry submitters noted consumer evidence found improved preparation instructions with a statement on not adding other food or flavourings significantly

improved caregiver understanding (SD4 of FSANZ 2021 CP1). These submitters stated that instead of an extension to the warning statements, they could support additional text in a new direction such as 'do not change proportions of powder or water' or 'do not add other food'. In contrast, all government submitters (6) and health professional submitters (3) supported this proposed approach. One government submitter noted the consumer evidence identified by industry submitters. Only one submitter (industry) commented on FSANZ's proposal to maintain the existing requirement for the ready-to-drink warning statement, expressing support (Table 8.7.3)

Table 8.7.3 Responses to submitter issues raised relating to warning statements about following instructions exactly

Issue	Raised by	FSANZ response
Opposed the additional text in the warning statement for the following reasons: • existing labelling instructions are clear • limited evidence of adding other foods • space constraints, noting the legibility requirement for font size. • consumer evidence indicated warning statements may not be effective to communicate this information. • would create concern or confusion for the majority of caregivers who would ordinarily not consider this practice. • NZ draft dietary guidelines include advice not to add anything else to the bottle, for example cereal or baby rice.	Industry (8)	FSANZ is now proposing a shorter warning statement for all product types, and to include new directions that instruct caregivers not to dilute, add other food or change proportions. See section 8.7.4.
Suggested revised wording for the powdered infant formula warning statement: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not add anything or change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill.*	Government (1)	Based on industry feedback, FSANZ is proposing a single warning statement about following instructions exactly and new directions for preparation and use for powdered, concentrated and ready-to-drink formulas. See section 8.7.4.

8.7.4 Discussion

FSANZ considers there is sufficient consumer evidence for additional labelling to advise caregivers not to add anything other than water when reconstituting powdered formula. The majority of industry submitters noted they would support additional labelling to this effect as a new direction for safe preparation and use.

Industry submitters noted the consumer evidence supports this information being located as part of the preparation instructions. FSANZ acknowledges the consumer evidence indicates: some caregivers do not visually attend to warning statements for a variety of reasons ranging from being unaware of their presence to understanding them but choosing not to follow the warning (e.g. altering the proportions of powder to water, adding flavourings or other food) caregivers perceive the preparation instructions have (albeit slightly) greater importance than warning statements some caregivers who reported adding flavourings to formula noted the instructions did not advise against this practice adding the text *'Never add more or less formula powder or water than recommended unless directed by a healthcare professional. Do not add any other food (e.g. cereal) or flavouring to the feed'* to the preparation directions can significantly improve caregiver understanding to not add other flavourings or foods.

Based on the consumer evidence and industry submitter comments, FSANZ has reconsidered the proposed approach for the warning statements about following instructions and is now proposing to relocate the text in the warning statements relating to making up formula to the directions. For consistency, these changes are also proposed to apply to the warning statement for ready-to-drink infant formula products.

The proposed new direction (in words and pictures) for the preparation and use of infant formula products would instruct:

- For powdered and concentrated infant formula products - not to change proportions of [powder/concentrate] or add other food except on medical advice

- For ready-to-drink infant formula products - not to dilute or add anything except on medical advice.

For consistency with other directions in sections 8.2 and 8.3 of this report, the wording and pictures of these directions would not be prescribed.

For clarity, the new direction would be included with existing directions as shown:
- each bottle should be prepared individually
- if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours
- potable, previously boiled cooled water should be used
- if a package contains a measuring scoop—only the enclosed scoop should be used
- for powdered and concentrated formula - not to change proportions of [powder/concentrate] or add other food except on medical advice
- for ready-to-drink formula - not to dilute or add anything except on medical advice
- formula left in the bottle after a feed must be discarded within 2 hours.

The warning statements in paragraphs 2.9.1—19(1)(a), (b) and (c) could then be consolidated into a single prescribed warning statement for all product types as follows:

> *'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill'.*

In addition to clarifying the preparation instructions for caregivers, a shorter warning statement would likely be more accessible to caregivers, and simplify the requirements for industry. Changes to the labels of ready-to-drink infant formula product labels are likely to affect only a small number of products (FSANZ noted in FSANZ 2021 CP1 that it understands ready-to-drink formulas are only available domestically through health professionals).

8.7.5 Preferred option

FSANZ's preferred option is to require a new direction for the preparation and use of infant formula products:
- for powdered and concentrated formula - not to change proportions of [powder/concentrate] or add other food except on medical advice
- for ready-to-drink formula - not to dilute or add anything except on medical advice.

FSANZ is also proposing to consolidate the warning statements for powdered, concentrated and ready-to-drink infant formula products into a single prescribed warning statement applicable to all product types that states:

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

8.8 'Breast milk is best for babies' warning statement

8.8.1 Current regulation

Paragraph 2.9.1—19(1)(d) requires most infant formula product labels to include the prescribed warning statement *Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.* This is required to be under a heading stating *Important Notice* (or words of similar effect). This warning statement is subject to the requirements for the size of type set out in section 2.9.1—20.

8.8.2 Previous consideration

Based on the assessment in FSANZ 2021 CP1 (section 5.5.3), FSANZ proposed to retain the existing 'breast milk is best' warning statement as currently required by paragraph 2.9.1—19(1)(d).

8.8.3 Stakeholder views

Fifteen of the 17 submitters that commented on this issue supported FSANZ's approach. A government submitter commented on the specific wording (Table 8.8.3)

8.8.4 Preferred option

FSANZ's preferred option is to retain the existing 'breastmilk is best for babies' warning statement as currently required by paragraph 2.9.1—19(1)(d).

Table 8.8.3 Responses to submitter issues in relation to the 'Breast milk is best for babies' warning statement

Issue	Raised by	FSANZ response
Considered the 'breast milk is best 'wording is not contemporary health communication language and it can be counterproductive in protecting breastfeeding (provided the reference for Berry and Gribble, 2008. Breast is no longer best: promoting normal infant feeding. Maternal and Child Nutrition 4 pg 74-79). Supported the intent of the statement to highlight the superiority of breastfeeding but suggests FSANZ consider undertaking additional research on more appropriate language to convey this message.	Government (1)	FSANZ's literature review (which included Berry and Gribble 2008) concluded there was insufficient evidence to determine whether loss-framed (emphasising the risks of formula feeding) or gain-framed (emphasising the benefits of breastfeeding) messages would have an impact on breastfeeding intentions or outcomes. Further, the review indicated the majority of women decide to breastfeed or formula feed either before they conceive or when pregnant (refer to Attachment A2.2 to SD2 of FSANZ 2016 CP). A 2016 focus group study of 136 Australian and New Zealand caregivers commissioned by FSANZ found that while most thought the warning statement was unnecessary because the information was 'common knowledge', some caregivers viewed it positively while others did not. In section 5.5.3 of FSANZ 2021 CP1, FSANZ noted the current statement aligns with the WHO Code and the corresponding Australian and New Zealand agreements, Codex CXS 72-1981 and public health messages about the superiority of breastfeeding compared to formula feeding. FSANZ considers the existing requirement should be retained and notes the majority of submitters supported this approach.

8.9 Prescribed name

8.9.1 Current regulation

Standard 1.2.1 requires a food to be labelled with the name of the food.

Paragraph 1.2.2—2(1)(a) states the name of the food is the prescribed name if the food has a prescribed name. 'Infant formula' and 'Follow-on formula' are prescribed names in accordance with section 2.9.1—17.

8.9.2 Previous consideration

The previous scope of Proposal P1028 did not include follow-on formula and therefore FSANZ's assessment focussed on product identification relating to 'Infant formula' (in FSANZ 2016 CP and FSANZ 2021 CP1) and IFPSDU (in FSANZ 2017 CP and FSANZ 2021 CP3). Based on the assessment in section 5.6.1 of FSANZ 2021 CP1, FSANZ proposed to maintain the requirement to use the prescribed name 'Infant formula' as the name of the food on the labels of infant formula.

8.9.3 Stakeholder views

All 17 submitters who provided comment were supportive of FSANZ's proposed approach for 'Infant formula' as a prescribed name. Two government submitters noted the prescribed

name was important to ensure caregivers can select the appropriate product for their infants.

8.9.4 Discussion

Similar to ‘Infant formula’, prescribing the name ‘Follow-on formula’ provides important information to enable caregivers to distinguish between products intended for different age groups and choose an appropriate formula for their infant.

From an international perspective, FSANZ notes there is no consistency in the prescribed name for follow-on formula. EU 2016/127 states the name ‘Follow-on milk’ must be used if the formula is manufactured entirely from cow’s milk or goats’ milk proteins. Formulas that do not meet this criterion must be identified as ‘Follow-on formula’.

Codex CXS 156-1987 specifies ‘Follow-up Formula’ as the name of the food or any appropriate designation that may be used in accordance with national usage. This standard is currently under review and the name ‘Follow-up formula for older infants’ has been proposed for products intended for infants aged 6 - 12 months.

In the United States of America, 21 CFR 101.3 requires a common or usual name of the food as the statement of identity. Infants are defined as not more than 12 months of age and the regulations do not distinguish between formula for infants less than 6 months of age and formula for infants older than 6 months.

FSANZ is unaware of any issues regarding the domestic requirement for the prescribed name ‘Follow-on formula’. As such, FSANZ considers the prescribed name is appropriate for follow-on formula and the requirement should be maintained.

8.9.5 Preferred option

FSANZ’s preferred option is to maintain the requirement for ‘Infant formula’ and Follow-on formula’ as prescribed names for these products.

8.10 Statement that infant formula product may be used from birth

8.10.1 Current regulation

Paragraph 2.9.1—19(4)(a) requires for infant formula, a statement on infant formula labels indicating the product may be used from birth. The definition of infant formula (see section 2.9.1—3) includes that the product satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months.

8.10.2 Previous consideration

Based on the assessment in section 5.6.2 of FSANZ 2021 CP1, FSANZ proposed to maintain the requirement for the existing statement indicating that the infant formula product may be used from birth.

8.10.3 Stakeholder views

All 17 submitters (eight industry, six government, three health professionals) who commented on this issue supported FSANZ’s proposed approach

8.10.4 Preferred option

FSANZ's preferred option is to maintain the requirement for the statement indicating that the infant formula product may be used from birth as currently required by paragraph 2.9.1—19(4)(a).

8.11 Statement that FOF should not be used for infants aged under 6 months

8.11.1 Current regulation

Paragraph 2.9.1—19(4)(b) requires a statement on follow-on formula labels indicating that follow-on formula should not be used for infants aged under the age of 6 months.

8.11.2 Previous consideration

FSANZ has not previously considered this statement because follow-on formula was previously not in scope for Proposal P1028.

8.11.3 Discussion

The Australian infant feeding guidelines states follow-on formula is suitable only for infants over 6 months. The New Zealand infant feeding guidelines recommend follow-on formula should not be given to babies under six months of age.

The existing statement is consistent with the Codex Follow up Standard (STAN 156-1987) which specifies that labelling shall include a statement that follow-up formula shall not be introduced as a substitute for breast milk during the first six months of life. The proposed revised draft Standard for FuFOI includes that *the label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age*.

Article 6(3)(a) of EU 2016/127 requires a statement that follow-up formula is not to be used as a substitute for breast milk during the first six months of life.

FSANZ has no evidence to indicate an issue with the current labelling requirement for follow-on formula. Noting there is international alignment, FSANZ considers the existing statement should be maintained and is seeking stakeholder views on this position.

8.11.4 Preferred option

FSANZ's preferred option is to maintain the requirement for a statement on follow-on formula labels indicating that follow-on formula should not be used for infants aged under the age of 6 months as currently required by paragraph 2.9.1—19(4)(b).

8.12 Statement about age to offer foods in addition to formula

8.12.1 Current regulation

Paragraph 2.9.1—19(4)(c) requires a statement on infant formula product labels (except for pre-term formula by virtue of 2.9.1—19(5)) indicating that it is recommended infants from the age of 6 months should be offered foods in addition to infant formula products.

8.12.2 Previous consideration

Based on the assessment in section 5.6.3 of FSANZ 2021 CP1, FSANZ proposed to maintain the existing labelling requirement on infant formula product labels indicating that infants from the age of 6 months should be offered foods in addition to infant formula products as currently required by paragraph 2.9.1—19(4)(c).

8.12.3 Stakeholder views

All 17 submitters who commented on FSANZ's proposed approach in FSANZ 2021 CP1 supported the need for the statement. Seven submitters (five industry, one government, one health professional) suggested a change to the wording. Another government submitter considered the current statement was consistent with Australian and New Zealand infant feeding advice.

Table 8.12.3 Responses to submitter issues relating to the statement about age to offer foods in addition to formula

Issue	Raised by	FSANZ response
Recommended changing the word 'from' to 'around' the age of six months for the following reasons: - Alignment with Australian and New Zealand infant feeding guidelines, and alignment with ASCIA guidelines for introducing solid foods for allergy prevention. - ESPGHAN recommends solids should not be introduced before 4 months of age, but should not be delayed beyond 6 months of age. - Provide clarity to caregivers who introduce solids in the 5th month or have been advised to start solids prior to six months by a health professional.	Industry (5), Health professional (1), Government (1)	FSANZ considers the current wording of paragraph 2.9.1—19(4)(c) to be appropriate to support infant feeding guidance noting the wording of the statement is not prescribed. See section 8.12.4.

8.12.4 Discussion

Standards within the Code are legislative instruments and are not health guidance documents. FSANZ notes guidelines, such as the Australian and New Zealand infant feeding guidelines and ASCIA Guidelines for Infant Feeding and Allergy Prevention (ASCIA 2020), serve a different purpose to the Code by providing advice to caregivers and health professionals.

The requirement in Standard 2.9.1 for a statement about offering foods in addition to infant formula products supports infant feeding guidance to introduce additional foods in an infant's diet. The timing of this introduction is subject to growth and developmental need, as advised by health professionals, and in any case should generally occur from six months.

8.12.5 Preferred option

FSANZ's preferred option is to maintain, as it is currently worded, the statement indicating that infants from the age of 6 months should be offered foods in addition to the infant formula product in paragraph 2.9.1—19(4)(c)).

8.13 Statement on protein source

8.13.1 Current regulation

Paragraph 2.9.1—23(1)(a) requires infant formula product labels to contain a statement of the specific source, or sources, of protein in the product. Standard 2.9.1 specifies requirements for the quality and quantity of protein in infant formula products but does not prescribe the protein source.

8.13.2 Previous consideration

Based on the assessment in section 5.6.4 of FSANZ 2021 CP1, FSANZ proposed to clarify the source of protein in section 2.9.1—23 refers to the origin of protein (e.g. cow's milk) and not the protein fractions (e.g. whey protein or casein).

8.13.3 Stakeholder views

Of the 17 submitters commenting on this issue, government (6) and health professional (3) submitters supported FSANZ's proposed approach noting it would clarify protein fractions cannot be used as a potential claim, would clarify the intent for enforcement purposes, provide information for caregivers of infants with allergies and intolerances, reduce the risk of influencing caregivers to believe formulas with protein fractions in the statement are better than formulas without, and that there is a lack of nutritional justification for this information to be on IFP. Industry submitters (8) opposed the proposed approach for various reasons. A summary of issues raised in submissions is included in the Table 8.13.3 below.

Table 8.13.3 Responses to submitter issues relating to the statement on protein source

Issue	Raised by	FSANZ response
Opposed the clarification for the following reasons: - anecdotal evidence that caregivers request this information, suggesting it is useful, enabling informed choice. - no evidence of consumer confusion or issues with the status quo, or that this needs to be clarified. - the protein source statement is not the primary source of allergen information; it provides insufficient information to make safe food choices of allergenic infants as allergens may be present in other ingredients. - may limit the information provided to consumers and health professionals (e.g. 'partially hydrolysed', 'amino acids', 'a2' or the information that a product is whey dominant) and its omission is potentially misleading. - the EU permits declaration of the whey/casein ratio. - provision of additional information should not be mandatory.	Industry (8)	FSANZ considers the protein source (origin) provides information for caregivers to enable informed choice. Consumer evidence indicates caregivers lack understanding of protein fractions and look for the protein origin (section 5.6.4 of FSANZ 2021 CP1). The proposed approach is consistent with Codex and the EU Regulations. EU regulations requires protein to be declared and permits information about, its components and the whey: casein ratio voluntary whey/casein declarations in the nutrition information, but this information is prohibited elsewhere on the label. FSANZ considers the presence of protein fractions elsewhere on the label are nutrition content claims. Terms such as 'partially hydrolysed' and 'amino acids' relate to the composition and nature of the protein, rather than the source (origin).

8.13.4 Discussion

The requirement for the protein source statement has been in place since 2002 when the Standard 2.9.1 was gazetted.

As noted in section 5.6.4 of the FSANZ 2021 CP1, the original intent of the protein source statement was to provide clarity for caregivers to be able to make informed choices. Further, the statement was also introduced for consistency with Codex CXS 72-1981, which requires the sources of protein to be clearly shown on the label.

FSANZ also reported significant variability in protein source statements from a 2018 label survey. In a 2021 label survey, FSANZ observed the following statements on labels: 'whey partially hydrolysed protein from cow's milk', 'alpha-lactalbumin enriched whey protein concentrate from cow's milk', 'soy protein isolate', 'lactoferrin protein', 'Casein (or Whey) dominant based on cow's milk protein', 'whey casein balanced', '100% whey protein, 'extensively hydrolysed cow's milk protein', 'a unique and premium whey and casein blend'. In some cases, the statements did not refer to the name of the food and in other cases only protein fractions such as 'whey' or 'casein' were mentioned, rather than the protein origin (e.g. cow's milk, soy protein). FSANZ also observed product labels that had no protein source statement at all.

Noting government and health professional submitters view such references as potential claims, and consumer evidence (see table 8.3.13), FSANZ considers references to protein fractions in the protein source statement is not useful for caregivers. FSANZ considers the protein origin (e.g. 'cow's milk, 'goats' milk) is more appropriate because it aligns with international and overseas regulations and provides clearer information to caregivers.

8.13.5 Preferred option

FSANZ's preferred option is to clarify that the 'source' of protein in section 2.9.1—23 refers to the origin of the protein (e.g. cow's milk) and not the protein fractions (e.g. whey protein or casein).

8.14 Co-location of protein source statement with the name of the food

8.14.1 Current regulation

Paragraph 2.9.1—23(1)(a) requires the mandatory statement about protein source to be located immediately adjacent to the name of the product. Standard 1.2.1 requires infant formula products to be labelled with the name of the food (see paragraph 1.2.1—8(1)(a)) and section 1.2.2—2 specifies that the name of the food is the prescribed name, if the food has a prescribed name. Section 2.9.1—17 states that 'Infant formula' and 'Follow-on formula' are prescribed names.

The Code does not specify where the prescribed name and by association, the protein source statement should be located on the label, or their format.

8.14.2 Previous consideration

Based on the assessment in section 5.6.5 of FSANZ 2021 CP1, FSANZ proposed to maintain the requirement for the co-location of the protein source statement and the name of the product. Further, FSANZ proposed to clarify:

- the ‘name of the product’ in paragraph 2.9.1—23(1)(a) is the prescribed name (‘Infant formula’); and
- the protein source statement adjacent to the prescribed name is not required every time the prescribed name occurs on the label.

8.14.3 Stakeholder views

Sixteen submitters (eight industry, five government, three health professionals) supported FSANZ’s proposal to maintain co-location requirement for the protein source statement and the name of the food.

Fifteen submitters (8 industry, 4 government and 3 health professionals) supported the proposed clarifications. Three government submitters supporting making the location of the required information more prominent for reasons that it would alert caregivers to the appropriate formula choice for infant age, it could reduce the safety risks for those infants with allergies, and Codex CXS 1-1985 specifies the name of the food appears in a prominent position. One health professional submitter proposed the name of the food and protein source statement is located on the back of pack. Table 8.14.3 includes a summary of submitter issues in response to the co-location of the name of the food and protein source statement and its position on IFP labels.

Table 8.14.3 Responses to submitter issues relating to the co-location of the protein source statement with the name of the food

Issue	Raised by	FSANZ response
Opposed a mandated position for this information because: - caregivers choosing formula based on health and safety concerns are likely to read the ingredient list first. - consumer evidence did not support the need for it - Codex CXS 72-1981 does not prescribe it - it would have significant cost and trade implications.	Industry (1)	Consumer evidence indicates some caregivers preferred protein source information be on the front of the tin, and that locating this information on the front assists caregiver decisions when they have reason to use it (i.e. caregivers of infants with allergies and intolerances). See SD4 to FSANZ 2021 CP1.
Noted anecdotal evidence that caregivers are unaware most infant formula is cow’s milk protein-based. Concerned that widespread negativity towards dairy on social media could influence caregivers to purchase alternative products, particularly if the protein source statement is located front of pack. Suggested undertaking consumer research and consider locating the statement on the back of pack.	Health professional (1)	FSANZ is proposing to define protein source to clarify which types of protein are permitted to be used in the manufacture of infant formula and follow-on formula (e.g. cow’s milk, goat’s milk, soy protein; see section 2.2.2 of SD2). Therefore, any of the products permitted for sale will be safe and suitable for healthy infants. FSANZ notes that providing this information enables informed choice.

8.14.4 Discussion

The Commission Delegated Regulation EU 2016/127 does not specify the location of the name of the food and states that information included in nutrition declaration (e.g. mandatory declaration for protein, and a voluntary declaration of its components and the whey: casein ratio) shall not be repeated on the labelling. FSANZ also notes the Codex CXS 1-1985

provision for the name of the food to appear in a prominent position, Further, there was submitter support for clarifying the protein source statement adjacent to the name of the food is not required every time that prescribed name occurs on the label.

FSANZ has previously reported that there is significant variability in the location of this information on labels (section 5.6.5 in FSANZ 2021 CP1). In a 2021 label survey, the protein source statement was commonly located below the list of ingredients. The least common locations found were under the NIS and on the front of the product label. Several products had multiple protein source statements made on their labels, similar to the 2016 label survey.

FSANZ considers there is merit in requiring the name of the food and protein source statement to be in a prominent position for several reasons. The approach will ensure the information is more visible to caregivers of infants with allergies and intolerances and assist them in making product comparisons. The requirement for a prominent position would align with Codex and provide flexibility for manufacturers, rather than a prescribed location. Government submitters indicated they could support this approach.

8.14.5 Preferred option

FSANZ's preferred option is to:

- maintain the requirement for the co-location of the protein source statement with the name of the food
- clarify the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.

8.15 Summary of preferred options

Based on FSANZ's assessment, the preferred option are to:

- maintain without change the mandatory requirement for directions:
  - to prepare bottles individually
  - instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours
  - instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.
- revise the directions:
  - for water used to reconstitute powdered infant formula to include the word 'cooled'.
  - instructing to discard unfinished formula to include the text 'within 2 hours'.
- not apply the following directions to ready-to-drink infant formula:
  - that each bottle to be prepared individually
  - to refrigerate formula and use within 24 hours if it is made up and stored prior to use
  - to use potable, previously boiled water.
- not apply the direction to only use the enclosed scoop to concentrated and ready-to-drink formula.
- maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions for preparation and use on infant formula products.

- maintain existing date marking requirements for infant formula products.
- maintain:
  - existing generic requirements for storage instructions
  - the specific requirement for infant formula products, to cover the period after the package is opened.
- maintain existing legibility requirements for generic or specific warning statements on infant formula product labels.
- require a new direction for the preparation and use of infant formula :
  - for powdered and concentrated infant formula - not to change proportions of [powder/concentrate] or add other food except on medical advice
  - for ready-to-drink infant formula - not to dilute or add anything except on medical advice.
- consolidate the warning statements for powdered, concentrated and ready-to-drink infant formula into a single prescribed warning statement applicable to all product types that states: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.*
- retain the existing 'breastmilk is best for babies' warning statement.
- maintain the requirement for 'Infant formula' and Follow-on formula' as prescribed names.
- maintain the requirement for the statement indicating that the infant formula product may be used from birth.
- maintain the requirement for a statement on follow-on formula labels indicating that follow-on formula should not be used for infants aged under the age of 6 months.
- maintain, as it is currently worded, the statement indicating that infants from the age of 6 months should be offered foods in addition to the infant formula product.
- clarify that the 'source' of protein refers to the origin of the protein (e.g. cow's milk) and not the protein fractions (e.g. whey protein or casein).
- maintain the requirement for the co-location of the protein source statement with the name of the food.
- clarify the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.

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