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

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Consultation paper 1 – Safety and food technology

Proposal P1028—Infant formula

Executive summary

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

Infant formula is 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, 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 paper is one of a series of three consultation papers which discuss the regulatory options for Standard 2.9.1 and Schedule 29. The consultation papers will inform the 1st Call for Submissions (CFS) which will summarise the entirety of considerations and outline the proposed regulatory approach.

Issues relating to the safety and food technology of infant formula, from manufacture of the product to preparation by caregivers, is the focus of this paper. This paper is organised into four sections:

- Food additives
- Contaminants
- Lactic acid producing micro-organisms
- Labelling for safe preparation and use

This paper follows previous consultations undertaken in 2012, 2016 and 2017 in which these topics were considered.

Based on its assessment to date, including consideration of stakeholder views from previous consultations, FSANZ has now proposed 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. Four supporting documents to this Consultation paper provide further detail on key issues.

We are seeking stakeholder comment on key issues and proposed approaches. Key questions for stakeholders are included throughout this paper and are listed in the final section to the paper. Some safety and food technology issues that have been reviewed and addressed previously will not be considered further in P1028. These issues are listed at the end of the paper.

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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
Amino acids	For this proposal, refers to L-amino acids which are the only forms that are biologically active/available
ANZ	Australia and New Zealand
ANZFA	Australia New Zealand Food Authority; the former name for FSANZ
ATDS	Australian Total Diet Study
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
CRIS	Consultation Regulatory Impact Statement
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
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
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
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

1.1 Proposal P1028

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

Infant formula is regulated within the Australia New Zealand Food Standards Code (the Code) through:

- Standard 2.9.1 – Infant formula products, and
- Schedule 29 – Special purpose foods.

While the standards in the Code that regulate infant formula are mostly working well, Proposal P1028 aims to ensure these standards are appropriate, clear and function well now and into the future. The overarching goal of Proposal P1028 is to ensure that infant formula remains safe and suitable, takes account of current science, market developments, and the international regulatory context. As part of its assessment of the proposal, FSANZ will consider key stakeholder views, relevant Ministerial policy guidance and alignment with updated international regulations. Proposal P1028 is being prepared under section 113(6) of the FSANZ Act and assessed under the Major Procedure.

The scope of Proposal P1028 includes all requirements for infant formula products (IFP) in Standard 2.9.1 excluding follow-on formula (FOF). IFPs include general infant formula and infant formula for special dietary use (IFPSDU) (both for infants aged from 0–<12 months) . Although some issues reviewed in the proposal may be relevant for FOF (for infants aged from 6–<12 months), these products are not in scope for P1028. However, because of the overlap in age ranges for IFP and FOF, relevant information related to international regulations for FOF may be considered.

1.2 The Proposal to date

This proposal is reviewing all of the aspects of regulation relating to infant formula and IFPSDU. Reviewing an entire standard which regulates food for a very vulnerable population is complex. Given this complexity, it is important to take the time to review the issues properly. This includes ensuring there are several opportunities for stakeholders to input into the process and for their views to be considered. To date, FSANZ has released two consultation papers on this proposal:

- The 2016 P1028 Consultation paper[1] focused on the regulation of infant formula. Infant formula products for special dietary uses and follow-on formula were excluded from scope.
- The 2017 Consultation paper focused on IFPSDU because many submissions to the 2016 paper requested IFPSDU be included in the Proposal's scope. This is because requirements for IFPSDU are founded on those for infant formula.

These two papers and targeted consultation have enabled FSANZ to examine the available evidence, scope the regulatory issues and consider options to improve the current regulation.

The reasons for preparing the Proposal and a description of the current standards for the regulations of infant formula is provided more fully in the 2016 Consultation paper[1].

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

1.3 Progressing the Proposal

To progress the consideration of regulatory options for the 1st CFS, FSANZ will release a series of three Consultation papers over the coming months. These papers address grouped aspects of the regulation and topics. Broadly, topics include safety and technology, nutrient composition, the regulatory framework, definitions, and labelling for informed choice. The series of papers will further narrow down the scope of the regulatory issues and reduce the volume of issues to be considered at each stage. Following these papers, the 1st CFS will summarise the consideration of issues and options, and consider the FSANZ Act objectives. This will be accompanied by the consultation regulatory impact statement (CRIS).

1.4 Consultation paper 1 – Safety and food technology

This consultation paper focuses on the safety and technology aspects of infant formula regulation. 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.

The safety and food technology issues covered in this paper are wide ranging, thus this document is organised into sections which cover specific aspects of the regulation. These are: food additives, contaminants, safety of lactic acid producing microorganisms, and labelling for the safe preparation and use of IFP. Information about issues has been sourced from: a FSANZ review of existing infant formula requirements in the Code, 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, and regulatory and policy activities at a national and international level.

Generally, the issues are addressed in relation to:

- safety concerns about certain substances
- clarity and enforceability of the Code
- international trade barriers created by existing regulations
- the communication of public health messages
- caregiver practices when preparing and storing infant formula products.

For many issues, we have considered the need for amendments to the Code to improve clarity or the need for additional risk management measures. Within each section, FSANZ has outlined a proposed approach and discussed the rationale for this approach. The proposed approaches are not final decisions on whether amendments to the Code will be made, as these will be made once an assessment and decision is taken under section 59 of the FSANZ Act (in the 1st CFS). We are seeking comments from stakeholders to further inform the decisions for the 1st CFS.

1.5 Background

1.5.1 Regulatory approach to developing or varying food standards

Section 18 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) sets out the three primary objectives in descending order of priority that FSANZ is required to meet in developing or varying a food standard. These are:

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

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

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

These objectives and principles are all relevant for the revision and clarification of standards. For this proposal, the first objective is paramount given the vulnerability of formula-fed infants, particularly those for which infant formula provides the sole source of nutrition during the first months of life. It is also important that parents/carers have accurate and adequate information about products to make an informed choice.

1.5.2 International and overseas regulations

In developing or reviewing food standards, FSANZ must have regard to, among other things, the promotion of consistency between domestic and international food standards. As the developer of internationally recognised food standards, the approach of Codex Alimentarius (Codex) has been considered in assessing the issues discussed in this paper[3]. The most relevant Codex standard for this proposal is the Codex *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)(Codex, 1981). Other Codex standards, guidelines and codes of practice are also relevant to issues discussed in this consultation paper, and are outlined in each section.

Where relevant, the approach taken in major overseas jurisdictions is also considered. In particular, this relates to IFPSDU, many of which are imported into Australia and New Zealand. The European Union (EU) is the major source of imported product, thus the relevant EU regulations (noting that EU IFPSDU are regulated as Food for Special Medical Purposes) are also outlined where relevant.

1.5.3 Ministerial policy guidelines

As indicated above, FSANZ must also have regard to Ministerial policy guidance in developing and varying standards in the Code. The relevant policy is the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (the Policy Guideline)[4]. The Policy Guideline contains several *Specific Policy Principles* that address product composition, labelling and advertising. The Policy Guideline also refers to the regulation of infant formula "being consistent to the greatest extent possible" with relevant World Health Organization (WHO) and World Trade Organization (WTO) agreements, and Codex standards. The specific policy principles relevant to the topics considered in this Consultation paper:

d) The composition of infant formula products must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.

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[2] Now known as the Food Ministers' Meeting; previously called the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[3] https://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx
[4] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Infant%20Formula%20May%202011.pdf

i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that: i) does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii) has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.

k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand.

m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.

1.6 Submissions to previous Consultation papers

The number of submitters to the previous P1028 Consultation papers is provided at Table 1.1. A smaller subset of these submissions provided views on the specific issues presented in this paper (noted where relevant).

Table 1.1 Submissions to previous Consultation papers

Sector	Number of submitters	
	2016 Consultation paper (IF)	2017 Consultation paper (IFPSDU)
Government	7	7 (2 late)
Industry	24	8
Health professional	6	11
Consumer	3 (1 late)	2
Total	41	28

2 Food additives

Food additives play an important part in ensuring our food is safe and meets the needs of consumers. They perform roles such as improving the stability and shelf life of foods, ensuring homogeneity of added substances such as nutrients, and preserving appearance and the eating quality of foods. Some of these functional properties are very important for infant formula.

A food additive may only be added to infant formula products if permitted in the Code and it complies with an appropriate specification. 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). The Code specifies which food additives are permitted in Schedule 15 and this includes maximum permitted levels (MPLs) for different food products. Before a food additive is permitted for use in food, FSANZ ensures the food additive is both safe at the permitted level in the particular food and that there is a technologically justified purpose for its use.

Food additive permissions for infant formula products have not been reviewed since the late

1990s. This proposal is considering the need to harmonise permissions with the Codex food standards and in some cases European regulations to improve international consistency and to maintain importation of infant formula products, especially IFPSDU which generally are not manufactured in Australia and New Zealand. This section reviews current permissions for food additives, addresses carry-over permissions and the organisation of the food additive food class system specifically for infant formula products (excluding FOF) within Schedule 15. We also propose the preferred options in relation to changes to Standard 2.9.1 and/or Schedule 15.

2.1 Background

2.1.1 Current regulation

The Code

Paragraph 1.1.1—10(6)(a) 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 this Code. Standard 1.3.1–Food additives contains the relevant permissions.

Food additive permissions for infant formula are listed in the table to section S15—5 *Schedule 15–Substances that may be used as food additives*. 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* (Table 2.1). *Schedule 3–Identity and Purity* lists the appropriate specifications for food additives. A permitted food additive must also comply with an appropriate specification.

Table 2.1 Relevant food classes and subclasses for infant formula in the Code

Food class number	Description
13.1	Infant formula products
13.1.1	Soy-based infant formula
13.1.2	Liquid infant formula products
13.1.3	Infant formula products for specific dietary use based on a protein substitute

Codex

There are several relevant Codex standards and guidelines:

- CXS 72-1980 –Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
- CXS 192-1995 – General Standard for Food Additives (GSFA)
- CXG 36-1989 – Class Names and the International Numbering System for Food Additives
- CXA 6-2015 – List of Codex Specifications for Food Additives.
- CXG 10-1979 – Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children
- CXG 75-2010 – Guidelines on Substances used as Processing Aids
- Combined Compendium of Food Additive Specifications, Joint FAO/WHO Expert Committee on Food Additives (JECFA)

The infant formula standard (CXS 72-1980) covers infant formula (Section A) and formula for special medical purposes intended for infants (Section B). Section A, Part 4, lists food

additive provisions[5] which apply either to all types of infant formula or specifically for hydrolysed protein or amino acid-based formulas. Section B of that standard refers back to the relevant food additives in Section A. These food additive provisions were updated in 2016, occurring after the release of our 2016 Consultation paper.

The Codex General Standard for Food Additives (GSFA) (Codex 1995a) was also updated in 2016 to include new food additives for several infant formula food categories. The GSFA uses a hierarchical food category system for food additive provisions however the food categories do not directly align with the food classes used in the Code[6]. The relevant GSFA food categories are provided in Table 2.2.

Table 2.2 Relevant food categories for infant formula in the GFSA

Food category number[7]	Description
13.1	Infant formulae, follow-up formulae, and formulae for special medical purposes for infants
13.1.1	Infant formulae
13.1.3	Formulae for special medical purposes for infants

There are some differences in the food additive provisions between the two food subclasses (13.1.1 and 13.1.3) though there are also a number of similarities.

The List of Codex Specifications for Food Additives CXA 6-2015 (Codex 2015b) details all the specifications for food additives adopted by reference by Codex. The specifications have been prepared by JECFA and are published in the Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 and subsequent monographs (2017, monographs 20) (FAO 2014). Recent updates to include monographs 22 (2018) and monographs 23 (2019) are being considered as part of the Code Revision (2020), proposal P1051. The JECFA specifications are primary sources of specifications in Schedule 3 of the Code.

European Union

Several regulations related to food additives exist in the EU. Regulation (EC) 1333/2008 sets the rules on all aspects of food additives: definitions, conditions of use, labelling and procedures. It also contains several annexes outlining the technological functions of food additives and lists food additives approved for use. All food additives must be authorised ensuring that:

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

Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives provides a Union list of permitted food additive permissions for different food

[5] Codex uses the term provisions while the Code refers to permissions
[6] Note that the Code uses the term food classes and subclasses, while Codex and EU regulations refers to food categories and subcategories but they are referring to the same thing. This report will use the term food class when it is referring to the Code.
[7] Food category 13.1.2 relates to FOF which is out of scope for P1028.

categories in Annex II. The hierarchy of relevant food categories in Annex II of Commission Regulation (EU) No 1129/2011 for infant formula, specifically related to this Proposal is provided in Table 2.3[8] (these are referred to throughout this Consultation paper).

Commission Regulation (EU) 231/2012 contains the specifications for food additives listed in Annexes II and III to Regulation (EC) 1333/2008. European regulations refer to E numbers (European food additive numbers) which are essentially the same as the International Numbering System (INS) used by Codex and in the Code, e.g. phosphoric acid is both E 338 and INS 338.

Table 2.3 Relevant food categories for IF in European food additive regulations

Food category number	Description
13.1	Foods for infants and young children
13.1.1	Infant formulae as defined by Commission Directive 2006/141/EC
13.1.5	Dietary foods for infants and young children for special medical purposes as defined by Commission Directive 1999/21/EC and special formulae for infants
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants

2.1.2 Previous FSANZ consideration

2016 Consultation paper

FSANZ considered whether there was a need to harmonise food additive permissions with the Codex standards to improve international consistency and for ease of trade. A comparison between the current food additive permissions for infant formula in the Code with CXS 72-1981 and CXS 192-1995[9] identified a number of differences between the Code and Codex. FSANZ sought information on the technological justifications and available safety data for those food additives not permitted in the Code to enable assessment by FSANZ.

2017 Consultation paper

This Consultation paper specifically considered the regulation of IFPSDU. As the majority of IFPSDU products available in Australia and New Zealand are imported from the EU and a small number of other countries, continued supply of these specialised products is a priority as they are essential for the sub-population of infants who have specific physical or physiological conditions, diseases or disorders. As the EU was identified as the major source of these products, FSANZ considered the alignment of the Code with Codex as well as EU permissions. While some IFPSDU products are manufactured in the United States (US), the US Food and Drug Administration's (FDA's) implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR) do not contain a single list of food additives permitted in infant formula products (including exempt infant formulas). FSANZ concluded that it is not

[8] EU regulations also have the specific category 13.1.2 called "Follow-on formulae" as defined by Directive 2006/141/EC. This category is out of scope for this Proposal as follow-on formula is not being considered.
[9] Permissions for IFPSDU (food category 13.1.3) were not considered as the product category was out of scope of the Proposal at that time.

possible to consider harmonisation with US food additive permissions.

Food additive permissions in the EU regulations and Codex that are not in the Code were compared in the 2017 Consultation paper. FSANZ's preliminary view was to harmonise food additive permissions (Table 7 in the 2017 Consultation paper) where it was demonstrated that a suitable safety assessment had been undertaken by JECFA, there was a demonstrated history of use of the relevant IFPSDU product (e.g. sold under EU permissions), and where their use was technologically justified. Note that harmonisation with international regulations is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders. Information to inform FSANZ's assessment was sought from stakeholders.

2.1.3 Food additive approach in this paper

This section focuses on the clarity of the current regulations and international harmonisation, where there is no risk to infant health and safety. The information provided by submitters to the 2016 and 2017 consultation papers has informed the consideration. Further safety assessment has been undertaken (Supporting Document 1), enabling consideration of risk management measures and options.

FSANZ has developed a risk management framework comprising of three principles to guide consideration of the risk management approach for food additives. The first principle is protection of infant health and safety. The second principle is that the number of food additives used in infant formula should be the least number necessary to achieve the required technological functions. Finally, the third principle is consideration of harmonisation with international standards. This is consistent with the need to have regard to the promotion of consistency between domestic and international food standards. Since almost all IFPSDU specialised products are not produced in Australia or New Zealand but need to be imported mainly from the EU, consistency with EU regulations is very important for such products. Adoption of these three principles also aims to ensure 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.

It is also important to state where consistency currently exists between the food additive permissions for IFP in the Code and food additive provisions in Codex standards (essentially CXS 72-1981). They are not considered as part of this Consultation paper but will be part of the future proposed drafting.

2.2 Food class system for food additive permissions

2.2.1 Current regulation

As previously indicated in section 2.1.1, food additive permissions in the Code are organised into a hierarchical food class system (in table to section S15—5 and Figure 2.1 below). The system assigns each broad food class a number (e.g. 13 – Special purpose foods), with different types of that food being assigned a 'sub-number' (e.g. 13.1). The general food class for infant formula is 13.1 – infant formula products, with three subclasses of foods. Any food additives listed in 13.1 can be used in products from each subclass (Figure 2.1). The specific additives listed under subclasses are restricted to that particular subclass i.e. an additive permitted for use in 13.1.2 for liquid products cannot be used in all infant formula products. This means liquid infant formula products (subclass 13.1.2) are permitted to use food additives listed for infant formula products (class 13.1), but not those listed for subclasses 13.1.1 and 13.1.3. A similar approach is used in the GSFA and by the EU with minor differences in terminology ('food classes' in the Code and 'food categories' in EU and GSFA), heading descriptions, and numbering (see Tables 2.1, 2.2, and 2.3).

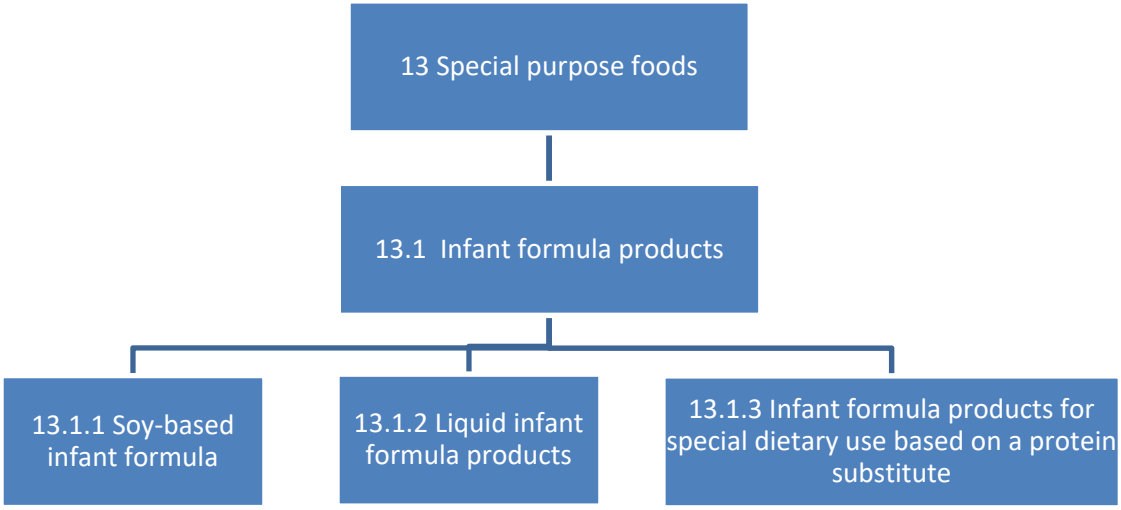

Figure 2.1: Current food classes for food additive permissions in infant formula products in Schedule 15

2.2.2 Previous consideration

Submitters responding to the 2012 Consultation paper noted a lack of clarity on whether the subclasses of infant formula are mutually exclusive. In the 2016 Consultation paper, we sought further information focusing on the interpretations of the carrageenan permissions in liquid and soy formula as an example.

The 2017 Consultation paper included discussion on the differences in the food classes and numbering system between the Code, Codex and the EU regulations. It was noted that the Code contains only one subclass for protein substitute products, which does not capture all IFPSDU. Stakeholders were asked if just one class for all IFPSDU should be used for all additional food additives, or should additional or modified subclasses be devised (pending the changes in categorisation of products in Standard 2.9.1). The 2017 Consultation paper also considered more broadly the regulatory framework for IFPSDU (i.e. definitions and differentiation of IFPSDU within the Code and Standard 2.9.1). This may impact the current food classes in Schedule 15.

2.2.3 Stakeholder views

Three submissions in response to the 2016 Consultation paper agreed that food additive permissions for subclasses of infant formula are unclear. In 2017, nine submissions (4 Industry, 3 health professional organisations, 1 government and 1 individual) responded to FSANZ's question regarding IFPSDU food classes (summarised in Tables 2.4 and 2.5).

Table 2.4 Summary of submitters comments on infant formula food classes

Comment	Submitter
Unclear permissions	
The current food class differentiation creates some uncertainty related to carrageenan given the clarification in the revised Code [S15-2] regarding hierarchy.	Government
Changes to the food classes	
Do not support the current arbitrary framework separating products based on product type, food matrix and ingredient. Food additives should be available for	Industry

Comment	Submitter
the proposed technological function and not be limited by arbitrary separation.	
Propose removing the current subclasses so that only one category applies. This removes duplication and inconsistencies between subclasses allowing manufacturers to use the appropriate food additive for the purpose and product. This will better align and harmonise with overseas markets as current subclasses do not align with other markets.	Industry
Do not agree with additional or modified subclasses, since this would add additional complication.	Health professionals
The Code should start with one food class that applies to all infant formula including IFPSDU, to allow for a consistent range and use levels which is then independent of ingredients, or purpose of the product, with conditions of use applied as appropriate. Further provisions can be developed if required or specific conditions can be provided.	Government
Carrageen permission	
Consider that if there is a technological need for carrageenan in dairy based liquid products then same need is relevant for soy liquid formula	Government
Support the continued permission of carrageenan for use in both milk-based and soy-based liquid infant formula products.	Industry, Government

Table 2.5 Summary of submitter comments on other food additive issues

Comment	Submitter	FSANZ response
Subclasses help clinicians who prescribe IFPSDUs in judging the correct formula for the individual, as each is a case unique in itself. Preterm product should always be clearly differentiated.	Health professionals	The categorisation of types of IFPSDU will be discussed in a subsequent consultation paper. All stakeholder view and comments will be considered. This section is considering whether additional food additive classes in the Code should be created. The food additive classes are only listed in the Code and serve to permit the use of food additives only when safe and appropriate for the product function.
Propose the creation of a new subclass to address pasteurised RTF liquid product fortified with heat-sensitive bioactive protein. New technology and research is needed to address the loss of heat sensitive bioactives added to fortify liquid products that are pasteurised.	Individual	The proposal is only considering how to improve the clarity of the current food classes and harmonising with the international approach. Consideration of new technologies and food additive requirements is better covered by an application to amend the Code.
Concern that there are no thickener food additives on the market that meet the microbiological limits that are applicable to the processing of infant formula. This is a safety concern for preterm/term infants. FSANZ should legislate for such a product to include microbiological limits.	Health professionals	In the Code there are microbiological limits which apply to the final foods rather than food additives. Individual food additives are required to comply with published specifications of identity and purity (which include microbiological criteria). A future consultation paper looks to address the uncertainty of products like thickening agents for infants.

2.2.4 Discussion

Use of notes and conditions to manage permissions

Generally there was support for a single food additive class for IFPSDU, rather than a number of subclasses. A number of submitters suggested distinctions could be made by using qualification statements linked to permissions (similar to both Codex standards and EU regulations). As noted above, the Code currently restricts food additive permissions for infant formula to the minimum necessary to achieve the required technological functions. This is consistent with the approaches in the EU and Codex.

The Codex infant formula standard (CXS 72-1980) lists all permissions for infant formula together and a separate list for formula for special medical purposes intended for infants. Different conditions of use are specified within each list. The EU approach is similar. This approach minimises the number of groups and subgroups of infant formula products. Different conditions of use, qualification notes and restrictions are used to manage the variations in permissions. FSANZ agrees that the use of qualification notes for form (powdered vs liquid) and specialised composition such as hydrolysed protein could clarify how powdered and liquid products are separated into different food classes in Schedule 15 and which sit separately to different protein sources (from a composition perspective). Use of the conditions column can restrict use to specific products (i.e. liquid or powdered form) and manage any differences in maximum permitted levels. This would be consistent with Codex CXS 72-1980 and the GFSA. The EU approach is similar, as food additive use is restricted to specific products such as hydrolysed proteins, peptides or amino acids through the restriction/exceptions column of the EU list which includes various qualifications for use conditions.

Number of infant formula product classes of food additives

FSANZ has considered three options for the number of classes of food additives:

- Option 1: Retaining status quo (no change to the subclasses) will not address the current lack of clarity, does not future proof the schedule and will likely result in duplication of permissions across the subclasses (Figure 2.1).
- Option 2: Create additional subclasses and/or modify the current subclasses (Figure 2.2). Most submitters did not support the addition of additional food classes, noting it is difficult to differentiate products based on ingredients or composition. FSANZ considers this option is likely to increase confusion and introduce unnecessary complication into Schedule 15.
- Option 3: Simplify the approach by reducing the number of subclasses (Figure 2.3). This option only works with the use of the conditions column to qualify or differentiate the permission. This approach can more clearly limit the use of food additives, is consistent with how Schedule 15 already functions and will be harmonised with international food additive provisions.

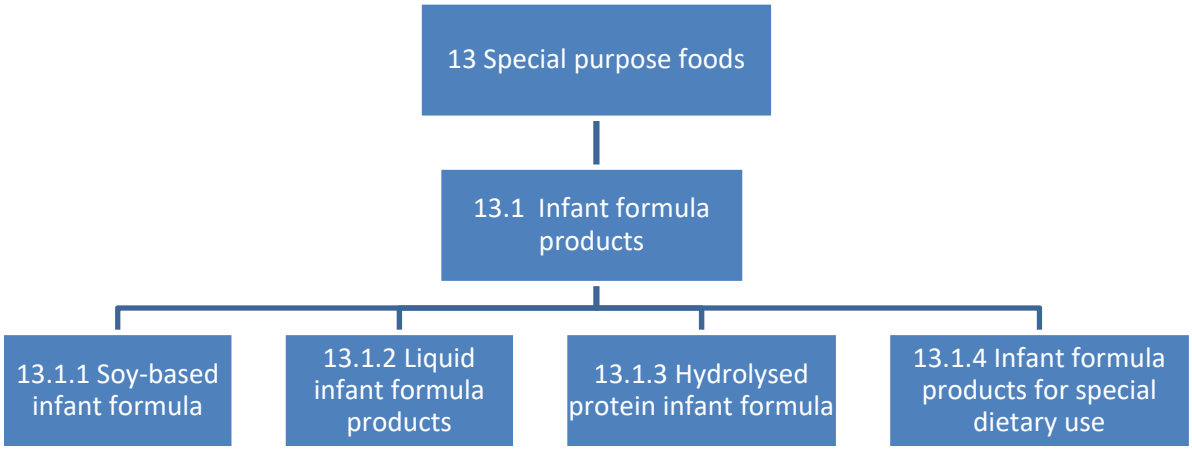

Figure 2.2: Option 2 – creation of additional subclasses

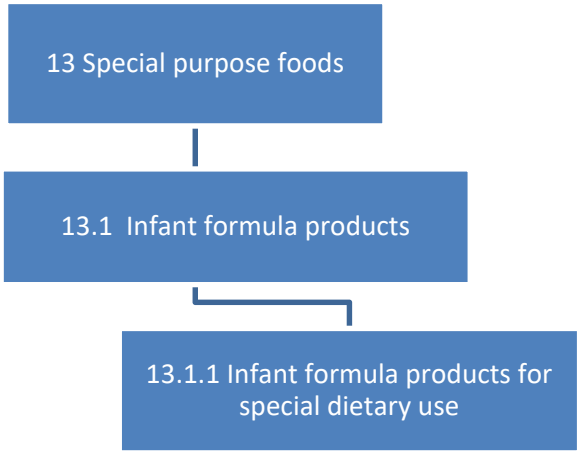

Figure 2.3: Option 3 - one infant formula and one IFPSDU subclass

2.2.5 Proposed approach

FSANZ considers a combination of minimising the food classes and use of qualification notes and conditions would best address the clarity issues and be consistent with international approaches. FSANZ proposes to reduce the subclasses to include just one for IFPSDU (Option 3, Figure 2.3).

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

Food additives used as ingredients in food production may often be present in the final food although not directly added to the food. This occurrence is known as ‘carry-over’. The carry-over principle for food additives enables the presence of food additives in a final food when they are used for a technological function in ingredients or raw materials used to produce

that final food, but in which it provides no technological function i.e. it is 'carried-over' into the final food.

2.3.1 Current regulation – Code, Codex and EU

Previous consultation papers identified a lack of clarity about application of the carry-over principle for infant formula in the Code compared to international regulations. Table 2.6 summarises the food additive carry-over permissions in the Code, Codex and the EU.

Table 2.6 Comparison of carry-over requirements for infant formula food additives in the Code, Codex and EU regulations

Regulation	Carry-over of food additives permitted in infant formula?	Relevant regulation and extract
The Code	Yes	General carry-over allowance for food additives applies to all food classes; there is no exemption for infant formula products. Subsection 1.3.1—3(2): *A substance that is permitted for use as a food additive may be present in any food as a result of carry-over from a raw material or an ingredient if the level of the substance in the food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and GMP.*
Codex Infant formula Standard GFSA	No	Clause 4 CXS 72-1981: 'Only the food additives listed in this Section or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CAC/GL 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: *The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and* *The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (Codex STAN 192-1995).'* Clause 4.3 of GSFA: ***'Foods for Which the Carry-over of Food Additives is Unacceptable*** *Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.* *a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.'*
Europe EC Reg 1333/2008	No	Article 18 (Carry-over principle) of Regulation (EC) No 1333/2008: *Paragraph 1 [carry-over principle] shall not apply to infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children as referred to in Directive 89/398/EEC, except where specifically provided for.*

2.3.2 Previous consideration

The 2016 Consultation paper discussed the differing interpretations of the Code based on the information provided to FSANZ after the 2012 Consultation paper. Some stakeholders consider that the generic requirements of subsection 1.1.1—10(6) means that carry-over of food additives is prohibited unless the additive is already listed for use in infant formula; and this overrides the specific permission in subsection 1.3.1—3(2). Others were of the view that carry-over of food additives was not permitted unless a specific permission existed for infant formula. FSANZ noted that in the current Code (post proposal P1025 – Code revision) the generic requirements of subsection 1.1.1—10(6) apply to all foods including IFP and IFPSDU. It was noted that some submitters' interpretation that carry-over does not apply to infant formula is consistent with the Codex and EU approaches.

Based on these stakeholder views and interpretation, and the desire for the Code to be consistent with Codex and EU regulations, FSANZ's preliminary view in 2016 was that it would be appropriate to restrict carry-over of food additives in IFP including IFPSDU. Stakeholders were asked to comment on the proposed approach and provide a rationale to support their view in submissions to the 2016 Consultation paper.

2.3.3 Stakeholder views

Industry submitters opposed the proposed approach of restricting the carry-over of food additives in IFP including IFPSDU. There was also uncertainty about the Code's carry-over requirements for IFP in the Code. The main argument appeared to be that preventing carry-over of food additives would cause trade disruption since many IFPSDU are imported into Australia and New Zealand. These products currently meet international food additive permissions that are not in line with Code requirements. The industry requires consistent food additive permissions to align with Codex provisions and EU regulations so that removal of carry-over provisions in the Code for IFP could mean imported product would not be compliant.

A number of submitters to the 2016 Consultation paper were of the view that carry-over of food additives was allowed by Codex. As above, their concern was that not allowing carry-over of food additives to infant formula and IFPSDU in the Code would cause trade barriers and place supplies in jeopardy as well as cause technological challenges, since many products are imported. It was also viewed as important that all the food additive provisions in Codex STAN 72-1981 and nutrient carriers in CAC/GL 10-1979 need to be allowed for use in infant formula and IFPSDU in Australia and New Zealand. These permissions may apply if they are used as a result of carry-over from raw materials or ingredients used in manufacture.

Enforcement agencies and some manufacturers also supported FSANZ's initial view that carry-over of food additive permissions in raw materials and ingredients should not apply for food additives unless there are specific permissions for food additives in infant formula and IFPSDU; consistent with Codex and EU regulations.

A summary of submissions and FSANZ's response to question Q2.32 "Should the carry-over principle for food additives apply for infant formula? Please provide your rationale" in the 2016 Consultation paper (which dealt only with infant formula) is provided in Table 2.7.

Table 2.7 Summary of submitter comments on the carry-over principle for food additives

Comment	Submitter	FSANZ response
General concern and view that the industry currently	Industry	As shown in Table 2.6,

Comment	Submitter	FSANZ response
understood that the food additive carry-over principle does apply for infant formula as for all food products. To change this would cause industry disruption. Highlights the importance of this issue to ensure permissions from EU and Codex included in the Code so they are not disadvantaged or cause trade disruption.		Codex permits the carry-over of food additives only from ingredients and raw materials into infant formula when there is also a provision for that food additive in infant formula.
If carry-over DOES NOT apply and the permissions for different food additives are not allowed then many infant formula would not be compliant with the Code. A number of food additives are permitted and required in ingredients that are used in the production of infant formula.	Industry	Noted, this is important for the consideration of this proposal.
All sources of food additives for infant formula needs to be permitted, including those added to: ingredients and raw materials; preparations of food additives or nutrients; and as processing aids in ingredients, preparations of food additives or nutrients.	Industry	Noted, this is important for the consideration of this proposal.
Noted that Codex has carry-over provisions in very limited instances. The Code should reflect these provisions but in general carry-over should not be permitted for infant formula.	Government, Industry	Noted
The carry-over principle should not apply to infant formula provided that exclusions are granted for the use of nutrient carriers in special nutrient forms. This view is based on the FSANZ opinion in section 9 (Processing Aids) of SD2 (see 2016 Consultation paper) that such nutrient carriers are considered as processing aids and not food additives. A sentence to that effect should be made explicit in the Code, either in Standard 1.3.1 or Standard 1.3.3.	Industry	FSANZ notes the comment but does not support as Standards 1.3.1 and 1.3.3 apply to all foods under the requirements of the Code, not just infant formula.
Supports the interpretation that the current Code does not permit carry-over of food additives into infant formula, unless there is an express permission for that food additive in infant formula. Tighter controls should apply for food additives used in infant formula, as these products can be the sole source of nutrition for a vulnerable population group. It believes there is some confusion over using the terms 'carry-over' and 'carry-over principle' which should be made clearer.	Government	Noted, FSANZ has tried to further explain the situation of 'carry-over' for infant formula, as there is confusion noted in comments received.
Notes section D of Codex Guideline CAC/GL 10-1979, contains a limited number of food additives permitted in nutrient preparations added to infant formula. Suggests these food additives are considered part of P1028 but only for the use in nutrient preparations added to infant formula; not for direct addition to infant formula and not to be captured by carry-over.	Government	This was noted in the 2017 Consultation paper. Consideration of processing aids (which is understood to be the suggestion) are that no changes are required for infant formula due to this proposal. See further discussion below.

Comment	Submitter	FSANZ response
The use of food additives added to food additive preparations (i.e. food category 0 in the table to section S15—5). Query whether this category be restricted so that it does not apply to infant formula?	Government	This is not directly part of this consultation paper. It is not thought appropriate or required for such a restriction to be made. See further discussion below.
Provided a simple explanation on how Codex addresses the carry-over principle for food additives in infant formula: '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.	Government	Noted, this is a useful summary of the differences.

2.3.4 Discussion

Additives in nutrient preparations

Section D of the *Codex Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) lists five food additives for 'special nutrient forms'. These are permitted for use as 'nutrient carriers' to convert some vitamins and other nutrients into suitable preparations. In the EU, Commission Regulation (EU) No 1130/2011 outlines the Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients. The aim of the use of those food additives is to have a technological function in nutrients or nutrient preparations e.g. as stabilisers or coatings for the nutrients within the preparation.

The particular five nutrient carriers listed as food additives in CAC/GL 10-1979 can be considered as generally permitted processing aids in the Code so no changes to the Code are required.

The use of food additives used in food additive preparations (table to S15—5, food class 0) in infant formula and IFPSDU has not been specifically considered. Currently the Code does not consider permissions for food additives in food additive preparations differently for infant formula, i.e. such permissions apply for infant formula as for all other food classes. This situation is not considered or captured by carry-over as they are not related to separate ingredients or raw materials. It is not clear what examples of food additive preparations are relevant for infant formula and IFPSDU since common examples of such food additive preparations for other food classes are concentrations of colouring and flavouring preparations, which are not relevant for infant formula and IFPSDU.

Trade barriers related to carry-over principle clarification

Several submitters noted that the approach FSANZ proposed in 2016 would result in non-compliant products and trade barriers. FSANZ's 2016 approach was based on our considerations of comments received on the 2012 paper and questions posed in that consultation.

As discussed above, both Codex and the EU explicitly prohibit carry-over of food additives in infant formula and IFSPDU, while the Code (based on comments received) appears open to interpretation (or at least interpreted differently by different stakeholders).

2.3.5 Proposed approach

FSANZ reaffirms its previous consideration that the Code should be as consistent as possible with Codex and the EU and relevant international food additive regulations for IF including IFPSDU. This includes prohibiting the use of carry-over provisions for food additives unless permissions exist for such food additives used in raw materials and ingredients used to produce infant formula and IFSPDU. Codex and EU regulations do not permit the general carry-over of food additives for infant formula and IFPSDU except where explicit food additive permissions (provisions) already apply to them, so the industry is familiar with, and able to comply with, such regulations and provisions.

The critical matter appears to be to ensure consistency with food additive permissions in the Code with relevant international infant formula and IFPSDU regulations. In this case, the carry-over principle is no longer an issue because the Code would be consistent with international infant formula regulations. The proposed approach is consistent with the general principle that food additive use should be minimised in products for infants who are a vulnerable population.

2.4 Harmonisation of food additive permissions

2.4.1 Overview

As noted above, FSANZ has considered the differences in food additive permissions between the Code, Codex and EU regulations to assess whether it would be appropriate to harmonise the permissions where appropriate safety assessments and technological justifications exist.

Application of risk management principles

Section 2.1.3 of this paper outlines the three risk management principles to guide FSANZ's consideration of food additive permissions. Regarding public health and safety, FSANZ will consider harmonisation of the Code with Codex or EU permissions where an evaluation of the information demonstrates international permissions are based on an existing safety assessment by the Joint FAO/WHO Expert Committee on Food Additives and consideration of any recent published information; that intake or use levels of the food additive in specific population groups for many years are known to be without reported adverse effects in the public literature; and where their use is technologically justified.

For IFPSDU, the continued supply of these specialised products is a priority consideration as they are essential for the small sub-population of infants who have specific physical or physiological conditions, diseases or disorders. Thus a permission that exists in international jurisdictions can provide evidence that the food additive has been consumed safely by these infants, particularly as they are used under medical supervision. According to the policy principle for regulation of infant formula products[10], substances that do not have a history of safe use in Australia and New Zealand require a premarket assessment to be undertaken. As data supporting demonstrated history of safe use is often not available for IFPSDU, no published evidence of harm and as well as advice from health professionals or expert bodies

[10] Food Regulation - Policy guideline on infant formula products https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Infant-Formula-Products

may be considered to be comparable.

Previous consideration

In the 2016 Consultation paper, FSANZ considered additives permitted in Codex standards (as the global reference point). In the 2017 Consultation paper, the European Regulations were added into the consideration as most highly specialised IFPSDU products are imported into Australia and New Zealand from the EU. Both papers listed the differences and sought information to inform FSANZ's assessment. Specific questions were asked to elicit data on safety and technological need for additives in both papers.

This paper

This Consultation paper considers (1) the information provided in submissions on the safety and technological need for additive permissions and (2) the conclusions of the FSANZ risk assessment to propose an approach in terms of harmonising permissions and any risk management options. The following sections summarise whether an evaluation of the evidence supports harmonisation of food additive permissions, considering whether the permitted use is based on safety assessment by the Joint FAO/WHO Expert Committee on Food Additives, that intake or use levels of the food additive in specific population groups for many years are known to be without reported adverse effects in the public literature, and where the use is technologically justified. We have requested that submitters (particularly health professionals) provide further comment on some specific food additives where information to support the proposed approach is incomplete.

In this paper, food additives that are acidity regulators are considered as a group (section 2.4.2, Table 2.7). The other ten food additives are considered individually as they have a number of technological purposes such as emulsifiers, stabilisers and thickeners (section 2.4.3-2.4.12, Table 2.8).

Table 2.7 Comparison of infant formula food additive permissions in the Code, Codex, and European Regulations: acidity regulators

The Code	Codex				EU regulations Annex II of Commission Regulation (EU) No 1129/2011			
Name (INS number)	**Name (INS number)**	**Standard[a] and food category**	**Max use levels (mg/kg)**	**Conditions**	**Name (E number)**	**Food category**	**Max use levels (mg/kg)**	**Restrictions/exemptions**
Calcium carbonates (INS 170)	Calcium carbonate (INS 170(i))	None			Calcium carbonate (E 170)	13.1.5.1	GMP	None
	Calcium hydrogen carbonate (INS 170(ii))	None						
Calcium citrates (INS 333)	Monocalcium citrate (INS 333(i))	None			Calcium citrates (E 333)	13.1.5.1	GMP	None
	Dicalcium citrate (INS 333(ii))	None						
	Tricalcium citrate (INS 333(iii)	None						
Phosphoric acid (INS 338)	Phosphoric acid (INS 338)	None			Phosphoric acid (E 338)	13.1.1	1000[b]	In conformity with the infant formula nutrient limits[e]
						13.1.5.1	1000[b]	Only for pH adjustment Individually or in combination
Sodium phosphates (INS 339)	Sodium dihydrogen phosphate (INS 339i)	CXS 72	450	As phosphorus singly or in combination and within the limits for sodium, potassium and phosphorous in section 3.1.3(e) in all types of infant formula	Sodium phosphates (E339)	13.1.1	1000[b]	E339, E340 are authorised individually or in combination in conformity with the infant formula nutrient limits[e]
	Disodium hydrogen phosphate (INS 339ii)					13.1.5.1	1000[b]	E 339, E 340 and E 341 are authorised individually or in combination
	Trisodium phosphate (INS 339iii)							
Potassium phosphates (INS 340)	Potassium dihydrogen phosphate (INS 340i)	CXS 72	450	As phosphorus singly or in combination and within the limits	Potassium phosphates (E340)	13.1.1	1000[b]	E 339 & E 340 authorised individually or in combination in conformity with the infant formula nutrient limits[e]

The Code	Codex				EU regulations Annex II of Commission Regulation (EU) No 1129/2011			
Name (INS number)	**Name (INS number)**	**Standard[a] and food category**	**Max use levels (mg/kg)**	**Conditions**	**Name (E number)**	**Food category**	**Max use levels (mg/kg)**	**Restrictions/exemptions**
	Dipotassium hydrogen phosphate (INS 340ii)			for sodium, potassium and phosphorous in section 3.1.3(e) in all types of infant formula		13.1.5.1	1000[b]	E 339, E 340 & 341 authorised individually or in combination
	Tripotassium phosphate (INS 340iii)							
Calcium phosphates (INS 341)	Calcium dihydrogen phosphate (INS 341(i))	None			Calcium phosphates E (341)	13.1.5.1	1000[b]	E 339, E 340 and E 341 are authorised individually or in combination
	Calcium hydrogen phosphate (INS 341(ii))	None						
	Tricalcium phosphate (INS 341(iii))	None						
Sodium carbonates (INS 500)	Sodium carbonate (INS 500i)	CXS 72 & GSFA 13.1 1& 13.1.3	2000	Notes c and d	None			
	Sodium hydrogen carbonate (INS 500ii)				None			
Potassium carbonates (INS 501)	Potassium carbonate (INS 501i)	CXS 72 & GSFA 13.1 1& 13.1.3	2000	Notes c and d	None			
	Potassium hydrogen carbonate (INS 501ii)				None			
Sodium hydroxide (INS 524)	Sodium hydroxide (INS 524)	CXS 72 & GSFA 13.1 1& 13.1.3	2000	Notes c and d	Sodium hydroxide (E 524)	13.1.5.1	GMP	Only for pH adjustment

The Code	Codex				EU regulations Annex II of Commission Regulation (EU) No 1129/2011			
Name (INS number)	**Name (INS number)**	**Standard[a] and food category**	**Max use levels (mg/kg)**	**Conditions**	**Name (E number)**	**Food category**	**Max use levels (mg/kg)**	**Restrictions/exemptions**
Potassium hydroxide (INS 525)	Potassium hydroxide (INS 525).	CXS 72 & GSFA 13.1 1& 13.1.3	2000	Notes c and d	Potassium hydroxide (E 525)	13.1.5.1	GMP	Only for pH adjustment
Calcium hydroxide (INS 526)	Calcium hydroxide (INS 526)	CXS 72 & GSFA 13.1 1& 13.1.3	2000	Notes c and d	Calcium hydroxide (E 526)	13.1.5.1	GMP	Only for pH adjustment

Notes:

a *Relevant Codex text: Codex STAN 72-1981 (CXS 72), and/or GSFA (Codex STAN 192-1995) food category 13.1.1 (Infant formulae) and 13.1.3 (Formulae for special medical purposes for infants)*

b *Maximum level is expressed as P_2O_5. It is noted that 1000 mg/kg phosphorus as P_2O_5 is approximately equivalent to 450 mg/kg as phosphorus.*

c *GSFA: Within the limits for sodium, calcium, and potassium specified in the CXS 72-1981: singly or in combination with other sodium, calcium, and/or potassium salts. On the ready-to-eat basis*

d *CXS 72: 2000 mg/kg singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3(e) in all types of infant formula*

e *In conformity with the limits set in Directives 2006/141/EC, 2006/125/EC, 1999/21/EC [limits for phosphorous]*

Table 2.8 Comparison of infant formula food additive permissions in the Code, Codex, and European Regulations: thickeners, emulsifiers and stabilisers

The Code	Codex			EU regulations Annex II of Commission Regulation (EU) No 1129/2011		
Name (INS number)	**Name (INS number)**	**Standard and food category**	**Max use levels (mg/kg) and conditions**	**Name (E number)**	**Food category**	**Max use levels (mg/kg) and restrictions/exemptions**
Citric and fatty acid esters of glycerol (INS 472c)	Citric and fatty acid esters of glycerol (CITREM) (INS 472c)	CXS 72 GFSA 13.1 (so 13.1.1 & 13.1.3)	9000 mg/kg for liquid infant formula 7500 mg/kg for powdered infant formula As consumed	E 472 c	13.1.1	7500 mg/kg , only when sold as powder 9000 mg/kg, only sold as liquid where the products contain partially hydrolysed proteins, peptides or amino acids
					13.1.5.1	7500 mg/kg , only when sold as powder 9000 mg/kg , only sold as liquid
Starch sodium octenylsuccinate (INS 1450) No permission for infant formula	Starch sodium octenylsuccinate (INS 1450)	CXS 72 GFSA 13.1.3	20,000 mg/L for use in hydrolysed protein and/or amino acid based infant formula only As consumed	E 1450	13.1.5.1	20000 mg/kg, only in infant formulae and follow-on formulae
Locust bean (carob bean) gum (INS 410)	carob bean gum (locust bean gum) (INS 410)	CXS 72 GSFA 13.1.3	Infant formula products at 1000 mg/kg As consumed	Locust bean gum E 410	13.1.5.1	10,000 mg/kg From birth onwards in products for reduction of gastro-oesophageal reflux
Pectins (INS 440) No permission for infant formula	Pectins (INS 440)	No relevant permission for infant formula exists		E 440	13.1.5.1	10000 mg/kg, From birth onwards in products used in case of gastro-intestinal disorders
Xanthan gum (INS 415) No permission for infant formula	Xanthan gum (INS 415)	No relevant permission for infant formula exists		E 415	13.1.5.1	1200 mg/kg, From birth onwards for use in products based on amino acids or peptides for use with patients who have problems with impairment of the gastrointestinal tract, protein mal-absorption or inborn errors of metabolism
Guar gum 412	Guar gum (INS 412)	CXS 72 GFSA 13.1.1 & 13.1.3	1000 mg/kg in hydrolysed protein liquid formula only. On the ready-to-eat	E 412	13.1.1	1000 mg/kg, only where the liquid product contains partially hydrolysed proteins
					13.1.5.1	10,000 mg/kg, From birth onwards in products in liquid formulae containing

The Code	Codex			EU regulations Annex II of Commission Regulation (EU) No 1129/2011		
Name (INS number)	**Name (INS number)**	**Standard and food category**	**Max use levels (mg/kg) and conditions**	**Name (E number)**	**Food category**	**Max use levels (mg/kg) and restrictions/exemptions**
			basis.			hydrolysed proteins, peptides or amino acids
Sodium alginate (INS 401) No permission for infant formula	Sodium alginate (INS 401)	No relevant permission for infant formula exists		E 401	13.1.5.1	1000 mg/kg , from four months onwards in special food products with adapted composition, required for metabolic disorders and for general tube-feeding
Carboxymethyl-cellulose (INS 466)	Sodium carboxymethyl-cellulose (INS 466)	No relevant permission for infant formula exists		Carboxy methyl cellulose E 466	13.1.5.1	10000 mg/kg, from birth onwards in products for the dietary management of metabolic disorders
Sucrose esters of fatty acids (INS 473) No permission for infant formula	Sucrose esters of fatty acids (INS 473)	No relevant permission for infant formula exists		E 473	13.1.5.1	120 mg/kg , only products containing hydrolysed proteins, peptides or amino acids

2.4.2 Acidity regulators

Previous consideration

In 2016 an additional twelve acidity regulators were identified as permitted for use in infant formula in Codex (CXS 72-1981). FSANZ sought information on the technological justification and need as food additives noting that the substances are also used as processing aids and as permitted forms of minerals used in infant formula products.

In 2017 (addressing IFPSDU), 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. Ten additional food additives were identified. The full list of acidity regulators that are being considered for alignment is shown in Table 2.7.

Stakeholder views

Five submissions (four from industry and one from government) were received to the 2016 Consultation paper. Industry submitters supported the substances as being safe and technologically justified as either food additives (acidity regulators), processing aids or permitted forms of nutrients. Industry supplied technological justification for permitting these food additives for infant formula (Table 2.9).

Submitters noted that the safety and technological purpose for each additive has been assessed and demonstrated through the permission and use as per the Codex texts. It was also highlighted that many are also permitted forms of minerals in infant formula. There was support for harmonisation of the permissions for trade of infant formula.

The government submission supported seeking further industry information on the technological purpose of these food additives, noting JECFA may be reviewing food additives permissions for infant formula products and it may be premature to adopt Codex provisions.

Table 2.9 Summary of submitter comments for acidity regulators

Additive	Technological justification	History of use for infants
Calcium carbonates INS 170	Several technological functions when added to infant formula . As an acidity regulator in acidic solution it increases the pH, as well as in some solutions it provides buffering capacity. It can also be used as an anticaking agent on some raw materials. As a powder it can be used as an insoluble salt such that it will not interact with milk proteins in solution and so not induce protein flocculation during heat treatments	Evidence of safety as they are permitted forms of calcium in the Code and in the Codex CAC/GL 10-1979.
Calcium citrates INS 333	Several technological functions when added to infant formula . As an acidity regulator in acidic solution it increases the pH, as well as in some solutions it provides buffering capacity. It can also be used as an anticaking agent on	Evidence of safety as permitted forms of calcium in the Code, Codex and EU regulations

Additive	Technological justification	History of use for infants
	some raw materials. As a powder it can be used as an insoluble salt such that it will not interact with milk proteins in solution and so not induce protein flocculation during heat treatments.	
Phosphoric acid INS 338	Technological function as a pH adjuster used during the course of manufacturing. Used to acidify at low pH solutions containing milk protein ingredients before the heat treatment in order to prevent the aggregation and coagulation of milk proteins during the heat treatment (Bernal and Jelen 1985). No phosphoric acid remains in the final product because it is quantitatively transformed to phosphate salts due to the final pH of products and the presence in all of them of important concentrations of several reactive cations (Ca, Mg, Na, K, Na, K, Fe, etc.).	Evidence of safety from permitted food additive in the EU in infant formulas and in FSMP as an acidity regulator. Also suggested that permission as a processing aids in the Code further demonstrates safety. Noted the level of Phosphorus is well controlled as there is a maximum amount in Standard 2.9.1 and the Ca:P ratio is also regulated.

FSANZ's risk assessment

A summary of the risk assessment conclusions for each of the types of acidity regulators are provided below. The full detailed risk assessments are provided in Supporting Document 1.

Calcium carbonates (INS 170), calcium citrates (INS 333) and calcium hydroxide (INS 526) (excerpt from Table 2.7)

The Code	Codex			EU regulations		
Name (INS)	**Name (INS)**	**Standard/ food category**	**Max use levels (mg/kg)**	**Name (E number)**	**Food category**	**Max use levels (mg/kg)**
Calcium carbonates (INS 170)	Calcium carbonates[1] (INS 170)	None		Calcium carbonate (E 170)	13.1.5.1	GMP
Calcium citrates (INS 333)	Calcium citrates[2] (INS 333)	None		Calcium citrates (E 333)	13.1.5.1	GMP
Calcium hydroxide (INS 526)	Calcium hydroxide (INS 526)	CXS 72 & GSFA 13.1 1& 13.1.3	2000	Calcium hydroxide (E 526)	13.1.5.1	GMP

[1] Specified as calcium carbonate and calcium hydrogen carbonate
[2] Specified as monocalcium citrate, dicalcium citrate, and tricalcium citrate

FSANZ considers that permitting calcium carbonates and calcium citrates as food additives (acidity regulators) in IFPSDU at GMP, and calcium hydroxide in all infant formula at an MPL of 2000 mg/kg, does not pose toxicological concerns. Calcium carbonates, calcium citrates and calcium hydroxide have been evaluated as food additives by JECFA. The Committee noted that there is a wide latitude for dietary variations in calcium content without toxicological effects, and established an ADI of 'not specified' for all three food additives. An ADI not specified is established for compounds of very low toxicity that are not considered to represent a risk to health based on current usage levels.

JECFA also considered the safety of dietary exposure to citric acid from infant formula as

part of its evaluation of citric and fatty acid esters of glycerol. While there was some evidence of diarrhoea in infants at high doses, the risks are low at the levels at which calcium citrate will be used as an acidity regulator.

Calcium carbonates, calcium citrates and calcium hydroxide are also already permitted forms of minerals for addition of calcium to infant formula products, food for infants and food for special medical purposes in Schedule 29–7. Therefore their use as food additives does not raise additional toxicological concerns provided that acceptable total levels of calcium in the diet and nutritionally appropriate ratios of calcium to phosphorus ratio are maintained.

At the proposed MPL for calcium hydroxide of 2000 mg/kg, the recommended maximum level of calcium set out in S29–10 could be exceeded slightly (~108 mg/100 mL versus ~97 mg/100 mL, based on the proposed maximum energy content of 295 kJ/100 mL infant formula ready for consumption). It is not anticipated that this slight exceedance would be of toxicological significance.

Sodium carbonates (INS 500), sodium hydroxide (INS 524), potassium carbonates (INS 501) and potassium hydroxide (INS 525)
(excerpt from Table 2.7)

The Code	Codex			EU regulations		
Name (INS number)	**Name (INS number)**	**Standard and food category**	**Max use levels (mg/kg)**	**Name (E number)**	**Food category**	**Max use levels (mg/kg)**
Sodium carbonates (INS 500)	Sodium carbonates[1] (INS 500)	CXS 72 & GSFA 13.1 1& 13.1.3	2000	None		
Potassium carbonates (INS 501)	Potassium carbonates[2] (INS 501)					
Sodium hydroxide (INS 524)	Sodium hydroxide (INS 524)			Sodium hydroxide (E 524)	13.1.5.1	GMP
Potassium hydroxide (INS 525)	Potassium hydroxide (INS 525)			Potassium hydroxide (E 525)	13.1.5.1	GMP

[1] Specified as sodium carbonate and sodium hydrogen carbonate
[2] Specified as potassium carbonate and potassium hydrogen carbonate

Sodium carbonates, sodium hydroxide, potassium carbonates and potassium hydroxide have been assessed by JECFA and ADIs ‘not specified’ have been established for all of these additives.

Sodium carbonates, sodium hydroxide, potassium carbonates and potassium hydroxide are also already permitted forms of minerals for addition of sodium and potassium to infant formula products, food for infants and food for special medical purposes in Schedule 29–7. Therefore their use as food additives does not raise additional toxicological concerns provided that limits on sodium and potassium content in infant formula, prescribed in S29–9 are maintained.

FSANZ notes that at the proposed MPL for sodium carbonates and sodium hydroxide of 2000 mg/kg, it is possible that the maximum level of sodium set out in S29–9 could be exceeded. For example, based on the proposed maximum energy content of 295 kJ/100 mL in formula ready for consumption, use of sodium hydroxide at the MPL would be expected to result in a sodium concentration of approximately 114 mg/100 mL, compared with a permitted maximum of approximately 44 mg/100 mL. Maximum potassium levels would not

be expected to be exceeded at the proposed levels.

Phosphoric acid (INS 338), sodium phosphates (INS 339), potassium phosphates (INS 340) and calcium phosphates (INS 341)
(Excerpt from Table 2.7)

The Code	Codex			EU regulations		
Name (INS number)	**Name (INS number)**	**Standard and food category**	**Max use levels (mg/kg)**	**Name (E number)**	**Food category**	**Max use levels (mg/kg)**
Phosphoric acid (INS 338)	Phosphoric acid (INS 338)	None		Phosphoric acid (E 338)	13.1.1	1000[b]
					13.1.5.1	1000[b]
Sodium phosphates (INS 339)	Sodium dihydrogen phosphates[1] (INS 339)	CXS 72	450	Sodium phosphates (E339)	13.1.1	1000[b]
					13.1.5.1	1000[b]
Potassium phosphates (INS 340)	Potassium dihydrogen phosphates[2] (INS 340)	CXS 72	450	Potassium phosphates (E340)	13.1.1	1000[b]
					13.1.5.1	1000[b]
Calcium phosphates (INS 341)	Calcium dihydrogen phosphates[3] (INS 341)	None	None	Calcium phosphates E (341)	13.1.5.1	1000[b]

[1] Specified as sodium dihydrogen phosphate, disodium hydrogen phosphate, and trisodium phosphate
[2] Specified as potassium dihydrogen phosphates, dipotassium hydrogen phosphate, and tripotassium phosphate
[3] Specified as calcium dihydrogen phosphates, calcium hydrogen phosphate, and tricalcium phosphate

JECFA has established a group Maximum Tolerable Daily Intake (MTDI) for phosphorus from all sources of 70 mg/kg bw/day, expressed as phosphorus. The MTDI was established on the basis of findings of nephrocalcinosis in studies in rats. EFSA re-evaluated the use of phosphates as food additives in 2019, and concluded that based on the available data their use did not give rise to safety concerns in infants below 16 weeks of age consuming formula and food for special medical purposes.

Sodium phosphates, potassium phosphates and calcium phosphates are currently permitted forms of electrolytes for addition to infant formula products, food for infants and food for special medical purposes in Schedule 29—7 of the Code. Phosphoric acid is not currently permitted but it is included in the JECFA PMTDI which applies to phosphoric acid and phosphate salts. Therefore the of use phosphoric acid, sodium phosphates, potassium phosphates and calcium as food additives does not raise additional toxicological concerns provided all compositional limits for calcium, sodium, potassium and phosphorus specified in the Code are met.

The maximum limit for phosphorus or calcium is not expected to be exceeded, but at the proposed MPL for sodium phosphates and potassium phosphates of 450 mg/kg as phosphorus, the maximum levels of sodium or potassium set out in S29—9 could be exceeded. For example, based on the proposed maximum energy content of 295 kJ/100 mL in formula ready for consumption, use of trisodium phosphate at the MPL would be expected to result in a sodium concentration of approximately 100 mg/100 mL, compared with a permitted maximum of approximately 44 mg/100 mL. Use of tripotassium phosphate at the MPL may result in a potassium concentration of approximately 171 mg/100 mL, compared with a permitted maximum of approximately 147.5 mg/100 mL.

Discussion and proposed approach

Technological use of substances and technological justification

Based on information provided by submitters to the 2016 Consultation paper (Table 2.9), FSANZ considers the use of these substances as acidity regulators is justified. We also note that these substances can have additional technological purposes in infant formula products.

Current international reviews

FSANZ is aware that the CCFA and JECFA have identified food additives permitted in infant formula which could be eligible for a safety review specific to infants. One submitter noted the potential of JECFA reviewing the safety of a number of food additives for use in infant formula, suggesting FSANZ should delay consideration. To date, no changes to food additive permissions for infant formula have been decided by CCFA or CNFSDU, though FSANZ will maintain a watching brief to check if any changes are proposed. At this stage FSANZ does not consider that permitting additional acidity regulators to be consistent with Codex and the EU would be pre-emptive, as it would facilitate trade harmonisation.

Potential intakes - risk management

As discussed, a number of these acidity regulators are also used as nutritive substances. This is not uncommon and is managed through the Code as explained in the notes to Paragraph 1.1.1–10.[11] Standard 2.9.1 and Schedule 29 outline the guidance upper levels, maximum levels and ratios for essential minerals and electrolytes. These include requirements and limits for calcium, sodium, potassium and phosphorous and a calcium to phosphorous ratio.

FSANZ's safety assessment confirmed the safety of the food additives as acidity regulators in infant formula at the levels in the Codex standards and EU regulations, but noted the potential for possible exceedances of the maximum levels outlined in section S29—9. Both Codex and EU regulations set qualifications that use of these acidity regulators must be within the limits on calcium, sodium, potassium and phosphorus content in infant formula. FSANZ considers that the potential for intakes to exceed the use of conditions for the additives in a similar manner to that used in Codex and the EU, therefore condition statements linked to food additive permissions could be used.

It is noted, for information, that the EU regulation for various phosphorus containing acidity regulators (various phosphates) with the MPL of 1000 mg/kg of phosphorus as phosphorus (V) oxide (P_2O_5), is approximately equivalent to 450 mg/kg as phosphorus (in Codex provisions), due to the proportion of phosphorus in P_2O_5 (approximately 45%).

A check of the Code identified that relevant phosphate food additives are listed in Schedule 16 as GMP food additives. There is currently only one numerical MPL in Schedule 15 for magnesium phosphates (INS 343) of 10,000 mg/kg for food class 1.5 – Dried milk, milk powder, cream powder.

The Code does not state how permissions in the Code for phosphorus containing food additives are expressed for assessment of the MPL so the default situation is they are as the

[11] **Note 2 -** There is an overlap between some of these categories. For example, some substances may be used as a food additive or as a nutritive substance. For such substances, there will be different provisions permitting use of the substance for different purposes.
Note 3 - In some cases, a provision refers to the total amount of a substance added to a food. In these cases, the total amount applies irrespective of whether the substance was used as a food additive, used as a processing aid or used as a nutritive substance.

substances themselves, since as noted above there is only one instance of a numerical MPL for such phosphate additives.

However, if FSANZ's proposed amendments permitting phosphate acidity regulators for IF with numerical MPLs are agreed then how the MPL is expressed is required. It is suggested that the preference is as phosphorus (consistent with Codex) rather than as P_2O_5 (consistent with EU regulations). This would require a consequential amendment to subsection 1.3.1—4(6). Proposed wording could be:

Recommendation for subsection 1.3.1—4(6) regarding phosphates

(l) sodium, potassium, calcium and ammonium phosphates calculated as phosphorus.

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

Currently the Code permits citric and fatty acid esters of glycerol (CITREM) (INS 472c) for use at 9000 mg/L in food class 13.1.3 *Infant formula products for specific dietary use based on a protein substitute* (a sub-class of 13.1 *Infant formula products*). As shown in Table 2.8, the EU and Codex permits use in all types of infant formula. The Code only sets one MPL while both EU & Codex differentiate the MPL for powdered (7500 mg/kg) and liquid (9000 mg/kg) products.

Previous consideration

FSANZ sought information as part of the 2016 Consultation paper on the technological justification for extending the use of the food additive to all types of infant formula to assist FSANZ's consideration. Information was also requested in the 2017 Consultation paper relating specifically to IFPSDU as to whether there are any technologically justified concerns with changing the permissions for the food additive to 9000 mg/kg for liquid products and 7500 mg/kg for powdered products.

Stakeholder views

Four industry submissions provided a technological justification supporting extending the permission to all infant formula. Industry queried whether different MPLs are required, that MPL should be 9000 mg/L for both liquid and powdered forms (Table 2.10).

Table 2.10 Summary of submitter comments on citric and fatty acid esters of glycerol (CITREM) (INS 472c)

Technological justification	History of safe use for infants
Preferred emulsifier to improve the stability and organoleptic properties of products containing (partially) hydrolysed proteins, peptides or amino acids. The technological purpose is to ensure palatability and prevent phase separation of reconstituted formula. Such products are not just for IFPSDU since some standard infant formula may also contain hydrolysed protein.	JECFA assessment undertaken in 2014 Aware of use of the food additive in IFPSDU in other international markets.

FSANZ's risk assessment

JECFA has previously concluded that the use of CITREM in infant formula and formula for special medical purposes at concentrations up to 9000 mg/L (7500 mg/L in reconstituted infant formula and powder and 9000 mg/L in ready-to-feed liquid formula) does not raise any toxicological concerns. A literature search did not identify any new information that would indicate a need to amend this conclusion.

Free citric acid released from CITREM containing-formula is unlikely to cause diarrhoea at lower use levels (e.g. up to 2700 mg/L), whereas at higher use levels (up to 9000 mg/L) there is a possibility of diarrhoea from free citric acid. It is not possible to quantify the risk based on the very limited data available, but it is likely to be low.

Discussion and proposed approach

FSANZ understands the different MPLs relate to the different requirements of the liquid form compared to the powdered form. Higher levels are required in liquid products to ensure that the formula remains stable over its shelf life to minimise the risk of fat separation and sedimentation of insoluble particles. Stability of the emulsion is also important to maintain acceptable sensory aspects of appearance, colour and odour. FSANZ notes that while safety is demonstrated at 9000 mg/kg, the preference is to minimise food additive use in infant formula.

Given the conclusions of the safety assessment and the use of hydrolysed protein products in general infant formula products FSANZ considers it is appropriate to harmonise with Codex and EU. This would extend permission to use in infant formula as well as IFPSDU.

Based on information available, there is no need for the same MPL for liquid and powdered products. FSANZ proposes 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.

2.4.4 Starch sodium octenylsuccinate (INS 1450)

Starch sodium octenylsuccinate (INS 1450) (also commonly named octenyl succinic acid (OSA)-modified starch) is not permitted in the Code for use in any types of infant formula products.

Codex has provision for the food additive in infant formula (food category 13.1.3) in the GSFA, and in Codex STAN 72-1981 (for use in hydrolysed protein and/or amino acid based infant formula only) both at 20,000 mg/L (mg/kg). The EU permits use only in infant formula for special medical purpose up to 20,000 mg/L.

Previous consideration

In 2016, FSANZ noted the Codex permission in hydrolysed products and considered the additive out of scope of the Proposal as IFPSDU were not being considered at that time. The 2017 Consultation paper sought information on suitable international safety assessments, a demonstrated history of safe use and a technological justification for its use.

Stakeholder views

Industry comments to the 2016 Consultation paper noted a JECFA assessment concluded the food additive is safe for all infant formula products and suggested it should be considered for permission in the Code. Industry also noted that the permission in the EU regulations provided additional history of safe use. The technological justification for use of the food

additive is due to its emulsifying properties, both during processing and after reconstitution. It also has a function in reducing free fat formation and oxidation. It is specifically effective when used with extensively hydrolysed protein and free amino acid formulas.

FSANZ's risk assessment

JECFA has previously concluded that based on the available data, the consumption of starch sodium octenylsuccinate in infant formula products for special dietary uses at a maximum level of 20,000 mg/L does not raise health concerns. A literature search did not identify any new information that would indicate a need to amend this conclusion.

Discussion and proposed approach

FSANZ has considered the information outlined above to determine whether it is appropriate to permit use in all types of infant formula, only in IFPSDU with or without restrictions. As noted in Table 2.8, Codex and the EU restrict use to regulations for infant formula for special medical purposes. Codex further restricts use for products containing hydrolysed protein and/or amino acid based only up to 20,000 mg/kg.

FSANZ considers permitting use in infant formula for special dietary uses with the restriction of only being used for products containing hydrolysed protein and/or amino acids is appropriate. This approach is consistent with the food additive principles and is consistent with both Codex and EU regulation.

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

Locust bean (carob bean) gum is currently permitted in the Code for use in all infant formula products up to 1000 mg/L. This is consistent with Codex. European regulations only permit use in 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 restricted to products for the reduction of gastro-oesophageal reflux.

Previous consideration

The 2017 Consultation paper proposed to harmonise with the EU regulation and sought views on this approach. Information was also requested on any additional national safety assessments, demonstrated history of safe use and technological justification for its use.

Stakeholder views

Industry submissions provided information (Table 2.11) on the use and technological justification and requested that the MPL be increased from 1000 mg/L to 10,000 mg/kg (L) for all infant formula. Submitters generally supported alignment with EU permissions noting the highly specialised IFPSDU products are mostly imported. Continued supply of these products is essential to manage the dietary needs of infants who have specific medical conditions.

In addition, the Royal Australasian College of Physicians (RACP), provided comments on the safety of this substance in relation to its uses as a thickener to be added to breast milk or formula. RACP raised concerns in general about case study reports in the literature suggesting an association between the use of gum-based thickeners and gastrointestinal disorders in pre-term infants.

Table 2.11 Summary of submitter comments on locust bean (carob bean) gum (INS 410)

Technological justification	History of use for infants
Can be used as a thickener, stabiliser, emulsifier and gelling agent. Specific use as a thickening agent for IFPSDU to provide clinically effective dietary management of gastroesophageal reflux. Acts on the stomach acidity by thickening and increasing the viscosity of the alimentary bolus to reduce gastroesophageal reflux with the impact of gravity. The advantage over other additives is that it can form viscous solutions at relatively low concentrations that are not impacted by pH or temperature. It also does not alter the taste of the infant formula and it also does not add additional energy since it is made up of non-digestible polysaccharides.	Demonstrated by the use in infant formula on the market since the 1990s. Has been used in these products in Europe for over 20 years at 10,000 mg/L and so therefore has a history of safe use. Its use was permitted by the Scientific Committee on Food (SCF) in 1994. EFSA further endorsed the 2003 conclusions of the SCF that there is a need for the use of the food additive in infant formula for use with a small number of infants with gastro-oesophageal reflux disease under medical supervision. Recent review of the toxicology and clinical evidence that concluded locust bean gum is safe for use as a thickener in IFPSDU for use in the treatment of uncomplicated but frequent troublesome regurgitation in infants (Meunier et al 2014).

FSANZ's risk assessment

Studies involving direct oral administration to neonatal animals are required for evaluation of food additives in infant formula, but are not available for locust bean gum. JECFA previously concluded that without such studies the available data are not sufficient for the evaluation of locust bean gum for use in infant formula at the proposed use level of 10,000 mg/L. A literature search did not identify any new toxicological studies with neonatal animals that would change this conclusion.

EFSA has not yet completed a re-evaluation of locust bean gum in foods for infants under 12 weeks of age, however in its 2017 re-evaluation of other uses it noted that infants and young children consuming foods for special medical purposes may show a higher susceptibility to gastrointestinal effects due to their underlying medical condition. EFSA concluded that the available data did not allow an adequate safety assessment of locust bean gum in these foods for infants and young children. EFSA is due to re-evaluate use of locust bean gum in foods for infants below 16 weeks of age and has called for toxicological data to support the assessment.

There are two case reports of isolated adverse events in extremely low birth weight infants fed formula containing locust bean gum, including fatal necrotising enterocolitis (NEC). Based on the available information it is not possible to determine if there is a causal association with carob bean gum based on the available information. JECFA reached the same conclusion in considering these case reports, while EFSA also noted the lack of pathophysiology for the cases of NEC.

JECFA did not specifically comment on the safety of locust bean gum at the MPL of 1,000 mg/L currently permitted in the Codex Standard and the Code, although it was noted that this level is much lower than the proposed use level of 10,000 mg/L. Studies in infants at concentrations up to 6000 mg/L locust bean gum, 3300 mg/L cold soluble locust bean gum galactomannans or 4500 mg/L hot soluble locust bean gum galactomannans did not report

any serious adverse events, indicating that use in infant formula at the current MPL is unlikely to be of toxicological concern.

Discussion and proposed approach

The current permission for infant formula in the Code and Codex provide a history of use at 1000 mg/L. FSANZ's risk assessment concluded the current permissions are unlikely to be of toxicological concern. Therefore, FSANZ considers it is appropriate to retain the current permission for use in infant formula to 1000 mg/kg.

Given the risk assessment conclusions of FSANZ, JECFA and EFSA do not currently support addition up to 10,000 mg/L and that the EFSA re-evaluation of the substance for infants below 16 week of age is still pending, some caution is required in considering extension of the permission at the higher level to IFPSDU. Therefore, FSANZ considers alignment with the restriction in the EU permission for use only in 'products for reduction of gastro-oesophageal reflux', may be appropriate but we seek additional information, particularly from health professionals, about the need to permit addition of locust bean gum at a higher level for IFPSDU. Additionally, information from manufacturers about industry use levels in IFPSDU is requested. This information would assist in ensuring that importation of these specialised products is maintained.

2.4.6 Pectins (INS 440)

Pectins are permitted in the Code but are not permitted for any types of infant formula products. Currently there are no provisions for pectins in Codex infant formula standards. Pectins are permitted in the EU only in food category 13.1.5.1 - Dietary foods for infants for special medical purpose and special formulae for infants in products from birth onwards for infants with gastrointestinal disorders. The MPL is 10,000 mg/L.

Previous consideration

In 2017 FSANZ proposed to align with the EU permission only for use in IFPSDU products for infants with gastrointestinal disorders. Views on this approach as well as information on safety and technological justification was requested.

Stakeholder views

Industry supported alignment with EU and sought further permissions for use in infant formula that contains a non-intact protein base at a MPL of 2000 mg/L. The summary of submissions are provided in Table 2.12.

Table 2.12 Summary of submitters comments on pectins (INS 440)

Technological justification	Safety/History of safe use for infants
Technological purposes fall under the functional classes - thickener (increases the viscosity of a food) - stabiliser (maintains the homogeneous dispersion of two or more immiscible substances in a food). Pectin addition minimises protein agglomeration and sedimentation during thermal processing, and over shelf life. Thermal processes can impact the stability of emulsions.	Pectins have been used in IFPSDU in Europe for a number of decades and therefore has a history of safe use. JECFA (2016) assessed safety of infants <12 weeks concluded no safety concern. Safety and good tolerance was assessed and established in 5 recently published clinical trials involving over 300 infants aged less than 18 months, 2/3 were suffering from cow's milk protein allergy. Infants were fed formulas

Pectin helps form stable emulsions and increases viscosity in the formula matrix, which serves to minimise product separation and maintain homogeneity during shelf life. The level selected to use in product is the minimum required to achieve the desired physical properties throughout shelf life.	containing 0.5 g/100 mL of a fibre complex including pectins for up to 6 months. The studies concluded that infants had adequate growth against comparators, and good acceptability.

FSANZ's risk assessment

JECFA has concluded that based on the available data, the consumption of pectins in all infant formula products at a maximum level of 2000 mg/L does not raise safety concerns. However, prior to that consideration JECFA evaluated a proposed maximum level of 5000 mg/L. Estimated exposure at 5000 mg/L was in the region of the no observed adverse effect level (NOAEL) in a neonatal pig study and close to the lowest observed adverse effect level (LOAEL), which was based on decreased feed intake and body weight gain. Estimated exposures at 5000 mg/L were therefore considered to be of concern.

EFSA published a re-evaluation of the use of pectin and amidated pectin in foods for infants below 16 weeks of age in 2021 (EFSA 2021). EFSA found that estimated exposures at the current EU MPL of 10,000 mg/kg and for high consumers at the maximum use level reported by industry (4170 mg/kg bw/day) resulted in margins of exposure MOEs lower than 1 compared with the NOAEL in neonatal pigs. EFSA also noted that at the current EU MPL, internal methanol exposure from methylated pectin could lead to adverse health effects in infants below 16 weeks of age. EFSA has recommended that additional clinical data should be generated to assess the safety of pectins when used in 'dietary foods for special medical purposes and special formulae for infants' and in 'dietary foods for babies and young children for special medical purpose; and that the current MPL be lowered to address these health concerns.

FSANZ calculated the estimated internal methanol exposure from use of 90% methylated pectin in infant formula at a maximum use level of 2000 mg/L, using JECFA's dietary exposure estimates and following the same methodology as EFSA. At this pectin concentration exposure to methanol is not expected to result in adverse health effects.

FSANZ did not identify any new information that would alter JECFA's conclusions that consumption of infant formula containing pectins at concentrations up to 2000 mg/L do not raise health concerns, but exposures from formula containing ≥ 5000 mg/L pectin are of concern.

Discussion and proposed approach

FSANZ has considered several options based on the safety assessment, current international permissions and information provided in submissions. JECFA's and FSANZ's risk assessment conclusion is that there is no safety concern with permitting the food additive for all infant formula products up to 2000 mg/L but exposures from formula containing ≥ 5000 mg/L pectin may be of concern.

EFSA's 2021 conclusion was that the current EU MPL of 10,000 mg/L (mg/kg) should be reduced. Furthermore, the report also indicated that industry use levels for the food category 13.1.5.1 were in the range 3466 mg/L (mean) to 4170 mg/L (maximum). However FSANZ also notes that no changes to the EU regulations have been made.

FSANZ proposes to permit pectins (INS 440) in the Code for IFPSDU at a MPL of 5000 mg/L

(mg/kg). FSANZ considers that this will not restrict access to specific types of IFPSDU which may be solely sourced from Europe into the Australian and New Zealand markets. However, FSANZ recognises the concerns raised in JECFA's and FSANZ's risk assessments. Therefore, FSANZ seeks additional information from health professionals, about the need to permit addition of pectins to IFPSDU and information from manufacturers about industry use levels of pectins in IFPSDU.

2.4.7 Xanthan gum (INS 415)

The EU permits 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. Currently xanthan gum is not permitted in the Code for use in infant formula (but is permitted in many food classes at GMP). Codex currently does not permit use in infant formula.

Previous consideration

In 2017, FSANZ proposed permitting xanthan gum only in alignment with the EU provision to enable continued supply of IFPSDU. Information was requested to support further consideration.

Stakeholder views

Industry requested FSANZ consider permitting xanthan gum in infant formula products up to 1000 mg/L for the functions of thickener and stabiliser. The use is in products that contain partially or extensively hydrolysed protein and/or free amino acids. The summary of submissions provided from industry is provided in Table 2.13.

One health professional body (RACP) noted that there are case study reports in the literature suggesting an association between use of gum-based thickeners and gastrointestinal disorders in infants, including NEC.

Table 2.13 Summary of submitter comments on xanthan gum (INS 415)

Technological justification	Safety/History of use for infants
Use as a thickener in powdered product to increase viscosity in reconstituted infant formula. Protein hydrolysis can reduce viscosity which xanthan gum addition helps to restore. Addition also stabilises the emulsion formed between hydrolysed protein or free amino acids and fat and water, which ensures a homogeneous shelf stable product. Advantageous as it can be used at relatively low levels to increase viscosity without gelling. Is suitable to be added to dry-blended infant formula as it can be hydrated using relatively low temperature water (that has been previously boiled).	JECFA82 (2016) assessment included a review of safety for infants between 0-12 weeks of age. Concluded that the intake of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L (0.1 g/100 mL) ready to consume formula. Has been permitted at 1200 mg/L under EU regulations for many years, and so has a history of safe use. The European SCF accepted the use of xanthan gum in IFPSDU in 1999.

FSANZ's risk assessment

JECFA has previously 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 with xanthan gum published since the JECFA evaluation do not indicate a need to revise the conclusions of JECFA's risk assessment.

Cases of late-onset NEC in (mostly premature) new-borns consuming formula to which a xanthan gum thickener was added have been reported. Based on the available information it is not possible to determine if there is a causal association with xanthan gum. JECFA reached the same conclusion in considering these case reports and noted that the xanthan gum concentrations in these case reports was likely to be higher than the maximum level of 1000 mg/L. EFSA noted that the described cases are not related to the food additive use of xanthan gum in infant formula but relate to its addition to formula or human milk as a thickener prior to consumption. The doses of xanthan gum associated with these cases, while unknown, were expected to be in gram amounts i.e. higher than the proposed MPL. The US FDA has also stated that further study is needed to determine if there is an actual link between consumption of xanthan gum-based thickener and development of NEC.

Discussion and proposed approach

FSANZ has considered the risk assessment conclusions, the information provided in industry submissions relating to technological need and justification for use of the food additive in infant formula and international use of the food additive in infant formula due to EU. FSANZ notes the international permissions are limited to the EU and only special medical purpose formulas based on amino acids or peptides for use with patients who have problems with impairment of the GI tract, protein malabsorption or inborn errors of metabolism. There is a history of safe use for this restricted use although the MPL is higher than the level assessed by JECFA. FSANZ proposes to align with the EU regulation to ensure importation of IFPSDU. This also aligns with the principle of minimising food additives in IFP. FSANZ seeks further information from health professionals on the need for the higher MPL for xanthan gum of 1200 mg/L.

2.4.8 Guar gum (INS 412)

Guar gum is permitted for all IFP in the Code at 1000 mg/L, since 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/kg. EU permits use in food category 13.1.1 at 1000 mg/L but only for liquid product containing partially hydrolysed proteins; and in food category 13.1.1.5 at 10,000 mg/L in liquid products containing hydrolysed proteins, peptides or amino acids.

The Code		**Codex**		**EU regulations**		
Food category	**Max use levels (mg/kg)**	**Standard and food category**	**Max use levels (mg/kg)[1]**	**E number**	**Food category**	**Max use levels (mg/kg)[2]**
13.1	1000	CXS 72 GFSA 13.1.1 & 13.1.3	1000	E 412	13.1.1	1000
					13.1.5.1	10000

[1] Conditions: in hydrolyzed protein liquid formula only; on the ready-to-eat basis
[2] Restrictions/exemptions: 13.1.1 only where the liquid product contains partially hydrolysed proteins;
13.1.5.1 from birth onwards in products in liquid formulae containing hydrolysed proteins, peptides or amino acids

Previous consideration

In 2017, FSANZ proposed to amend the permission by removing permission for use in infant formula (class 13.1) at up to 1000 mg/L, restricting to permission for use in specific IFPSDU: 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.

Stakeholder views

The summary of a submission received from one health professional (RACP) and FSANZ's response is provided in Table 2.14.

Table 2.14 Summary of submitter comments and FSANZ response on guar gum (INS 412)

Comment	FSANZ response
No support for removal of guar gum permission as a thickener as there is a need for thickening agents to assist with managing persistent, problematic regurgitation in preterm and term infants. As other thickening agents may be associated with GI problems in infants it is important guar gum is retained.	FSANZ proposed to retain a limited permission for use in the liquid form (as sold) special medical purpose products containing hydrolysed protein, peptides or amino acids. This is consistent with how it is permitted and used internationally.
FSANZ should set a maximum permissible amount for addition of guar gum to formula.	Noted. FSANZ is proposing an MPL for use of guar gum as a food additive in IFPSDU.
Recommends that microbiological limits applicable to infant formula be applied to the manufacture of thickening products.	Feed thickener products that are designed to be used with either breast milk or infant are being further considered in a subsequent consultation paper but if captured by Standard 2.9.1 can be subject to the microbiological criteria specified for infant formula products.

Risk assessment

FSANZ has not conducted any risk assessment for the use of guar gum in infant formula at levels up to 10,000 mg/L or conducted any review to determine whether there is a history of safe use at the proposed levels. It can therefore not establish whether the proposed levels are safe in the target population.

JECFA established an acceptable daily intake 'not specified' for guar gum at its 19th meeting (WHO/FAO 1975), however it has not considered use in infant formula and therefore it also provides no advice on safety in the target population.

The European Scientific Committee on Food (SCF) re-evaluated guar gum in the revision of essential requirements of infant formulae and follow-on formulae intended for the feeding of infants and young children in 2003. The Committee recommended that guar gum should not be used in infant formula, but it was considered acceptable to maintain use in follow-on formulae at a maximum level of 1000 mg/L (SCF 2003).

EFSA published a re-evaluation of guar gum in 2017. This assessment did not include infants under 12 weeks of age, but infants and young children consuming foods for special medical purposes and special formulae were considered. EFSA noted that infants and young children consuming these foods may be exposed to a greater extent than their healthy counterparts because the permitted levels of guar gum in products for special medical purposes are 10-fold higher than in infant formulae and follow-on formulae for healthy

individuals. Infants and young children consuming foods for special medical purposes and special formulae may show a higher susceptibility to the gastrointestinal effects of guar gum due to their underlying medical condition, but no adequate studies of the safety of guar gum in this population were available. As a result, it was concluded that the available data did not allow an adequate assessment of the safety of guar gum in infants and young children consuming these foods for special medical purposes (EFSA 2017a).

EFSA is conducting a further re-evaluation of guar gum, and has called for toxicological data to assess the safety of its use in foods for infants under the age of 16 weeks.

Discussion and proposed approach

FSANZ has not conducted any risk assessment on guar gum in infant formula at the proposed level of 10,000 mg/L, including any review to determine whether there is a history of safe use at the proposed levels. JECFA has also not considered its safety in infant formula. In its recent reassessment EFSA concluded that the available data did not allow an adequate assessment of the safety of guar gum in infants and young children consuming these foods for special medical purposes. Therefore it is not possible to draw a conclusion on the safety of guar gum at the proposed levels in the target population.

No industry stakeholders commented on the approach proposed in 2017. However the RACP did not support removal of guar gum from existing permissions (1000 mg/L) that would apply to IFPSDU. Noting the lack of a conclusion on safety from international risk assessments, and that the 10-fold higher permission in the EU (EU category 13.1.5.1) are restricted to specific products, FSANZ seeks further information on the need for the 10-fold higher MPL for IFPSDU.

2.4.9 Sodium alginate (INS 401)

The Code		Codex		EU regulations		
Food category	**Max use levels (mg/kg)**	**Standard and food category**	**Max use levels (mg/kg)**	**E number**	**Food category**	**Max use levels (mg/kg)[1]**
No permission for infant formula		No permission for infant formula		E 401	13.1.5.1	1000

[1] **Restrictions/exemptions:** from four months onwards in special food products with adapted composition, required for metabolic disorders and for general tube-feeding

Previous consideration

Sodium alginate was not considered in 2016. In 2017 it was identified as permitted in the EU for special medical purpose products. FSANZ proposed to align with the limited permission in the EU regulations.

Stakeholder views

Industry provided comments in 2017 requesting that sodium alginate be considered for permission in general infant formula. This was based on a EU SCF (1998) assessment which considered that the use of the food additive is acceptable at a MPL of 1000 mg/L in Formula for Special Medical Purposes (FSMP) used from age four months onwards. This was considered to provide a history of safe use for these products in Europe. It was also noted use in permitted milk products with added phytosterols. Sodium alginate has the functional class of thickener, stabiliser and emulsifier when used in infant formula products.

Risk assessment

FSANZ has not conducted any risk assessment for the use of sodium alginate in infant formula or conducted any review to determine whether there is a history of safe use at the proposed levels. It can therefore not establish whether the proposed levels are safe in the target population.

JECFA has established a group ADI 'not specified' for alginic acid and its ammonium, calcium, potassium and sodium salts, noting that these compounds are poorly absorbed. JECFA noted that laxative effects might occur at a high level of intake (WHO 1992). However JECFA has not undertaken a risk assessment of the use of sodium alginate in infant formula, therefore it also provides no advice on safety in the target population.

In the EU, the SCF (1998) concluded that the use of sodium alginate is acceptable up to a level of 1000 mg/L in foods for special medical purposes used from 4 months of age onwards (SCF 1998).

EFSA re-evaluated alginic acid and its salts, including sodium alginate in 2017 and considered the use of alginic acid and its salts in the food categories 'dietary foods for special medical purposes and special formulae for infants' and 'dietary foods for babies and young children for special medical purposes'. EFSA noted that infants and young children consuming foods from these categories may show a higher susceptibility to gastrointestinal effects of alginic acid and its salts than their healthy counterparts due to their underlying medical condition. No adequate studies addressing the safety of alginic acid and its salts in this population under certain medical conditions were available. EFSA concluded that the available data did not allow an adequate assessment of the safety of alginic acid and its salts in infants and young children consuming foods from these food categories (EFSA 2017b).

Discussion and proposed approach

FSANZ has not conducted any risk assessment on sodium alginate in infant formula including any review to determine whether there is a history of safe use at the proposed levels. JECFA has also not considered its safety in infant formula. In its recent reassessment EFSA concluded that the available data did not allow an adequate assessment of the safety of alginic acid and its salts in infants and young children consuming foods from these food categories. Therefore it is not possible to draw a conclusion on the safety of sodium alginate at the proposed levels in the target population.

Given the limited infant specific safety assessment available internationally FSANZ does not consider a general permission for use in infant formula is appropriate. Noting the EU permission for specific types of infant formula (category 13.5.1), FSANZ is proposing to align with the EU and permit sodium alginate (INS 401) in the Code for IFPSDU at a MPL of 1000 mg/L (mg/kg) 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 2017b), FSANZ is seeking data from industry on the current use levels to inform the final decision.

2.4.10 Sodium carboxymethylcellulose (INS 466)

The Code		Codex		EU regulations		
Food category	**Max use levels (mg/kg)**	**Standard and food category**	**Max use levels (mg/kg)**	**E number**	**Food category**	**Max use levels (mg/kg)[1]**
No permission for infant formula		No permission for infant formula		E 466	13.1.5.1	10,000

[1] **Restrictions/exemptions:** from birth onwards in products for the dietary management of metabolic disorders

Previous consideration

In 2017 FSANZ proposed to permit sodium carboxymethylcellulose up to 10,000 mg/L in IFPSDU specifically in products for dietary management of metabolic disorders. This alignment with EU will minimise potential interruptions to trade.

Stakeholder views

Industry responded to the 2017 Consultation paper requesting that sodium carboxymethyl-cellulose be permitted for infant formula with a non-intact protein base. They noted EFSA's re-evaluation of the food additives for infants less than 12 weeks of age was in progress. The summary of the response is provided in Table 2.15.

Table 2.15 Summary of submitter comments on sodium carboxymethylcellulose (INS 466)

Technological justification	Safety/History of safe use for infants
Functions as a thickener and emulsification stabiliser to prevent minerals precipitating out of solution and preventing emulsion breakdown causing phase separation and foaming of the product.	35th JECFA meeting (1990) concluded that modified celluloses (including carboxymethylcellulose) are of low toxicity and an ADI of "not specified" was assigned. No evidence of mutagenicity, carcinogenicity, developmental effects and have low bioavailability and not have any effects on developmental toxicity.

Risk assessment

FSANZ has not conducted any risk assessment for the use of sodium carboxymethyl-cellulose in infant formula or conducted any review to determine whether there is a history of safe use at the proposed levels. It can therefore not establish whether the proposed levels are safe in the target population.

Sodium carboxymethylcellulose was evaluated as part of a group of modified celluloses by JECFA at its 35th meeting. A group ADI 'not specified' was allocated, although the Committee pointed out that their laxative properties should be taken into account when they are used as food additives (WHO 1990). Enzymatically hydrolysed sodium carboxymethylcellulose and cross-linked carboxymethylcellulose have also been evaluated by JECFA, and both have been included in the group ADI 'not specified' for modified celluloses (WHO 2000, 2002). These evaluations did not consider use in infant formula.

EFSA re-evaluated celluloses including sodium carboxymethylcellulose in 2018 and concluded that there was no need for a numerical ADI for these substances. There was no safety concern for the general population at the reported use levels. Infants under 12 weeks of age were not included as part of the evaluation. In considering the use of sodium carboxymethylcellulose in 'dietary foods for special medical purposes and special formulae for infants' and 'dietary foods for babies and young children for special medical purposes', EFSA concluded that the available data did not permit an adequate assessment of the safety

of sodium carboxymethylcellulose in infants and young children consuming these foods (EFSA 2018a). EFSA is currently re-evaluating the use of sodium carboxymethylcellulose as a food additive in foods for infants below 16 weeks of age, and has called for toxicological data to support the assessment.

Discussion and proposed approach

EFSA's re-evaluation in 2018 noted that no data were submitted for the food categories 13.1.5.1 and 13.1.5.2, thus it was concluded that sodium carboxymethylcellulose is not currently used in IFPSDU. 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 products. We are seeking any information from stakeholders on current use and levels to inform a final decision.

2.4.11 Sucrose esters of fatty acids (INS 473)

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. For category 13.1.1 the 'unity principle' applies; that means that "*if more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in the foodstuff*". The technological purpose (and functional class) for these four food additives is emulsifier. The Code has a similar qualification (section 1.3.1—6) which applies when the food additives are performing the same technological purpose.

Previous consideration

In 2017, FSANZ proposed to add permission for 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.

Stakeholder views

In 2017 industry requested that FSANZ consider permitting sucrose esters of fatty acids for all infant formula products. The summary of comments are provided in Table 2.16.

Table 2.16 Summary of submitter comments on sucrose esters of fatty acids (INS 473)

Technological justification	Safety/History of safe use for infants
The technological purpose is as an emulsifier with unique properties as it has very broad hydrophilic-lipophilic balance range which provide an important function to certain formulations. It emulsifies oil in low viscous liquids. Applications in infant formula products include emulsification of long chain polyunsaturated fatty acids and stabilisation of products made from non-milk protein sources. Lack of homogeneity of infant formula products (either during production or finished product stability) can result in inaccurate delivery of nutrition to infants. Additional functions include starch interaction, protein interaction, sugar crystallization and aeration.	49th meeting of JECFA (1999) concluded there was no evidence of toxicity. An ADI of 30 mg/kg bodyweight per day due to possible laxative effects from human tolerance studies was determined. Has been permitted for use in EU for many years

Risk assessment

FSANZ has not conducted any risk assessment for the use of sucrose esters of fatty acids in infant formula or conducted any review to determine whether there is a history of safe use at the proposed levels. It can therefore not establish whether the proposed levels are safe in the target population.

JECFA established a group ADI of 0–30 mg/kg bw for sucrose esters of fatty acids and sucroglycerides (INS 474) at its 49th meeting, on the basis of their potential to induce laxative effects in adult volunteers at doses > 30 mg/kg bw per day, without applying an uncertainty factor (WHO 1999). At its 71st meeting, JECFA noted that some of the components of sucrose esters of fatty acids may be present in significant amounts in sucrose oligoesters type I and type II (INS 473a) and established a group ADI of 0–30 mg/kg bw for sucrose esters of fatty acids, sucrose oligoesters type I and type II and sucroglycerides (WHO 2010). JECFA has recently requested refined dietary exposure estimates for these substances because current, conservative dietary exposure estimates for some age groups exceed the ADI (WHO/FAO 2020). JECFA has not specifically assessed these additives for use in infant formula, however, therefore it also provides no advice on safety in the target population.

EFSA has established a group ADI for sucrose esters of fatty acids and sucroglycerides of 40 mg/kg bw/day based on a no observed adverse effect level (NOAEL) of 2000 mg/kg bw/day from a long-term toxicity/carcinogenicity study in rats (EFSA 2004). An exposure assessment published in 2018 concluded that estimated dietary exposures to sucrose esters of fatty acids exceeded the group ADI for many population groups, especially toddlers and children (EFSA 2018b). Infants under 12 weeks of age were not included in this evaluation, but EFSA is currently undertaking a risk assessment of sucrose esters of fatty acids in foods for infants below 16 weeks of age and has called for toxicological data to support the evaluation.

Discussion and proposed approach

FSANZ has not conducted any risk assessment for the use of sucrose esters of fatty acids in IFP or conducted any review to determine whether there is a history of safe use at the proposed levels. JECFA and EFSA have also not established the safety of sucrose esters of fatty acids in infant formula. Therefore it is not possible to draw a conclusion on the safety of sucrose esters of fatty acids at the proposed levels in the target population.

FSANZ is proposing to permit use of sucrose esters of fatty acids (INS 473) for IFPSDU. Noting the lack of safety assessment for infants less than 16 weeks, FSANZ proposes to limit the permission to IFPSDU containing hydrolysed proteins, peptides and amino acids up to 120 mg/L (mg/kg). FSANZ considers that this will not restrict access to specific types of IFPSDU which may be solely sourced from Europe into the Australian and New Zealand markets. However, FSANZ recognises the concerns raised in international risk assessments. Therefore, FSANZ seeks additional information from health professionals, about the need to permit addition of sucrose esters of fatty acids to IFPSDU and information from manufacturers about industry use of sucrose esters of fatty acids in IFPSDU in Australia and New Zealand.

2.4.12 Diacyltartaric and fatty acid esters of glycerol (472e)

Diacyltartaric and fatty acid esters of glycerol are currently permitted for use as an emulsifier for IFPSDU based on a protein substitute (food class 13.1.3) with a MPL of 400 mg/kg. There are no Codex provisions or EU permissions for the food additive for any form of infant formula.

Previous consideration

In 2017 FSANZ proposed to remove permission on the basis that there are no equivalent permissions in Codex or the EU. Information was sought on a technological justification for the use in IFPSDU, and submitters were asked whether there would be any technologically justified concerns with its removal.

Stakeholder views

Two industry submissions did not support removal of the permission. The rationale given was that manufacturers should have access to a range of food additives to select the most appropriate food additive for the product. It was stated that the additive can be added to assist emulsification. No specific information to justify retaining permission was provided.

Discussion and proposed approach

The additive is not permitted in EU regulation nor Codex and no information to justify its use was supplied in submissions and no evidence of its current use in products was provided. The justification from the industry submissions provided did not provide any strong reason for maintaining its permission. Therefore, FSANZ proposes to remove the permission in the Code.

FSANZ notes 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.

2.4.13 Summary of proposed approach for food additive permissions

FSANZ has considered two options:

1. Status quo – No alignment with Codex or the EU
2. Amend the Code to align with Codex and EU

FSANZ considers that Option 1 would not be based on risk analysis, given the safety assessment conclusions, history of safe use and technological justification provide. This option does not promote consistency between domestic and international food standards.

FSANZ's proposed approach is Option 2: to permit additional additives to harmonise with both Codex and EU. The assessment has considered safety, technological justification and limits use to specific conditions where appropriate. The summary of FSANZ's proposed approach for the consideration of aligning the permissions of the various food additives with Codex and EU is provided in Table 2.17.

For some food additives, FSANZ has noted where risk assessment indicates a lack of safety information and therefore, it is not possible to draw a conclusion on the safety of these substances at the proposed levels in the target population. In these cases (all relate to IFPSDU which are generally imported into the Australian and New Zealand market), we have requested information from health professionals and/or industry to support the proposed permission. These questions are summarised in Section 7 of this report.

Table 2.17 Summary of FSANZ's consideration of aligning food additive permissions with Codex and EU regulations*

Food additive	INS	Proposed approach	MPL	Conditions
Calcium carbonates	170	Permit for IFPSDU to align with EU	GMP	

Food additive	INS	Proposed approach	MPL	Conditions
Calcium citrates	333	Permit for IFPSDU at GMP to align with EU	GMP	
Phosphoric acid	338	Permit for IF to align with EU	450 mg/kg (as phosphorus)	The calcium to phosphorus ratio needs to comply with that prescribed in subsection 2.9.1—12(4).
Sodium phosphates	339	Permit for IF to align with Codex	450 mg/kg (as phosphorus)	The calcium to phosphorus ratio needs to comply with that prescribed in subsection 2.9.1—12(4).
Potassium phosphates	340	Permit for IF to align with Codex	450 mg/kg (as phosphorus)	The calcium to phosphorus ratio needs to comply with that prescribed in subsection 2.9.1—12(4).
Calcium phosphates	341	Permit for IF to align with EU	450 mg/kg (as phosphorus)	The calcium to phosphorus ratio needs to comply with that prescribed in subsection 2.9.1—12(4).
Sodium alginate	401	Permit for certain to align with EU	1000 mg/kg	From 4 months onwards in products for dietary management of metabolic disorders
Locust bean (carob bean) gum	410	Maintain current permission for IF being consistent with Codex & Permit for certain IFPSDU to align with EU	IF 1000 mg/kg; IFPSDU 10,000 mg/kg	IFPSDU permission: from birth onwards in products for reduction of gastro-oesophageal reflux
Guar gum	412	Maintain current permission for IF being consistent with Codex and EU. Permit in certain IFPSDU to align with EU	IF 1000 mg/kg; IFPSDU 10,000 mg/kg	IFPSDU permission: from birth onwards in products containing hydrolysed proteins, peptides or amino acids
Xanthan gum	415	Permit in all IF to be consistent with JECFA. Permit in certain IFPSDU to align with EU	IF 1000 mg/kg; IFPSDU 1200 mg/kg	IFPSDU permission: 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
Gellan gum	418	Not permit until JECFA or EFSA has completed a safety assessment that concludes it is safe for use in IF.		
Pectins	440	Permit for IF to be consistent with JECFA Permit in certain IFPSDU to align with EU	IF 2000 mg/kg; IFPSDU 10,000 mg/kg	IFPSDU permission: from birth onwards in products used in case of gastro-intestinal disorders
Sodium carboxymethylcellulose	466	Permit in certain IFPSDU to align with EU	IFPSDU 10,000 mg/kg	IFPSDU permission: from birth onwards in products for management of metabolic disorders
Citric and fatty acid esters of glycerol	472c	Permit in IF, consistent with Codex and EU; different MPLs for powder and liquid products	7500 mg/kg 9000 mg/kg	Powder Liquid
Diacetyltartaric and fatty acid esters of glycerol	472e	Remove current permissions in the Code to be consistent with Codex and EU		
Sucrose esters of fatty acids	473	Permit in certain IF to align with EU	IF 120 mg/kg	Only in products containing hydrolysed proteins, peptides or amino acids
Sodium carbonates	500	Permit for IF to align with Codex	2000 mg/kg	

Food additive	INS	Proposed approach	MPL	Conditions
Potassium carbonates	501	Permit for IF to align with Codex	2000 mg/kg	
Sodium hydroxide	524	Permit for IF to align with Codex	2000 mg/kg	Consequential addition also needed to Schedule 8
Potassium hydroxide	525	Permit for IF to align with Codex	2000 mg/kg	Consequential addition also needed to Schedule 8
Calcium hydroxide	526	Permit for IF to align with Codex and EU	2000 mg/kg	
Starch sodium octenylsuccinate	1450	Permit in certain IFPSDU to align with Codex and EU	20,000 mg/kg	Only for use in products based on hydrolysed protein and/or amino acids

* IF = infant formula

2.5 Clarifications to the Code

2.5.1 Previous consideration

The 2016 Consultation paper noted that the maximum permitted level for hydroxypropyl starch in the Code for soy-based infant formula is believed to be an error. It is listed as 25,000 mg/L rather than what is believed to be the correct figure of 5000 mg/L. The lower MPL was recommended in the original Proposal P93 and is also consistent with Codex. Industry were asked if the correction would cause any problems.

Stakeholder views

Industry responses indicated they considered it to be an error and that amending the figure would not have any impact on them. Information suggested manufacturers used the lower figure which it understood to be the correct figure.

Proposed approach

Amendment to the Code to address the MPL for hydroxypropyl starch for soy-based infant formula will be made to correct what everyone understands is an error. It will be reduced from 25,000 mg/L to 5000 mg/L to be consistent with the original intent of P93, and to be consistent with Codex.

2.5.2 Carrageenan permission for liquid soy-based infant formula products

Previous consideration

In 2016 FSANZ noted in the Code carrageenan is only listed for liquid infant formula (sub-class 13.1.2) and there is no permission for carrageenan in soy-based infant formula (sub-class 13.1.1). Codex permits it for all liquid infant formula but specifies two maximum levels: one for milk and soy based formulas (0.03 g/100 mL; being 300 mg/L) and one for hydrolysed protein- and/or amino acid based formula (0.1 g/100mL; being 1000 mg/L). It was also noted that JECFA's 2014 assessment supported its use in all forms of infant formula products. Submitters were asked whether there is a technological justification for permitting carrageenan in liquid soy-based infant formula products and how the current permissions were being interpreted.

Stakeholder views

Four submissions responded to these questions, with some submitters noting there was a lack of clarity since the changes to the Schedule in 2016 due to the revised Code (P1025).

This related to the revised Code adding specific subclasses for the different types of infant formula which originally did not have specific subclass numbers. Doing this clarified the intent of the hierarchical nature of food additive permissions but was not a change. One government submitter felt the current drafting prohibited carrageenan in soy-based formula. Another government submitter supported continued use for both milk and soy-based formula, noting that FSANZ could review the intent of the drafting in Proposal P93. Industry submitters noted that carrageenan should be permitted for liquid infant formula, whether they are soy-based or milk based. The technological functions in infant formula are:

- as an emulsifier, explicitly in product made with hydrolysed proteins
- as a stabiliser by preventing phase separation, including insoluble sediments and ensuring fat layers stay incorporated within the infant formula. This ensures uniformity of nutrients over the shelf life of the infant formula and appropriate delivery of nutrients in a homogeneous product.

Its additional advantages are:

- increases viscosity and improves mouthfeel
- does not impact on the efficacy of delivery of nutrients, in particular vitamins and minerals
- reduced level of use compared to other stabilisers/emulsifiers.

Discussion and proposed approach

Carrageenan as a food additive and specifically for its use in infant formula has been comprehensively assessed and concluded to be safe. It was assessed at the 79th JECFA meeting (2014) with the conclusion "that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern".

FSANZ investigated the original drafting intent for permitting carrageenan in different infant formula products from Proposal P93 which developed Standard 2.9.1. It was no different to that currently in Schedule 15. That is 0.03 g/100 mL (300 mg/L) for liquid infant formula (current subclass 13.1.2 "Liquid infant formula products"), and 0.1 g/100 mL (1000 mg/L) for infant formula products based upon protein substitutes for a specific dietary use (which was re-worded as the current sub-class of 13.1.3 "Infant formula products for special dietary use based on a protein substitute"). No reference to drafting related to carrageenan permission for soy-based infant formula was located.

FSANZ proposes to ensure clarity of the permission that allows carrageenan use in all liquid infant formula, including soy-based products.

2.5.3 Permitted starches, removal of qualification statements

Previous consideration

Section 8.4.2 in the 2016 Consultation paper raised the idea of removing the condition statements next to the three starches (INS 1413, 1414 and 1450) within the food classes 13.1.1 and 13.1.3. The condition statement is that "Section 1.3.1—6 applies". This is sometimes known as the 'unity principle' and is similar to the qualification in Codex STAN 72-1981 related to these starches which requires that these starches "can be used singly or in combination". 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."

Unfortunately the question that was proposed to relate to this issue was not included in the 2016 Consultation paper, but a repeat of an earlier question dealing with the MPL for hydroxypropyl starch was included as question 2.35.

However, the INC in its submission to the 2016 Consultation paper supported FSANZ's proposed approach.

Proposed approach

FSANZ's view in the 2016 Consultation paper, which it still holds, is that these condition statements are 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.

2.6 Updates to nomenclature and INS numbers

2.6.1 Previous consideration

The 2016 paper noted there are some inconsistencies in nomenclature and INS numbers used in the Code and Codex. To align the Code with Codex would have flow on consequences for other food categories, and therefore will not be considered further under this Proposal. Stakeholders were asked whether there are any issues due to the lack of consistency in the nomenclature of food additives.

2.6.2 Stakeholder views

Five submitters (2 jurisdictions, 3 industry, 1 health professional), unanimously expressed the view that though it is always appropriate to be as consistent as possible there were no issues perceived by industry with the current nomenclature and INS numbers. Industry and other impacted stakeholders did not see any need to address this inconsistency as part of this Proposal. They considered the appropriate approach to addressing food additive names and INS numbers would be via a dedicated food additives proposal.

2.6.3 Discussion and proposed approach

FSANZ agrees with the submissions; it is inappropriate to make unilateral changes to food additive nomenclature and INS numbers to be more consistent with Codex. This is primarily because such changes also impact on all other food classes with labelling and cost impacts that have not been consulted on. Any major change to update food additive nomenclature and INS numbers would need to be part of a dedicated proposal where any proposed changes would be consulted widely on.

3 Contaminants

Chemicals contaminants can be naturally occurring components of foods, elements naturally found in the in the environment, produced by microorganisms or be industrial chemicals. These chemical contaminants may occur at low concentrations in foods, including infant formula products. It is not possible to completely avoid the presence of very low level contamination, however there are various ways to minimise exposure through foods.

3.1 Current regulations

3.1.1 Code requirements

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 specify the maximum levels (MLs) of a number of contaminants for infant formula products.

As a general principle, the levels of contaminants and natural toxicants in all foods should be kept As Low As Reasonably Achievable (the ALARA principle). Where the Code serves an effective risk management function, MLs have been established for some contaminants in infant formula products, including for IFPSDU, consistent with protecting public health and safety. The principles underpinning the approach to MLs in the Code were outlined in the 2016 paper and are summarised below.

MLs will be specified:

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

3.1.2 Codex

Codex sets either MLs or Guideline Levels (GL). A GL is the maximum level of a substance in a food or feed commodity which is recommended by Codex to be acceptable for commodities moving in international trade. Codex GLs are 'historical' levels which Codex has decided should be reviewed if appropriate for their possible conversion to MLs after a risk assessment performed by JECFA. In contrast to GLs, MLs are the maximum concentration of the substance recommended by Codex to be permitted in that commodity. However, it is important to note that Codex is not a regulatory body or enforcement agency so it does not set legal limits or enforceable standards. Individual countries may adopt into Codex standards into their legislation as legal limits.

The Codex General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) (Codex 1995b) lists guideline levels (GLs[12]) and MLs for all infant formula. There are no MLs specific to IFPSDU. Codex infant formula standard (CXS 72-1981) requires infant formula and formulas for special medical purposes intended for infants to comply with CXS 193-1995. In infant formula both MLs and GLs have been established.

[12] Codex STAN 72-1981 defines a guideline level as the maximum level of a substance (i.e. contaminant) in a food commodity (infant formula) recommended as acceptable for commodities moving in international trade. This is different from a maximum level, which is the legally permitted level for a particular substance (Codex, 1995).

The Codex Committee on Contaminants in Foods (CCCF) establishes or endorses permitted maximum levels or guidelines levels for contaminants and naturally occurring toxicants in food and feed taking into consideration any risk assessment by JECFA.

The Codex principles for establishing MLs note that:

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

3.1.3 EU requirements

The EU *Commission Regulation 1881/2006 – Setting maximum levels for certain contaminants in foodstuffs* lists MLs for infant formula and dietary foods for special medical purposes intended for infants. The regulation includes MLs for aflatoxins B1 and M1, cadmium, lead, ochratoxin A, polycyclic aromatic hydrocarbons (PAHs) and tin (inorganic) relevant to infant formula and FSMP for infants. The preamble text of the EC Regulation 1881/2006 notes that setting MLs ensures:

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

As noted in the preamble of the regulation, it is considered an appropriate risk management approach for the health protection of infants, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children.

3.1.4 USA requirements

The US FDA establishes Action levels for poisonous or deleterious substances to control levels of contaminants in human food and animal feed. These action levels and tolerances represent limits at or above which FDA will take legal action to remove products from the market[13]. Notices are published in the Federal Register as when action levels are established or as existing action levels are revised or revoked.

The regulations relevant to the manufacture and distribution of infant formula are listed under the Federal Food, Drug and Cosmetic Act, with Title 21 in the Code of Federal Regulations applying to food. Part 106 of Title 21 outlines the infant formula requirements pertaining to current good manufacturing practice, quality control procedures, quality factors, records and reports, and notifications. This is relevant to contaminants in terms of risk based programmes for manufacture, requirements for manufacturers to ensure water used in manufacture adheres to drinking water standards[14]. This part also outlines any testing needed for contaminants based on industry action levels and guidelines.

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed
[14] set by the Environmental Protection Agency

There are industry action levels for poisonous or deleterious substances, specifically for aflotoxin M1 in milk (0.5 ppb), and lead in silver plated containers for use by infants of (0.5 µg/ml leaching solution).

For metals such as arsenic, lead, cadmium and mercury, the US FDA monitors levels in infant formula through total diet surveys, then any testing needed is included and enforced in risk based programmes for infant formula manufacture.

The USA has not established regulatory MLs for inorganic arsenic in rice although, in 2016, they issued an action level of 0.1 ppm for inorganic arsenic in infant rice cereals. Guidance for industry regarding the action level, together with supporting documentation presenting the background and rationale for the action level, was issued by the US FDA in August 2020.

3.2 Previous considerations

2012 Consultation paper

The 2012 Consultation paper sought views on whether full alignment of infant formula contaminant levels with Codex infant formula contaminant levels is appropriate.

Several submissions drew attention to the more comprehensive list of MLs (i.e. additional substances) for infant formula in the EU regulations. However, they did not suggest full alignment on the basis that the lack of alignment was not creating trade difficulties.

2016 Consultation paper

In 2016, FSANZ reviewed the MLs for infant formula in the Code and in Codex STAN 193-1995 and produced a Risk Profile of Contaminants in Infant Formula (Attachment 2.4 of SD2 safety and food technology). Arsenic was also considered because of a recent international assessment.

Other issues relating to current regulation of contaminants in the Code, specifically the location of MLs in the Code, and ML concentration units used for infant formula were also raised by submitters.

2017 Consultation paper

In 2017, FSANZ reviewed regulatory issues relating to infant formula for special dietary use (IFPSDU). The 2017 paper considered European MLs for both infant formula and dietary foods for special medical purposes intended for infants. The EU specifies MLs for contaminants that are not listed in either the Code or Codex standards. FSANZ did not seek specific information on contaminant specifications (Table 3.1).

Table 3.1 Summary of the Code, Codex and EU MLs for infant formula (IF) contaminants

Contaminant	The Code		Codex		EU Regulations	
	Level	Food	Level	Food	Level	Food
Non-metals						
Melamine	None		1 mg/kg	Powdered IF	None	None
	None		0.15 mg/kg	Liquid IF as consumed		
Mycotoxins						
Aflatoxins	None		None		0.025 µg/kg	IF & FOF
M1[15]					0.025 µg/kg	Dietary foods for special medical purposes intended specifically for infants
B1	None		None		0.10 µg/kg	Dietary foods for special medical purposes intended specifically for infants
Ochratoxin A	None		None		0.50 µg/kg	Dietary foods for special medical purposes intended specifically for infants
Others						
MCPD (Sum of 3-MCPD and 3-MCPD fatty esters)	None		None		125 µg/kg	IF, FOF & FSMP intended for infants and young children (powder)
					15 µg/kg	IF, FOF & FSMP intended for infants and young children and young-child formula (liquid)
Glycidyl esters	None		None		6.0 µg/kg *as glycidol	Liquid IF
Vinyl chloride	0.01 mg/kg	All food excluding packaged water	0.01 mg/kg (GL)	Food	None	
Acrylonitrile	0.02 mg/kg	All food	0.02 mg/kg (GL)	Food	None	
	None		None		1.0 µg/kg	IF & FOF

[15] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02006R1881-20100701

Contaminant	The Code		Codex		EU Regulations	
	Level	Food	Level	Food	Level	Food
Polycyclic aromatic hydrocarbons: Benzo(a)pyrene					1.0 µg/kg	Dietary foods for special medical purposes intended specifically for infants
Perchlorate	None		None		0.01 mg/kg	IF, FOF & FSMP intended for infants and young children[16]
Metals						
Aluminium	0.1 mg/100 mL	Soy-based IFP	None		None	
	0.05 mg/100 mL	IF other than soy-based infant formula				
Arsenic	None		None		None	
Cadmium	None		None		0.010 mg/kg wet wt	powdered IF & FOF manufactured from cows' milk proteins or protein hydrolysates
					0.005 mg/kg wet wt	liquid IF & FOF from cows' milk proteins or protein hydrolysates
					0.020 mg/kg wet wt	powdered IF & FOF from soya protein isolates, alone or in a mixture with cows' milk proteins
					0.010 mg/kg wet wt	liquid IF & FOF manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins
Lead	0.02 mg/kg	IFP	0.01 mg/kg	IF (ready to use)	0.050 mg/kg wet wt	Powdered IF & FSMP intended for infants and young children
					0.010 mg/kg wet wt	Liquid (sold as) IF & FSMP intended for infants and young children
Tin	250 mg/kg	All canned food	250 mg/kg	Canned (other than beverages)	50 mg/kg wet weight (inorganic tin)	liquid IF & FOF

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

3.3 Maximum levels for contaminants

3.3.1 Acrylonitrile

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as a packaging material. Both the Code and Codex set a level for all foods. Both Codex and the Code include levels (ML and GL, respectively) which are aligned (Table 3.1).

Previous consideration

In the 2016, FSANZ proposed no change to the ML for acrylonitrile on the following basis:

- Acrylonitrile does not have a health based guidance value (HBGV). However, as it is considered a potential human carcinogen, exposure is required to be kept as low as possible. The 2016 risk profile concluded that there were rarely any detections in foods thus dietary exposure to acrylonitrile in infant formula is not considered a health risk.
- Acrylonitrile is widely used and there is still the potential for migration of residual acrylonitrile into packaged foods, including infant formula.
- The current ML manages that risk and is aligned with the GL in with Codex STAN 193-1995.

The 2017 consultation paper did not specifically discuss Acrylonitrile.

Stakeholder views

All submissions to CP 2016 supported FSANZ's approach.

Proposed approach

As no further issues were identified and submitters supported the approach, FSANZ proposes no change to the ML of 0.02 mg/kg for acrylonitrile listed in Schedule 19—5. The ML for acrylonitrile is for all foods, which includes to infant formula products.

3.3.2 Aluminium

Aluminium can be present in food as a result of its natural occurrence in the environment, leaching from food contact materials, and the use of aluminium-containing food additives.

Paragraph 2.9.1—8(c) currently includes MLs for aluminium in soy based and all other infant formula of no more than 0.1 mg/100mL and a higher limit of 0.05 mg/100mL, respectively. The higher ML for aluminium in soy-based formula was set during Proposal P93 as evidence suggested that the lower limit for formula may not be achievable for soy protein isolate (ANZFA 1999b). Codex does not specify an ML for aluminium in infant formula.

Previous consideration

In the 2016 consultation paper, FSANZ proposed to retain an ML for aluminium despite no ML in the Codex STAN 193-1995 for the following reasons:

- The relatively low health based guidance value (HBGV); namely, a Provisional Tolerance Weekly Intake (PTWI) of 2 mg/kg bodyweight (bw) established by JECFA in 2011 was considered to be health protective.
- Ongoing international discussions at the time on limiting aluminium dietary exposure because of potential health concerns.

FSANZ also sought information from stakeholders on whether setting a single ML of 0.05 mg/100 mL for all infant formula products would be achievable for soy-based infant formula. Also whether there would be any cost or trade implications of reducing the ML for the soy-based products.

Based on the comments to 2012 Consultation, FSANZ proposed to move the ML for aluminium from Standard 2.9.1 to Standard 1.4.1 and Schedule 19.

The 2017 consultation paper did not specifically discuss Aluminium.

Stakeholder views

Several submissions supported locating the aluminium ML in the same location in the Code as all other contaminant MLs.

Several industry submissions also supported removal of the ML from the Code, noting Codex has not adopted such a level for infant formula. Other submissions noted studies published overseas, which have identified aluminium in infant formula, thus removal of the aluminium ML would need to be justified by a risk assessment, particularly for premature infants who have reduced renal function.

Other submissions queried the potential risk to infants from exposure to aluminium in infant formula. There was support for lowering the aluminium ML of 0.1 mg/100 mL for soy based infant formula to align with the ML of 0.05 mg/100 mL for all infant formula products. Comments were made that this ML would be practical and achievable while still being protective for infants. Some submitters suggested that the costs to industry were considered secondary to the health and safety of vulnerable infants (Table 3.2).

Table 3.2: Summary of submitters comments and FSANZ's responses on aluminium

Comment	Raised by (number)	FSANZ response
No support to retain the ML		
Codex, EU and USA do not have an ML for aluminium. Need to align with international standards.	Industry	Refer to discussion section
Standard 2.9.1 should align with Codex (Codex STAN 193-1995) which does not include limits on aluminium in infant formula. Further, the EU (EC 1881/2006) and USA (CFR, Chap 21, parts 106 & 107) do not include a ML for aluminium as a contaminant in infant formula.	Industry	Refer to discussion section
Lowering the ML for soy-based products		
A Cochrane review of soya based infant-formulas showed higher aluminium levels than breast or cows' milk, with no evidence of a negative health effect of aluminium in full term infants fed modern soy based infant formula.	Industry	Noted.
Support to retain the ML		
Supports FSANZ's approach to retain an ML for aluminium. Note the 2011 JECFA evaluation recognises aluminium as a contaminant of concern.	Jurisdictions	Refer to discussion section
Aluminium and food packaging		

Comment	Raised by (number)	FSANZ response
The only infant formula packaging material in contact with infant formula is foil and the aluminium in foil is in a fixed state such that aluminium molecules will not transfer to the infant formula. Would suggest further evaluation by FSANZ as to whether the existing requirements for aluminium as a contaminant is retained.	Industry	FSANZ notes the submission and that it is unlikely that aluminium would migrate from foils in a fixed state. However, there are other reasons described in the discussion section for retaining an ML for aluminium.
Food contact materials containing aluminium were reviewed by JECFA in 2012 and there was no evidence or elsewhere in the scientific literature migration to infant formula posed a risk.	Industry	As above

Discussion

The literature suggests that aluminium in infant formula comes from several possible sources, however prior accumulation in the soybean plant can be a major contributor (Bhatia and Greer, 2008; Burrell and Exley, 2010; Chuchu et al. 2013). One study noted that aluminium levels in soy-based infant formula have decreased over time (Dabeka et al., 2011).

In the 23rd ATDS, aluminium was detected in 4/4 cow's milk-based infant formula composite samples (sampled when made up as per label instructions) at concentrations between 0.18 – 0.53 mg/kg = 0.018 – 0.053 mg/100 g (Average 0.029 mg/100 g). For 9 month old infants, estimated dietary exposure to aluminium was < 40% of the PTWI (FSANZ 2011).

In the 24th ATDS, aluminium was detected in 4/4 soy-based infant formula composite samples (made up as per label instructions) at concentrations between 0.26 – 0.36 mg/kg = 0.026 – 0.036 mg/100 g (Average 0.030 mg/100 g). For the same age group estimated dietary exposure was 50% of the PTWI (FSANZ 2014).

Aluminium was not analysed in the 25th ATDS.

The 2016 New Zealand Total Diet Study (NZTDS) found infants estimated weekly aluminium exposures were 3 mg/kg bodyweight, so higher than the PWTI. However the higher levels were mostly from baked goods (muffins, scones, cakes, slices) and possibly from flour containing aluminium based raising agents, not infant formula.

Although there is a preference by some submitters to align with Codex, and remove the ML for aluminium from the Code, FSANZ considers retaining the ML for aluminium best protects the health and safety of infants for the following reasons:

- The rationale in the 2016 Attachment 2.4 of SD2 safety and food technology) is still valid; in particular, the relatively low HBGV, and the ongoing international discussions on limiting aluminium dietary exposure.
- As composite samples were analysed in the 23rd and 24th ATDS and the upper range for aluminium approached the proposed ML of 0.05 mg/100 mL (23rd ATDS), retaining the ML will keep exposure to aluminium ALARA.
- There is no data from either the 25th ATDS or the 2016 NZTDS for soy-based infant formula.
- Lowering the ML for soy-based infant formula and having a single ML for aluminium in the Code is practical and there is no indication that this level cannot be met by manufacturers.

Proposed approach

FSANZ proposes to retain and set a single ML of 0.05 mg/100 mL for all infant formula products and move the ML for aluminium from Standard 2.9.1 to Standard 1.4.1 and Schedule 19.

3.3.3 Arsenic

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

There is currently no ML for arsenic (inorganic) or 'arsenic, total' in the Code for infant formula. There is no ML for arsenic (inorganic) in infant formula adopted by Codex. No specific comments were made in submissions in relation to arsenic.

Arsenic was considered at a 2011 JECFA meeting but a HBGV for arsenic (inorganic) was unable to be established because JECFA could not establish the threshold under which exposure is safe.

Previous consideration

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

In 2017, FSANZ reconfirmed this position. However, FSANZ considered that there may be a need for a ML for inorganic arsenic (for rice that may be used as an ingredient in infant formula) and that this could be assessed in a separate proposal if at a later time there is a sufficient scientific basis to support establishing an ML.

Stakeholder views

Two submissions to the 2016 paper noted Codex has set MLs for inorganic arsenic in polished rice of 0.2 mg/kg (2014) and husked rice of 0.35 mg/kg (2016) with an associated code of practice to help countries meet these limits. As rice may be used as an ingredient in non-dairy infant formula, it was suggested that it may be appropriate to consider an ML for inorganic arsenic in the Code (inorganic arsenic is considered to potentially be more toxic than organic forms of arsenic).

Discussion

An EFSA Report (2009)[17] identified high consumers of rice in Europe, such as certain ethnic groups, and children under three years of age as the most exposed to inorganic arsenic in the diet. Since the analysis of inorganic arsenic is reliable for rice and rice based products, the EC[18] set maximum levels of 0.1 mg/kg for inorganic arsenic for rice destined for the production of food for infants and young children.

International analytical surveys of food, (including Europe) in infant foods have detected the

[17] https://www.efsa.europa.eu/en/efsajournal/pub/1351
[18] https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue/arsenic_en

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

Total arsenic has been included as an analyte for infant formula in the 19th, 20th and 23rd ATDSs (ANZFA 2001; FSANZ 2003, 2011) and in the 2016 NZTDS (MPI 2018). Arsenic was detected in only one infant formula sample in these four analytical surveys at a level of 2.7 µg/kg. Concentrations in all other samples were below the limit of reporting.

FSANZ is also aware that rice-based infant formulas are available in both international and the Australia and New Zealand markets. FSANZ recently provided input into an analytical survey commissioned by the New Zealand Ministry for Primary Industries (MPI) and conducted by the laboratories at the Institute of Environmental Science and Research Ltd. The survey looked at inorganic arsenic in 200 rice and rice-based food products from Australia and New Zealand, including foods for infants and young children. Where present, inorganic arsenic levels in rice and rice-based products were low compared to levels reported from comparable studies overseas (Ashmore et al. 2019). More recent NZTDS and ATDS and USFDA results have also concluded either non detections for total arsenic or extremely low levels for inorganic arsenic.

Proposed approach

FSANZ proposes no ML for arsenic (inorganic) or ‘arsenic, total’ for infant formula products in the Code. This approach is consistent with Codex.

FSANZ will continue to monitor and review any findings and if needed consider a ML for inorganic arsenic (for rice that may be used as an ingredient in infant formula) in the future.

3.3.4 Cadmium

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

There is no Codex ML established for cadmium in infant formula and the Code does not include a ML for cadmium in infant formula. The EU has established a number of MLs for cadmium in infant formula based on soy protein isolates and hydrolysed cow’s milk proteins (see Table 3.1). A higher level is set for infant formula manufactured from soy protein isolates, as soy beans can naturally take up cadmium from the soil.

Previous consideration

The 2012 consultation paper considered that the that the Provisional Monthly Tolerable Intake (PMTI) for cadmium was higher than that for aluminium (for which an ML has been established), moreover there was no Codex ML or MLs established in many other developed countries (i.e. Canada, EU and USA) for cadmium in infant formula. In addition, in recent total diet studies, cadmium has only been detected at extremely low levels in infant formula: max of 0.0006 mg/kg (FSANZ 2011) and a max of 0.0007 mg/kg (MAF 2011). The FSANZ 2012 Consultation Paper asked stakeholders whether full alignment of infant formula

contaminant levels with Codex infant formula contaminant levels is appropriate. One submitter noted that the Code did not include a ML for Cadmium in infant formula and queried why.

In view of these considerations, it was FSANZ's preliminary view that the introduction of new MLs for cadmium in infant formula was not necessary.

Stakeholder views

There was one industry submitter to the 2017 Consultation Paper that commented in this issue. The submitter agreed that new MLs for cadmium are not justified.

Discussion

In Europe, in 2014[19] maximum levels for cadmium in several categories of infant formula were introduced to increase protection of infants. It was considered that infant formula and follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins, can contain higher cadmium levels than milk based products since soya beans naturally take up cadmium from the soil. Soya based formulae are an important alternative for infants suffering from lactose intolerance, therefore sufficient market supply must be ensured. The EC considered it appropriate to set a higher maximum level 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.

The 25th ATDS (FSANZ 2019) concluded that there were no public health and safety concerns relating to cadmium dietary exposure for the Australian population, other than a slight exceedance for infants aged 9 months at the 90th percentile of exposure (which ranged from 25–130% of the PTMI depending on the modelling scenario used). However, this temporary exceedance is not considered to be of concern due to the highly conservative method of assessment and nature of potential health effects which would only be associated with high levels of long-term exposure to cadmium over many years. There were no detections of cadmium in cow's milk-based infant formula composite samples (x4). However, no soy-based infant formula (or any other type) was sampled.

In the 2016 NZTDS, cadmium was not detected in any infant/follow-on formula samples and cadmium dietary exposure for infants (9-months) was below the PTMI (44%).

Proposed approach

FSANZ has considered two options for cadmium:

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

2. Harmonise with the EU MLs listed in Table 3.1 on the basis that soya protein isolates, alone or in a mixture with cows' milk proteins, can contain higher cadmium levels than milk based products since soya beans naturally take up cadmium from the soil.

[19] https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue/cadmium_en

FSANZ calls for comments on the impacts of these proposed options.

3.3.5 Lead

Lead is an element that occurs naturally and is widely found in the environment. The total elimination from food is therefore not generally possible. Schedule 19 includes a ML of 0.02 mg/kg for lead in infant formula.

Previous consideration

The Codex STAN 193-1995 was amended to include a revised maximum level for lead in infant formula of 0.01 mg/kg (as consumed) following the considerations of the 8th session of the Codex Committee on Contaminants in Foods (CCCF, July 2014). The CCCF based its decision on JECFA's withdrawal of the PTWI in 2011, as JECFA was unable to establish the threshold under which exposure is safe.

The Code includes a ML of 0.02 mg/kg for lead in Schedule 19. This no longer aligns with the ML in the Codex STAN 193-1995 of 0.01 mg/kg.

For this reason FSANZ proposed a reduced ML of 0.01 mg/kg and sought comment on the cost and trade implications of reducing the ML for lead in infant formula

Stakeholder views

One industry submission supported the current ML (0.02 mg/kg) in the Code. However, there were many industry submissions which favoured harmonisation with the lower level in the Codex standards (0.01 mg/kg).

Whilst industry appreciated that reducing the ML for lead has cost implications, these costs can be distributed over time to manage trade requirements as national legislation is aligned at different rates.

Some submitters suggested a preference for the ML to be expressed on a dry powder basis, rather than on an 'as consumed' basis. This is because most infant formula traded in Australia and New Zealand is in the powdered form, rather than ready to consume. Codex has previously applied a 7-fold concentration factor between powdered and ready-to-consume infant formula. Therefore, the limit for lead in infant formula should be 0.01mg/kg in infant formula that is ready to consume and 0.07mg/kg in powdered infant formula.

Discussion

Recent levels reported in Australian and New Zealand Total Diet Studies support the lower levels (ANZFA 2001; FSANZ 2003, 2011; MPI 2018). Similar advice on achievability of the lower levels was provided by the infant formula industry to the Australian and New Zealand CCCF delegations.

In view of the withdrawal of the PTWI by JECFA, it is important to ensure the ML for lead in infant formula is as low as reasonably achievable. Given the recent Codex adoption of the lower ML, FSANZ's view is that this reduced ML would be appropriate and achievable in infant formula available in Australia and New Zealand.

Proposed approach

FSANZ proposes to reduce the ML for lead from 0.02 mg/kg to 0.01 mg/kg in infant formula and apply this level on a ready-to-feed basis. This is consistent with the ML in the Codex

STAN 193-1995 of 0.01 mg/kg.

3.3.6 Additional MLs for lead in specification of food additives for use in infant formula

Discussion

Whilst the MLs for lead present in food additives were not included in the 2016 and 2017 consultation papers or raised in submissions, FSANZ has now considered information that has since become available from the JECFA 79th and 82nd sessions. At the 79th JECFA meeting (WHO/FAO 2014), concerns were raised that food additives used in infant formula and considered for risk assessment (pectin, citric and fatty acid esters of glycerol (CITREM) and starch sodium octenyl succinate) could exceed lead limits in infant formula if lead was present at the ML listed for each food additive (5 mg/kg in pectin and at 2 mg/kg in both CITREM and starch sodium octenyl succinate).

At the 82nd JECFA meeting, consideration of further data established the introduction of lower lead limits for use in infant formula (0.5 mg/ kg for pectin, CITREM, carob bean gum and xanthan gum). Based on the data, it was considered that these food additives would not exceed the Codex ML for lead (i.e. 0.01 mg/kg) if included in infant formula at the maximum use level. For starch sodium octenyl succinate and all other food additives used in infant formula, a review was recommended (WHO/FAO 2016).

Also at the 82nd JECFA meeting, the Committee further reaffirmed that it is the responsibility of the infant formula manufacturers to ensure that the lead levels in the final product (infant formula that is ready-to-consume) meet with the maximum limit for lead.

Since the 82nd meeting it appears that the updated monograph for CITREM is still tentative and will be withdrawn if further data is not available. Pectin does not appear to have a updated lead limit for infant formula since its 2016 evaluation. In 2018, Starch sodium octenyl succinate was reviewed by JECFA and a limit of lead of 0.1 mg/kg was included in the specifications. Adherence to this limit would result in the ML for lead in infant formula of 0.01 mg/kg not being exceeded[20].

As the monographs for food additives that can be used in infant formula are or are not updated with lead limits, any limits must be met as per Schedule S3—2 in the Code along with MLs for lead in final infant formula listed in Schedule 19.

Proposed approach

There is no need for FSANZ to amend the Code since JECFA monographs are accepted as primary sources in Schedule S3—2 and would need to be met for food additives added to infant formula, along with MLs for lead in final infant formula.

3.3.7 Melamine

Melamine has several industrial uses, including the production of laminates, glues, dinnerware, adhesives and coatings and was used as an adulterant in food products to give a higher apparent protein content in the 2008 infant formula incident in China (WHO 2008; Skinner et al., 2010).

No MLs have been established for melamine in the Code. Codex STAN 193-1995 includes a

[20] http://www.fao.org/3/ca2330en/CA2330EN.pdf#page=64

ML for melamine in powdered infant formula of 1 mg/kg and liquid infant formula ("as consumed") of 0.15 mg/kg. The Codex standard allows for the presence of melamine from its non-intentional and unavoidable presence in food and feed. Concentrations of melamine above the Codex MLs would be indicative of adulteration.

Previous consideration

Given melamine's presence in infant formula was the result of adulteration of infant formula rather than as a contaminant, FSANZ's approach was to not establish a ML for melamine.

The ML in Codex STAN 193-1995 is set to control illegal adulteration of melamine in infant formula. The Codex ML in powdered infant formula of 1 mg/kg and liquid infant formula ("as consumed") of 0.15 mg/kg allows for the presence of melamine from its non-intentional and unavoidable presence in food and feed. Concentrations of melamine above the Codex MLs would be indicative of adulteration. Because of this, FSANZ's initial view was that there is no basis for including an ML for melamine in the Code.

Stakeholder views

There was general support for the FSANZ approach to not establish a ML for melamine, given it is not a contaminant given the purpose for Codex setting an ML was for adulteration of infant formula. One submitter suggested a ML could provide an indication if adulteration of infant formula occurred.

Discussion

There is no evidence indicating that melamine is still being used as an adulterant in milk used in the production of infant formula. The 2008 infant formula incident in China appears to be an isolated one. Testing of melamine at the border in 2012 did not report the presence of melamine in a range of foods for infants and some other specific foods (e.g. rice husks, candy, biscuits) imported into Australia. New Zealand is no longer monitoring foods for melamine content at the border. Infant formula was not specifically tested because quarantine restrictions did not permit the import of infant formula from China.

The Australian state and territory Food Acts require food to be *safe and suitable.* These provisions allow enforcement to be undertaken in the event of any future adulteration events (adulterated food is not suitable and possibly not safe). Similar provisions exist in the New Zealand legislation. Setting a ML would result in ongoing enforcement costs which do not appear to be justified on the basis of risk.

Based on the absence of any associated risk, and consistent with the previous approach, there is no basis to align with the Codex ML for melamine and establish an ML in the Code. Further, the Australian state and territory and New Zealand Food Acts contain requirements for food to be safe and suitable. This would allow for enforcement action in the event of any future adulteration events.

Proposed approach

FSANZ proposes not to establish an ML for Melamine in the Code, despite MLs in place in the Codex STAN 193-1995.

3.3.8 Tin and inorganic tin compounds

Current regulation

Inorganic tin is found in food in the +2 and +4 oxidation states; it may occur in cationic form (stannous and stannic compounds) or as anions (stannites and stannic compounds).

Schedule 19 includes an ML of 250 mg/kg for tin in all canned foods.

Codex takes a similar approach, with a ML of 250 mg/kg for "canned foods (other than beverages)". The regulation also includes an ML for canned infant formula and follow-on formula, excluding dried and powdered product for tin (inorganic) of 50 mg/kg. This is lower than the Codex and ML in the Code for tin.

Previous consideration

The current ML for tin in the Code relates to all canned foods. Previous consideration during Proposal P157 – Metal Contaminants set the ML for tin for all canned foods, noting that tin is used to cover the inside of food and beverage containers (ANZFA, 1999b). As most powdered infant formula is packaged as a food in a can, FSANZ concludes that this would be within the scope of the current Standard.

Stakeholder views

One submission sought clarity on the requirements for Testing for Tin in the Code (Table to clause 2 in Standard 1.4.1) querying whether the tin ML was intended to apply to low moisture powdered products.

Other submissions identified that there is no definition of canned foods in the Code. Some suggested that infant formula could be considered as a food retorted in cans, thus it is not clear whether infant formula packed in metal cans are or are not a canned food.

Discussion

Proposal P157 Metal Contaminants established the ML for tin for all canned foods, noting that tin is used to cover the inside of food containers (ANZFA, 1999b). Most powdered infant formula is packaged as a food in a can; therefore, FSANZ considers that the current ML in the Code would capture infant formula.

It is FSANZ's view that there is no case for the exemption of infant formula *per se* from the scope of the tin ML of Schedule 19. The general contaminant definition for tin as a metal in Schedule 19 should be applied to infant formula.

Proposed approach

FSANZ proposes no change in the Code to the ML of 250mg/kg for tin and inorganic tin compounds set for all canned foods which would also apply to infant formula products. This approach is consistent with Codex.

3.3.9 Vinyl chloride

Vinyl chloride is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods.

Schedule 19 includes a ML of 0.01 mg/kg for vinyl chloride in all foods except packaged water. The ML for vinyl chloride therefore also applies to infant formula. Codex has established a GL in Codex STAN 193-1995 for vinyl chloride that is identical to the MLs in the Code of 0.01 mg/kg.

Previous consideration

In the 2016 Consultation paper, FSANZ proposed that the ML of 0.01 mg/kg for vinyl chloride in all foods except packaged water would also apply to infant formula. This meant no change to current Code requirements. This approach is consistent with the guideline level (GL) for Vinyl Chloride in Codex STAN 193-1995.

Stakeholder views

Four submitters to the 2016 Consultation paper commented on this issue and all four submitters supported FSANZ's view.

Proposed approach

The current ML for vinyl chloride remains relevant and no amendment to the level in the Code is necessary and this would also apply to infant formula. This would continue to align with the GL in Codex STAN 193-1995.

3.3.10 Mycotoxins: Aflatoxins B1 and M1

Aflatoxins are a family of toxins produced by fungi and found on agricultural crops. They are primarily produced by two species of Aspergillus: *A*. *flavus* and *A*. *parasiticus*. *A*. *flavus* produces aflatoxins B1 and B2, while *A*. *parasiticus* produces aflatoxins B1, B2, G1 and G2. Aflatoxin B1 in lactating dairy cattle can be transmitted into milk and milk products as the metabolite aflatoxin M1 (EFSA 2007; WHO 2017).

Schedule 19 includes MLs for aflatoxins in certain foods. However, no aflatoxin ML has been established for infant formula in the Code.

Table 2 shows that the EU specifies an ML for M1 in both infant formula and follow-on formula and dietary foods for special medical purposes intended specifically for infants and a limit for B1 in dietary foods for special medical purposes intended specifically for infants.

Codex has adopted an ML of 0.5 µg/kg in milk for aflatoxin, but has not established a level in infant formula.

Previous consideration

Aflatoxins were not specifically addressed in the 2016 Consultation paper. In the 2017 consultation, paper MLs in EU regulations, specifically Commission Regulation 1881/2006 for these substances (M1 and B1) were presented. Codex has an ML of 0.5 µg/g for aflatoxin in milk but not infant formula. Schedule 19 in the Code has MLs for aflatoxins, but not infant formula.

In the 23rd ATDS, results show that aflatoxin M1 was not detected in infant formula and levels in general foods did not pose a safety concern.

Stakeholder views

One submission in 2016 questioned whether aflatoxins are covered in the Code. This was

addressed in the 2017 consultation paper and is summarised above.

There were 5 submissions supporting FSANZ's previous approach in the 2017 consultation paper not to establish MLs for aflatoxins.

Discussion

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

As aflatoxins are genotoxic and carcinogenic, human exposure should be minimised to the level that is reasonably practicable. Internationally it is acknowledged that the complete elimination of mycotoxin contaminated commodities is not achievable at this time.

Codex has developed several Codes of Practice to assist with keeping dietary exposure to ALARA, including:

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

Proposed approach

In view of these considerations, FSANZ's view is that introducing new MLs for aflatoxin in infant formula is not necessary.

FSANZ considers that the Codex Code of Practice CAC/RCP 45-1997 is a useful risk management tool for manufacturers of IFPSDU products to reduce potential contamination of aflatoxins in infant formula products.

FSANZ proposes not to establish a ML or MLs for aflatoxins and specific aflatoxins M1 and B1.

3.3.11 Mycotoxins: Ochratoxin A

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

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

Previous consideration

The EU ML of IFPSDU is only for raw wheat, barley and rye. The Codex Code of Practice (CAC/RCP 51-2003) contains information relevant to ochratoxin A.

There is limited information on ochratoxin A in infant formula sold in New Zealand and Australia. The 23rd ATDS did not detect ochratoxin A in any foods, and only low levels have

been found in infant formula. So there is no evidence to support aligning with the EU and establishing a ML for ochratoxin A in the Code

Stakeholder views

Four submitters supported FSANZ's views.

Discussion

Information on the ochratoxin A content of infant formulas sold in Australia or New Zealand is not available, however in the 23rd ATDS ochratoxin A was not detected in any of the foods for which it was analysed.

In addition, available information in WHO GEMS database and overseas assessments have generally found only low levels of ochratoxin A contamination of infant formula. On this basis it is considered unlikely that levels of ochratoxin A in infant formula in Australia are a health concern.

Proposed approach

FSANZ proposes not to establish an ML for ochratoxin A.

3.3.12 Polycyclic aromatic hydrocarbons

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

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

Previous consideration

The 2017 consultation paper discussed the EU MLs of 1.0 µg/kg in relation to Australian data and a UK Food Standards Agency survey.

Discussion

A FSANZ commissioned analytical survey on PAHs in Australian foods, including infant formula, did not identify any health concerns for Australian consumers. This is consistent with the findings of a larger UK Food Standards Agency (UK FSA) survey in which levels of PAHs were below the EU maximum permitted limit (UK FSA 2006).

Exposure to genotoxic and carcinogenic PAHs should be as low as is reasonably achievable. FSANZ notes there is a Codex COP for reducing PAHs from smoking and direct drying (CAC/RCP 68-2009) to assist with achieving this.

Although Codex COP CAC/RCP 68-2009 is not specific to reducing PAHs in IFPSDU, FSANZ considers that the COP may help manufacturers reduce PAH levels in cereals (e.g. rice based) and vegetable fats and oils used in the manufacture of IFPSDU.

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

Given the data and survey did not identify any public health and safety concern from polycyclic aromatic hydrocarbons (PAHs) in infant formula or IFSDU there is no evidence to support aligning with the EU ML for PAHs.

Proposed approach

FSANZ proposes not to establish an ML for PAHs.

3.3.13 Perchlorate

Perchlorate occurs naturally in the environment but can also be present in foods as a result of degradation of fertilisers used on crops. Long-term consumption of products with perchlorate can cause inhibition of iodine uptake leading to iodine deficiency.

Previous consideration

Perchlorate was not discussed in the 2016 or 2017 Consultation papers.

International situation

No ML has been established for perchlorate by Codex. Perchlorate was evaluated by JECFA at their 72nd meeting in 2010. JECFA established a provisional maximum tolerable daily intake (PMTDI)[21] of 0.01 mg/kg bw but estimated dietary exposures including both food and drinking-water, were well below the PMTDI. The Committee considered that estimated dietary exposures were not a health concern. The 5th CCCF (2011) agreed that no follow-up was necessary since no health concern was identified at current estimated levels of exposure from food and drinking water.

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, and nutrition for medical use for infants and young children and toddler food.[22]

Discussion

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

Proposed approach

FSANZ proposes not to establish an ML for perchlorate.

3.3.14 Chloropropanol, glycidol and their esters

Chloropropanols and their fatty acid esters, are contaminants that can form during the

[21] The PMTDI represents the amount of a chemical in food or drinking water that can be ingested daily over a lifetime without appreciable health risk.
[22] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0685&rid=3

processing of oils, when the oils are being decolourised and deodorised. Glycidol is associated with the formation and decomposition of chloropropanols and forms monoesters with fatty acids (glycidyl esters) during the refining of oils. These process contaminants may be present in edible oils and foods that contain edible oil as an ingredient, including infant formula. There is some concern internationally about the levels of these substances in the food supply because there is evidence they cause cancer in laboratory animals.

Previous consideration

These substances were not discussed in the 2016 or 2017 consultation papers. While food safety and regulatory bodies around the world have known about 3-monochloropropanediol (3-MCPD) and 2-monochloropropanediol (2-MCPD) as contaminants in some foods for many years, 3-MCPD and its esters were identified for the first time in refined edible oils and foods containing oils like infant formula in around 2007. The discovery of 2-monochloropropanediol (2-MCPD) and its esters, and glycidyl esters in refined edible oils is a little more recent.

Discussion

3-MCPD esters and glycidyl esters in infant formula have been evaluated recently in by international regulatory bodies as well as in Australia and New Zealand.

Codex

3-MCPD esters and glycidyl esters were evaluated by the JECFA at their 83rd meeting in 2016. JECFA established a group PMTDI of 4 µg/kg bw for 3-MCPD esters. For glycidyl esters, JECFA identified a $BMDL_{10}$[23] of 2.4 mg/kg bw/day as a point of departure for calculating a margin of exposure (MOE)[24] (WHO 2017).

Based on the findings of its risk assessments, JECFA has recommended that appropriate efforts to reduce concentrations of 3-MCPD and 3-MCPD esters in infant formula should continue to be implemented. JECFA has also recommended continued implementation of efforts to reduce concentrations of glycidyl esters and glycidol in fats and oils, in particular when used in infant formula.

A Code of Practice for reducing 3-MCPD esters and glycidyl esters in refined oils and products made with refined oils was developed by Codex. FSANZ had input into this process and the Code of Practice was adopted in 2019 (CXC 79-2019).

Europe

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. 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. This ML is to be reviewed in view of lowering within 2 years from the date of application.

Australian and New Zealand

To understand how levels in Australian and New Zealand oils and infant formula compare to those found internationally, New Zealand Food Safety (NZFS), with input from FSANZ, coordinated an analytical survey, which included 3-MCPD and glycidyl esters in cooking oils and infant formula. The survey "Snapshot survey for 2-MCPD, 3-MCPD, glycidol and their

[23] $BMDL_{10}$: The benchmark dose lower confidence limit for a 10% increase in the incidence of an adverse effect.
[24] The ratio between the $BMDL_{10}$ and the estimated dietary exposure.

esters in selected vegetable oils and infant formulas in Australia and New Zealand" also helped to identify a suitable analytical method to support future testing for 3-MCPD and glycidyl esters.

In total, 56 samples of infant formula and 44 samples of oils were analysed by the laboratory. Overall, the survey found that levels of both 3-MCPD esters and glycidyl esters were broadly consistent with those found internationally and generally very low.

Based on the findings of the survey, 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 for 3 month old infants ranged between 0.93 and 3.39 µg/kg bw/day, below the PMTDI of 4 µg/kg bw/day, indicating that there are no public health concerns at current exposure levels. For glycidyl esters, the estimated dietary exposures for 3 month old infants ranged between 0.21 and 2.75 µg/kg bw/day. Based on these exposure estimates, the MOEs for glycidyl esters are within the range considered to be of possible concern by JECFA.

However, the preliminary nature of the survey, with non-representative sampling of infant formula and limited data points, limits the potential to draw any firm conclusions. The benefits of continuing to provide formula to infants far outweigh any potential health concerns associated with low levels of glycidyl esters that may be present in some formula products. Infant formula is the only safe alternative to breast milk for infants.

Current risk management

Industry and food safety bodies have known about these substances in edible oils (and, as such, foods made with edible oils like infant formula) for over 10 years now, so there are a range of measures in place to support a continued reduction of levels.

An industry toolbox was developed several years ago, and industry has been encouraged to continue reducing levels to as low as reasonably achievable (ALARA) by adopting the measures outlined in this Industry Toolbox (BLL and FoodDrink Europe).

The Codex Code of Practice, adopted in 2019, will also assist manufacturers to prevent and reduce levels of 3-MCPD esters and glycidyl esters in refined oils and food products containing refined oils. NZFS and FSANZ will look for opportunities to monitor its uptake and use, and to promote continued reduction in levels in vegetable oils and infant formula over time. In addition, FSANZ will continue to collaborate with international agencies, sharing data and information, with a view to identifying further mitigation measures.

Proposed approach

FSANZ proposes not to set any MLs for chloropropanols and their fatty acid esters in the Code based on this preliminary risk assessment. The survey was too limited to allow us to draw any conclusions about levels in these products in the broader food supply. In particular, only several samples of each brand and/or type of infant formula product were analysed. FSANZ will continue to collaborate with international agencies, sharing data and information, with a view to identifying further mitigation measures.

3.1.15 Summary of contaminant MLs

A summary of FSANZ's proposed options for contaminants is at Table 3.3.

Table 3.3: Summary of proposed options for contaminants

Contaminant	The Code		Codex		Potential amendments to the Code to align with Codex
	ML	Food(s)	ML	Food(s)	
Acrylonitrile	0.02 mg/kg	All food	0.02 mg/kg (GL)	Food	No amendments (aligned with Codex)
Aluminium	0.1 mg/100 mL	Soy-based formula	Not applicable		No amendments to Code to align with Codex.
	0.05 mg/100 mL	Infant formula other than soy-based infant formula			
Arsenic	Not applicable		Not applicable		Already aligned with Codex - no amendments required
Cadmium	Not applicable for infant formula		Not applicable for infant formula		FSANZ calls for comment on proposed options for cadmium
MCPD and glycidyl esters	Not applicable		Not applicable		FSANZ does not propose to introduce MLs for MCPD and glycidyl esters
Melamine	Not applicable		1 mg/kg	Powdered infant formula	FSANZ does not propose to introduce MLs for melamine.
			0.15 mg/kg	Liquid infant formula as consumed	
Mycotoxins: Aflatoxins B1 and M1	Not applicable for infant formula		Not applicable for infant formula		FSANZ does not propose to introduce MLs for aflatoxins.
Mycotoxins: Ochratoxin A	Not applicable		Not applicable		FSANZ does not propose to introduce MLs for ochratoxin A
Perchlorate	Not applicable		Not applicable		FSANZ does not propose to introduce MLs for perchlorate
Polycyclic aromatic hydrocarbons (PAH)	Not applicable		Not applicable		FSANZ does not propose to introduce MLs for PAH
Lead	0.02 mg/kg	Infant formula	0.01 mg/kg	Infant Formula (ready to use)	Reduce ML to 0.01 mg/kg to align with Codex.
Tin	250 mg/kg	All canned food	250 mg/kg	Canned foods (other than beverages)	Already aligned with Codex - no amendments required
Vinyl chloride	0.01 mg/kg	All food excluding packaged water	0.01 mg/kg (GL)	Food	Already aligned with Codex - no amendments required.

3.4 MLs for infant formula in the dry powder form or as consumed

Previous consideration

Currently the default unit for all contaminant MLs in Schedule 19 is mg/kg unless specified otherwise. The ML for aluminium in Standard 2.9.1 is expressed in terms of mg/100 mL (as consumed). The 2016 consultation paper proposed to apply all MLs for infant formula to a reconstituted ready-to-feed form, rather than to a product prior to drying, dehydration or concentration.

Stakeholders views

Table 3.4 summarises the issues raised in submissions.

Table 3.4: Submitters comments and FSANZ's responses on MLs for infant formula in the dry powder form or as consumed

Comment	Raised by (number)	FSANZ response
Oppose FSANZ's view to apply the ML to reconstituted ready-to-consume form and instead a preference to apply to powdered product before being prepared with water. The vast majority of infant formula that is both manufactured and sold in Australia and New Zealand is powder. Manufacturer testing is most readily undertaken on the powdered product. Prefers that limits for contaminants should be expressed as either 'mg/L' or 'mg/kg' rather than as mg/100 mL which is not aligned with international practice	Industry	FSANZ's position is to apply all MLs for infant formula to a reconstituted as consumed form, rather than to a product prior to drying, dehydration or concentration. This is consistent with provisions for lead expressed in Codex, EU and USFDA which apply to as consumed infant formula. For more detail see discussion section
Testing on a powdered product would also exclude the variability of contaminants in potable water supplies throughout Australia and New Zealand which are beyond the manufacturer's control.	Industry	Manufacturers have a responsibility and obligation to meet Australian and NZ drinking water standards, including for contaminants for infant formula 'as consumed'. NHMRC Australian drinking water guidelines updated in 2018 and NZ drinking water quality standard revised in 2008 which includes limits for contaminants present in Australian and New Zealand potable water.
Several industry submitters suggested that consideration should be given to secondary limits for ready-to-feed products where appropriate as in the provision expressed in Codex, EU and USFDA standards.	Industry	FSANZ preference for clarity and enforcement purposes is that a single ML for as consumed infant formula is established.
The departments support FSANZ's preliminary view to apply all MLs for IF to a reconstituted ready-to-feed form, rather than to a product prior to drying.	Government	Refer to discussion below.

Comment	Raised by (number)	FSANZ response
Supports continued application of MLs to the products as consumed. This avoids having two values in the FSC – one for powder, and one for the ready-to-drink	Government	Refer to discussion below.
Expressing a limit in units of 'mg/100 mL' does not make use of the convenient prefixes provided for by the Système International d'unités (SI) which would have been either 'mg/L' or 'mg/kg'. Preference is for regulations to control the base commodity as sold.	Industry	Refer to discussion below.

Discussion

The default unit for all contaminant MLs in Schedule 19 is mg/kg unless specified otherwise. The ML for lead for infant formula in Schedule 19 is in mg/kg. Subsection 2.9.1—4 (2) specifies that the compositional requirements of Standard 2.9.1 apply to 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 mentioned, the compositional requirements of Standard 2.9.1 apply to either ready to drink formula or reconstituted powdered or concentrated formula. In Standard 2.9.1 a limit of aluminium for infant formula products is given generally, with specific limits for soy-based formula, and pre-term formula. There is no specific reference to calculating these permitted contaminant levels on the basis of reconstitution of dried product/formula with water, or a calculation based on "the mass of the food (or ingredients of the food) prior to drying, dehydration…." as is the case for the ML concentrations in Schedule 19. However, the Full Assessment Report for P93, which established the ML, indicates that the intent was that the level applies to "human milk substitutes in ready-to-feed form, or when reconstituted from powder or liquid concentrate using aluminium-free water" (ANZFA, 1995).

Justification for the ML to be set for infant formula that is 'as consumed' is as follows:

- Consistency with international requirements. Codex and USFDA refer to 'as consumed', EU refers to ready-to-feed i.e. reconstituted in their legislation.
- FSANZ understands that a typical analysis for infant formula products is conducted on a liquid (prepared) product, not the powdered form.
- The Codex ML is based on infant formula that is ready to consume. Manufacturers can convert this to the powdered form where Codex's concentration factor is 7-fold (In REP11/CF and REP12/CF).
- Before the Codex ready-to-consume ML was in place, the infant formula industry indicated that there would be support for the ML set for the ready-to-feed level and minimal cost implications for industry.
- Having two MLs in the Code for powder and as consumed form is duplicative and may lead to uncertainty for industry and enforcement agencies.
- If powders are made up in different ratios then the amounts consumed by infants is variable. Whereas, applying the ML to the as consumed form would reflect the levels as consumed, including any effects from preparation with drinking water.

Proposed approach

FSANZ's approach is to apply MLs that are established for infant formula to an as consumed form in mg/kg.

3.5 Contaminant definition

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 STAN 193-1995).

Section S19—3 of the Code contains provisions related to calculating levels of contaminants and toxicants in food. Paragraph S19—3(1)(a) provides that "a reference to a metal is taken to include a reference to each chemical species of that metal". In addition, section S19—2 provides that arsenic is taken to be a metal.

Codex standards for MLs and GLs routinely specify the *contaminant definition*. The current MLs in the Code do not usually specify a *contaminant definition* because the identity of the toxicologically relevant contaminant to which the ML applies is clear. Appropriate analytical methods will be able to detect all relevant forms of a specific contaminant – indeed this is one of the considerations when MLs are established by FSANZ. However, it is noted that for clarity, inclusion of a contaminant definition could be useful for some of the metals relevant to infant formula.

Previous consideration

No definition of contaminant is included in State, Territory or the New Zealand Food Act 2014.

In 2016, FSANZ proposed not changing the definition of analytes which are common to both infant formula and other foods but will address this as part of a proposed future review of Standard 1.4.1.

Stakeholder views

There was full support for considering this in a future review of 1.4.1, noting that Codex standards for MLs and GLs routinely specify the contaminant definition[25].

Proposed approach

FSANZ is not proposing to change the definition of analytes which are common to both infant formula and other foods, but will address this issue as part of a possible future review of Standard 1.4.1

In a future review of Standard 1.4.1, if a definition for contaminant is considered, alignment with the Codex definition for contaminant would be favoured.

[25] Codex Alimentaruis defines a contaminant in Codex STAN 193-1995 as, "Any substance not intentionally added to food…, which is present in such food… as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food…, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs or other extraneous matter".

3.6 Other issues raised by submitters on contaminants

Issue	Raised by	FSANZ response
Substances in contact with infant formula (i.e. packaging). There is FDA guidance on chemical safety. Will FSANZ have similar guidance?	Health professional	Under Proposal, P1034 for chemical migration from packaging into food FSANZ assessed the risks associated with migration of packaging chemicals and analysed control measures used in the packaging supply chain to mitigate CMPF. A risk assessment based on an analysis of a database of over 1300 food contact substances found that exposures to most chemicals used to produce food packaging are low and unlikely to pose a public health and safety concern. This conclusion was supported by a number of analytical surveys investigating the presence of packaging chemicals in Australian and New Zealand foods. FSANZ has proposed to develop a food packaging information guide to provide a consolidated and comprehensive source of information for industry, address the gaps in awareness and knowledge for SMEs, provide general information on safety issues with CMPF for consumers, and describe the obligations on food businesses (particularly SMEs) to use safe packaging materials.

4 Lactic acid producing microorganisms

4.1 Current regulation

The Code

Section 2.9.1—6 of the Code permits the voluntary addition of lactic acid producing microorganisms to infant formula products. The permission was introduced into Standard 2.9.1 during Proposal P93 (ANZFA 1999a). Both the earlier Australian (Standard R7) and New Zealand (Regulation 242) standards permitted L(+) lactic acid producing cultures as an optional ingredient in infant formula products, as did the Codex standard at the time. It appears that the original intent of the permission across all of the standards was for use as a food additive i.e. acidity regulators and pH adjustment (ANZFA1999a). Over the years the permission in the Code appears to have lost the link to the original purpose of use, resulting in L(+) lactic acid producing microorganisms being used as optional ingredients for other purposes (e.g. as probiotics).

Prior to Proposal P1025 – Code Revision, the terms 'lactic acid cultures' and 'L(+) producing lactic acid cultures' were used in the Code. these terms were replaced with 'lactic acid producing microorganisms' to provide consistency in the Code.

Any new or novel microorganisms (not L(+) lactic acid producing) require premarket assessment as a novel food prior to use in infant formula. New or novel microorganisms are not being considered part of P1028.

Codex

Clause 3.2.4 of Codex STAN 72-1981 states that "Only L(+) lactic acid producing cultures may be used"; for infant formula and formulas for special medical purposes intended for infants.

EU

In the EU the union list of food additives (Annex II to Regulation No 1333/2008 of the European Parliament and of the Council26) allows the use of non-pathogenic L(+) lactic acid producing cultures for the manufacture of acidified milks for infant formula and Dietary foods for infants for special medical purposes and special formulae for infants.

4.2 Previous consideration

The current voluntary permission for lactic acid producing microorganisms in infant formula products was mentioned in the 2012 Consultation paper. However, no specific questions were asked in the paper, and no submitter feedback was received about this permission or on addition of microorganisms for other purposes (for example, as a probiotic). Accordingly, this permission was not discussed in the FSANZ 2016 Consultation paper as no specific issue had been identified.

[26] EU Commission Regulation No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives

4.3 Stakeholder views

Initial feedback to the 2016 consultation paper (received through targeted consultation with industry, jurisdictions and health professionals) suggested that the current voluntary permission for lactic acid producing microorganisms was an area of the Standard which lacked clarity. During targeted consultation, health professionals highlighted concern about the safety of L(+) lactic acid producing microorganisms for some groups of infants, particularly for premature and low birth weight infants.

4.4 Risk assessment

FSANZ has assessed the health and safety risks associated with the addition of any L-lactic acid producing microorganisms to infant formula products (refer to SD2). Whether any risk applies specifically to the use of L-lactic acid producing microorganisms for preterm, low birth weight and immunocompromised infants was also assessed. The risk from DL-lactic acid producing microorganisms of the order Lactobacillales was also assessed, as a large number of studies were identified that investigated probiotic supplementation of infants with DL-lactic acid bacteria.

This assessment has identified relevant, appropriately designed studies, including clinical trials, case reports, other relevant epidemiological studies and studies evaluating safety. These studies assessed the addition of lactic acid producing bacteria to infant formula in a viable form; supplementation through means other than infant formula; and fermentation of infant formula where no viable bacteria remain in the final product.

From published clinical trial data on the safety of a range of L-lactic acid producing microorganisms—including species of *Bifidobacterium*, *Propionibacterium* and *Lactobacillus*—FSANZ has not identified any risks for healthy, full term infants. Infant formulas supplemented with L-lactic acid producing bacteria were well tolerated, and no adverse events associated with the lactic acid bacteria were noted in the clinical trials assessed. FSANZ concludes that infant formula supplemented with non-pathogenic, non-toxigenic L-lactic acid producing microorganisms does not present a risk to public health and safety for healthy, full term infants.

The published clinical trials on the safety of a number of DL-lactic acid producing bacteria—alone or in combination with L-lactic acid producing bacteria—did not identify any risks for healthy full term and preterm infants. Infant formulas supplemented with DL-lactic acid producing bacteria were well tolerated, and no adverse events associated with the lactic acid bacteria were noted in the clinical trials assessed. FSANZ concludes that infant formula supplemented with non-pathogenic, non-toxigenic DL-lactic acid producing microorganisms does not present a risk to public health and safety for healthy, full term and preterm infants.

The intent of the original permission in the Code was for the addition of *non-pathogenic* lactic acid producing microorganisms. However, certain genera of lactic acid producing bacteria—such as *Enterococcus* and some spore-forming bacilli—are known to include pathogenic or toxigenic species. Therefore, FSANZ also assessed safety aspects of these potentially pathogenic genera.

Enterococci are ubiquitous in nature and are a normal component of the healthy intestinal microflora of humans and animals. The two most prominent species—*E. faecium* and *E. faecalis*—are opportunistic human pathogens which may also be used to produce foods (e.g. cheese and fermented meats) and which are also increasingly being developed for use as probiotics. Enterococci are often resistant to a wide range of clinically important antimicrobials. Hospital-associated *E. faecium* and *E. faecalis* strains also typically harbour

virulence genes that promote colonisation, biofilm formation and pathogenesis. Since there are very few clinical trials assessing the safety of enterococci, establishing safety for the addition of lactic acid producing enterococci to infant formula would require assessment on a case-by-case basis.

Spore forming *Bacillus* spp. are amongst a number of bacilli used in the food industry to produce enzymes and, increasingly, as probiotics. Production of L-lactic acid is strain specific—it is not uniformly distributed across the *Bacillus* genus or within species groups such as *B. subtilis* or *B. cereus*. The principal safety concern for infants is the capacity for toxin production. Since the potential for production of toxins or other toxic metabolites by lactic acid producing *Bacillus* spp. is unevenly distributed and must be conclusively excluded, and since there are very few clinical trials assessing their safety, establishing safety for their addition to infant formula would require assessment on a case-by-case basis.

For infants with underlying clinical complications—including preterm, low birth weight and immunocompromised infants—there are case reports of sepsis and bloodstream infections associated with dietary supplementation with non-pathogenic L- and DL-lactic acid producing bacteria. However, due to a lack of sufficient data on infectivity and exposure, FSANZ is unable to assess the level of the risk in these circumstances.

There is limited published data on the safety of fermented formulas, but no potential risks to public health and safety have been identified for healthy full term infants. Therefore, FSANZ concludes 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.

Very limited data is available on the safety of fermented formulas for preterm infants and other vulnerable groups. However, no potential risks to public health and safety have been identified for preterm infants. FSANZ therefore concludes that formula fermented with L-lactic acid producing bacteria is unlikely to present a risk to public health and safety in healthy preterm infants.

4.5 Discussion

Standards 2.9.1 permits the addition of “L(+) lactic acid producing microorganisms” to infant formula products. FSANZ’s risk assessment used the terminology “L-lactic acid” as the (+) relates to the stereochemical characteristics of lactic acid and is not needed for regulatory purposes. However, to maintain consistency with international regulations, FSANZ proposes to retain the current terminology of “L(+) lactic acid producing microorganisms” in the Standard.

The risk assessment concluded that infant formula supplemented with non-pathogenic, non-toxigenic L(+) lactic acid producing microorganisms does not present a risk to public health and safety for healthy infants. It seems appropriate, therefore, to maintain the current permission with some amendments for clarity and to minimise potential risk. As noted in the risk assessment, not all L(+) lactic acid producing microorganism are safe. International regulations (EU) clarify that ‘non-pathogenic’ lactic acid producing microorganisms must be used. The Code and model food acts have an overarching requirement for food to be safe and suitable. However the current permission could be strengthened with the inclusion of ‘non-pathogenic’.

Based on FSANZ’s risk assessment which concluded that there are no public health and safety concerns, there is no scientific or technical basis to restrict addition of L(+) lactic acid producing microorganisms.

4.5 Proposed approach

FSANZ considers that the Standard should be clarified for addition of L(+) lactic acid producing microorganisms to infant formula products, as discussed above. This should ensure that only non-pathogenic L(+) lactic acid producing microorganisms are added.

However we are aware that the issue has not been discussed broadly through the 2016 Consultation paper. Therefore we request that submitters comment on 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?

5 Labelling

Infant formula can be the only food an infant consumes in the first six months following birth, meaning it is extremely important that is prepared and used correctly. Currently the Code includes labelling requirements relating to directions for the safe preparation, use and storage of infant formula, certain warning and advisory statements, and other food safety labelling (such as date marks) as risk management measures. These labelling measures are intended to provide caregivers with the necessary information to enable them to understand and minimise the risks associated with the preparation and handling of infant formula. In addition, label information supports public health education and advice provided to caregivers about the safe use of infant formula.

Previous consideration and consultation

2012 Consultation paper

In the 2012 Consultation paper, FSANZ canvassed stakeholder views to identify regulatory issues arising from several existing food safety labelling measures for infant formula. Information was sought on the directions for use and storage, prescribed names and declaration of protein source, the 'Breast is best' warning statement and measuring scoop.

2016 Consultation paper

FSANZ considered stakeholder views from the 2012 Consultation paper, including any evidence provided. Existing food safety labelling measures were assessed for consistency with the Codex Standard CXS 72-1981 (Codex, 1981), with public health guidelines and an assessment of the microbiological risks and consumer evidence was made to inform FSANZ's preliminary view. FSANZ consulted on this preliminary view for some matters and sought further evidence for other issues.

Approach in this paper

FSANZ has considered stakeholder views and the information provided in submissions to 2016 Consultation paper, the findings from a microbiological safety risk assessment (refer to Supporting Document 3), consumer evidence on caregiver practices and understanding (refer to Supporting Document 4), current national and international guidelines, Codex and overseas regulations to assess whether existing food safety labelling requirements are appropriate for managing the risks associated with the preparation and handling of infant formula, and supporting the public health education and advice provided to caregivers about the safe use of infant formula.

FSANZ has put forward proposed approaches for those issues where the evidence supports a change to existing labelling requirements.

Consideration of other labelling requirements such as ingredient labelling (including food additives) will be addressed in a future paper on the provision of information.

5.1 Risk Assessment

5.1.1 Microbiological safety

In the 2016 Consultation paper, FSANZ reviewed microbiological risk management strategies for the preparation, use and storage of powdered infant formula (PIF), with a particular focus on storage time of prepared formula, and the temperature of water used for

reconstitution of powdered infant formula (refer to Appendix A2.1 of SD2). FSANZ used the risk assessment model developed by the Food and Agriculture Organization/World Health Organization (FAO/WHO) to estimate the relative risk that the main microbiological hazard identified—Cronobacter spp. (formerly known as Enterobacter sakazakii)—poses to infants from intrinsically contaminated PIF.

One submission to this consultation paper raised the concern the preparation and conditions proposed by FSANZ were not sufficient to ensure the safety of powdered infant formula. It was considered a shorter storage time than FSANZ had proposed was required to restrict pathogen growth in formula following reconstitution.

To address the concern raised, FSANZ re-ran the risk assessment model using a wider range of preparation and storage times. These were analysed against a baseline scenario of reconstitution of PIF with water at 37°C, followed by immediate consumption. The temperature of water used to reconstitute formula was varied between 10–50°C, and the duration of cooling and storage at 6°C was varied between 0-24 hours.

The modelling indicates that the temperature of the water used for reconstitution of PIF has a greater influence on risk than the time reconstituted formula spends under refrigerated storage. As the water temperature for PIF reconstitution is increased above 40°C, the relative risk of illness increased between 5–15 fold compared to the baseline, due to Cronobacter spp. being able to grow while the reconstituted formula cooled to refrigeration temperature (6°C). No difference in relative risk was observed for PIF stored under refrigeration for 24 hours compared to 4 hours when it was reconstituted with water at 20°C or lower (refer to Supporting Document 3).

5.1.2 Consumer evidence

For the 2016 Consultation papers, FSANZ undertook a rapid evidence assessment (literature review) (refer to Appendix A2.2 of SD2 of the 2016 Consultation paper) which examined:

- formula preparation, specifically whether caregivers:
  - boil water before using it to prepare formula
  - store formula at room temperature or in the refrigerator
  - discard unfinished feeds
  - add cereal or other foods to formula
  - add vitamins and minerals to formula
  - use the scoop enclosed with the formula
  - use and understand the preparation instructions on formula products
- caregivers' understanding of the prescribed term 'infant formula'
- whether the framing of a message about the benefits of breastfeeding (as a gain-framed or loss-framed message) is likely to impact caregiver perceptions or infant feeding choices
- whether caregivers use the protein source statement and whether they encounter difficulties locating it.

The assessment concluded there was little or no Australian or New Zealand research for many of these areas, which meant it was not possible to conclude whether there were risk management issues to be addressed. Submitters were asked to provide any relevant evidence on these topics.

Since this time, FSANZ undertook a targeted review of published and unpublished literature on consumer practices and knowledge (SD4). Consumer research included in this review

has sought to address a set of research questions relevant to: preparation instructions, warning and advisory labelling, and protein source information. The gathered consumer research while varied in research techniques (e.g. qualitative focus group and quantitative cross sectional survey design) offers insight into the nature of labelling of infant formula where findings align.

The consumer evidence found that caregivers consider preparation instructions an important part of the label. They also say they believe it is important to follow them exactly. However, the research shows that when they are asked about more specific practices, caregivers reveal deviating from the instructions. Common deviations that caregivers self-report include: not washing hands before preparing formula, not boiling water, not sterilising bottes and utensils, microwaving formula, and adding powder to the bottle before water. Some caregivers also report reusing unfinished feeds, altering the ratio of powder to water, and adding flavourings and other foods to bottles.

Research on caregivers' use of the label reveal a range of reasons for these deviations. In some cases caregivers are unaware of particular instructions and so do not follow them (e.g. discarding unfinished feeds rather than reusing them). In other cases caregivers have read the relevant instructions but did not understand them. For example, some caregivers do not understand the instruction to discard unfinished feeds. Observational research also shows that caregivers may believe they have read the instructions and believe they are following them but are actually preparing formula incorrectly. For example, some caregivers use the wrong quantity of powder relative to water.

For some instructions, caregivers report deliberately deviating from the instructions. They have noticed, read, and understood the instructions but have chosen not to follow them. For example, some caregivers self-report altering the proportions of powder to water (e.g. adding an extra scoop), adding flavourings or foods to formula, or reusing leftover feeds despite knowing this went against the preparation instructions. In some cases, caregivers claim they are doing this based on advice from health professionals.

Reasons for deliberately deviating from the instructions included: low perceived risk, increasing efficiency when preparing formula, the desire to avoid waste or expense of discarding formula, infant age considerations, and receiving conflicting preparation advice from other sources such as health professionals.

In some cases caregivers reported the lack of detail or explanation made the intent of instructions unclear. For example, they were unclear how long after feeding leftover formula should be discarded and some caregivers who reported adding flavourings to formula noted that the instructions did not advise against this.

Caregiver confidence in their abilities appears to also contribute to their adherence to following the instructions. Caregivers report reading the instructions when using infant formula for the first time, and using them less as they become familiar with preparing infant formula. This is consistent with more general research on warnings and instructions (Argo & Main, 2004). In their literature review, Argo and Main (2004) found that as consumers become more familiar with a product they are less likely to notice warnings on the product and are less likely to follow the precautions included in the warning. Some caregivers indicate they do not or would not review the preparation instructions if and when they change brand/product.

The research shows that caregiver understanding of some of the steps can be improved through changes to the instructions. In particular, understanding that flavourings and other foods should not be added to formula, leftover formula should not be reused, and water should be added to the bottle before formula can be improved.

Further highlighting of key steps to follow within the preparation instructions by means of emboldening or colouring, as well as drawing greater attention to the risks associated with not following the preparation instructions may increase adherence to the preparation instructions.

5.2 Risk management framework

FSANZ's risk management framework for food safety labelling of infant formula is comprised of three principles to guide consideration of our approach (Table 5.1). The first principle is public health and safety, which reflects FSANZ's priority objective of addressing the risk to public health and safety in the context of Australia and New Zealand. The second principle relates to existing Australian and New Zealand infant feeding guidelines (NHMRC 2012, MOH 2008) and the WHO PIF guidelines (WHO 2007) as a source of best practice public health guidance for caregivers and health professionals. The consumer behaviour literature review identified the third principle of 'clarity' as important for caregivers when using food safety labelling information.

Table 5.1 Principles and outcomes of FSANZ's risk management framework for labelling

Principle	Outcome
Public health and safety	Labelling of infant formula needs to address the specific public health and safety risks to formula fed infants in Australia and New Zealand associated with the preparation and use of infant formula
Best practice guidance	Labelling supports best practice public health guidance and education on the safe preparation and use of infant formula.
Clarity	Labelling provides caregivers with clear and readily understood information that assists them to safely prepare and use infant formula.

5.3 Preparation, use and storage directions to manage microbiological hazards

Powdered infant formula is not a sterile product, and like many other foods there are various risks associated with incorrect preparation, use and storage of infant formula, including microbiological hazards. Preparing and storing reconstituted infant formula, including concentrated formula, correctly can reduce potential risks. However it is important to note that there is no single risk reduction measure that, by itself, will ensure the microbiological safety of infant formula.

The product label is one source of information for caregivers on the correct handling of infant formula. Several current labelling requirements in the Code relate to directions for the safe preparation, use and storage of infant formula, with the purpose to inform caregivers of how to handle the product safely to minimise the risks from microbiological hazards.

Approach to this section

The directions in paragraphs 2.9.1—19(3)(a), (b), (c) and (e) of the Code are discussed in this section, including their relevance to ready-to-drink and concentrated formula.

The direction in paragraph 2.9.1—19(3)(d) to use the enclosed scoop provided is intended to manage negative health effects of over-concentration or dilution of powdered infant formula, rather than a microbiological hazard. This direction is discussed separately in section 5.4.3.

Also discussed in this section is the issue of standardising the words and pictures of all directions contained in subsection 2.9.1—19(3).

5.3.1 Directions for preparation and use

Current regulations

Australia and New Zealand

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

Subsection 2.9.1—19(3) requires the label on a package of infant formula to include directions (in words and pictures) for the preparation and use of infant formula, 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.

Both words and pictures are required to provide clear and unambiguous directions for preparation and use; however the exact wording is *not* specified.

Codex

The above requirements align with Section 9.5 of the Codex Standard (Codex 1981), which specifies that adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, appear on the label and in any accompanying leaflet. It also specifies clear graphic instructions illustrating the method of preparation of the product, and notes that powdered products should be reconstituted with water that is safe or has been rendered safe by previous boiling.

The Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (Codex 2008) (CoHP) provides practical guidance and recommendations to governments, industry, health professionals/caregivers of infants and young children, as appropriate, on the hygienic manufacture of powdered formula and on the subsequent hygienic preparation, handling and use of reconstituted formula. The CoHP has an emphasis on the control of microbiological hazards, in particular *Salmonella* and *Cronobacter* species.

Other guidelines

Australia and New Zealand each have national infant feeding guidelines. For Australia, the National Health and Medical Research Council (NHMRC) released a revised version of the *Infant Feeding Guidelines – Information for Health Workers* in 2012 (NHMRC 2012). These guidelines include a section on infant formula which discusses preparation of infant formula and the risks associated with incorrect preparation. The New Zealand guidance on the preparation, handling and storage of infant formula is part of the *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2)*; published by the Ministry of Health

in 2008 and updated in December 2012 (MoH 2012). The publication Feeding your baby infant formula is also available.

Internationally, the WHO released guidelines titled *Safe Preparation, Storage and Handling of Powdered Infant Formula* (the WHO PIF guidelines) in 2007 (WHO 2007). These were based on a 2006 microbiological risk assessment on the pathogen *Cronobacter* species in infant formula products by the FAO and WHO.

Previous consideration

In 2016, FSANZ's preliminary view was to retain the current labelling requirements for preparation and use.

Stakeholder views

Eight submitters (4 government, 4 industry) commented on the direction to prepare bottles individually and all supported FSANZ's preliminary view (Table 5.2).

Nine submitters (5 industry, 4 government) commented on FSANZ's preliminary view for the direction about storage of made up formula. Of these submitters, two government submitters supported maintaining the current requirement, noting it is consistent with current domestic and international guidelines, and FSANZ's assessment. Other submitter comments are in the Table below.

Six submitters (4 industry, 2 government) commented on FSANZ's preliminary view regarding the direction about the water used to reconstitute powdered infant formula. Four of these submitters supported FSANZ's proposal to retain the existing requirement.

Seven submitters (4 government, 3 industry) commented on FSANZ's preliminary view for the direction about discarding leftover formula. All seven submitters supported retaining the existing requirement.

Table 5.2 Submitter comments and FSANZ's responses on directions and preparation of use

Comment	Submitter	FSANZ response
Prepare bottles individually		
Suggested FSANZ consider extending direction to state each bottle should 'ideally be consumed immediately'.	Government	Australian and New Zealand infant feeding guidelines recommend to *ideally prepare only one bottle of formula at a time, just before feeding* however also provide guidance on preparing feeds in advance. FSANZ considers requirements for labelling advising refrigeration of made up formulas that are to be stored before use reduce microbiological risks associated with formulas that are not consumed immediately. A requirement to include an instruction on the label that each bottle should 'ideally be consumed immediately' may also cause confusion with the instruction regarding storage in the refrigerator and using within 24 hours.
Storage of made up formula		

Comment	Submitter	FSANZ response
Provided differing views about extending the instruction to include a refrigeration temperature of ≤4ºC: • Supported the existing direction if it includes a refrigeration temperature for safety reasons. • Opposed the inclusion of a refrigeration temperature because it would not reduce the risk to infants, noting surveys confirm less than half of New Zealand domestic refrigerators operate at 2-4ºC.	Government	The microbiological analysis referred to in FSANZ's risk assessment (Supporting Document 3) and a more recent risk assessment (Soboleva 2021) were conducted at a holding/cooling temperature of 6°C and found made up formula was safe when reconstituted with water at 20º and stored for up to 24 hours. These findings support retaining the requirement to refer to 'refrigerated' rather than state the refrigerator temperature is at or less than 4°C, as suggested.
Supported flexibility for less than 24 hours storage and that the wording of the instruction is not prescribed.	Industry Government	Refer to discussion below.
Water used to reconstitute powdered infant formula		
Noted development of an infant formula ready bottled water, where the water is pasteurised during production. Sought amendment to regulation to 'potable, previously boiled *or pasteurised* water'.	Industry	FSANZ considers it is unnecessary to refer to pasteurised water in the direction as the Code does not specify the water source. We note best practice public health guidance is to preferably use boiled tap water, although the Australian infant feeding guidelines also states that plain unopened bottled water can be used.
Noted FSANZ stated the current requirement is to use 'cooled' previously boiled water which is not the case.	Government	FSANZ acknowledges the reference to 'cooled' in relation to the direction in paragraph 2.9.1—19(3)(c) was incorrect in that Consultation paper.
Questioned whether the Code should specify the temperature of water used for reconstitution (e.g. 'cooled to room temperature') to avoid potential for *Cronobacter* growth.	Government	FSANZ considers there is no need to specify the temperature to which the formula is to be cooled, as the inclusion of 'cooled' should indicate to caregivers to cool the water to room temperature or below. The consumer evidence indicates that many caregivers will often allow previously boiled water to cool for at least 30 minutes, and it is also common practice for caregivers to prepare boiled water in bulk and store in refrigerated conditions prior to use (Supporting Document 4).
Discarding leftover formula		
Suggests adding 'within 2 hours' to avoid misinterpretation.	Government	Refer to discussion below.

Discussion

Prepare bottles individually

FSANZ's consumer evidence did not identify a problem with caregivers' comprehending the instruction to prepare bottles individually. There was some confusion about why the

preparation of individual bottles is recommended when advice indicates preparing feeds in advance is considered acceptable.

A review of qualitative and quantitative research in the United Kingdom found many caregivers are aware of recommendations to prepare infant formula feeds on an individual basis, although almost all caregivers consider this practice to be too difficult and impractical to implement consistently. A common practice amongst United Kingdom, Australian and New Zealand caregivers was to pre-fill bottles with pre-boiled water and store until adding powdered formula later, indicating that bottles were used when making up formula (Supporting Document 4).

FSANZ notes the available consumer evidence indicates it is common practice for caregivers to prepare and store formula in advance, however no evidence was found to suggest that when doing so, they are preparing formula in larger containers and then portioning into individual bottles. Current industry practice is to include the instruction on infant formula labels to prepare bottles individually in text and in a picture as required, where the picture clearly illustrates making up formula in an individual bottle rather than a larger container.

FSANZ considers the main intention of this instruction is that caregivers who are preparing multiple feeds at the same time (e.g. when they are preparing feeds in advance) measure the water and formula powder into each bottle individually i.e. that they do not measure all the water and formula powder needed into one large container, mix it and then divide it between bottles. This helps to address the public health and safety risk of incorrect proportions of formula to water being used during reconstitution. The instruction to prepare bottles individually also aligns with best practice guidelines. The majority of submitters supported the existing direction.

Based on the assessment and available consumer evidence, FSANZ considers the existing direction to prepare bottles individually is appropriate and should be retained.

Storage of made up formula

FSANZ's risk assessment investigated the effect of storage temperature on the microbiological safety of powdered infant formula. There was no difference in relative risk for prepared infant formula stored under refrigeration (6°C) for 24 hours compared to 4 hours when reconstituted with water at a temperature of less than 20ºC. The risk was found to increase for any storage time (2, 4 hrs) when reconstituted with water at 37º or higher. It was concluded that the temperature of the reconstitution water appears to have greater influence on risk than time spent under refrigerated storage (Supporting Document 3).

The label direction of 24 hours for storage time aligns with advice in the Australian infant feeding guidelines and the WHO Guidelines. However, it differs from New Zealand infant feeding guidelines which advise storing prepared formula at up to 4°C in the lower half of the fridge, at the back, and kept for only a maximum of four hours. FSANZ notes this guidance is currently being reviewed, and a more recent New Zealand risk assessment has concluded findings similar to FSANZ's risk assessment (Soboleva 2021).

The storage duration for made up formula is not specified in Codex CXS 72-1981 (Codex 1981). The WHO PIF guidelines state if feeds need to be prepared in advance, they should be prepared in individual bottles, cooled quickly and placed in the refrigerator (no higher than 5ºC) for use within 24 hours (WHO 2007). The Codex CoHP states that guidance to the caregiver should be provided on the need to refrigerate product, if formula is not used immediately (Codex 2008).

Consumer evidence indicates a general understanding by caregivers that formula prepared in advance must be refrigerated, although there was less awareness that the formula could be stored for no more than 24 hours. In an online study of 1333 Australian and New Zealand caregivers, 66% of respondents agreed it was okay to store made-up formula in the refrigerator for 24 hours. However, only 53% of respondents reported they made up a number of bottles of formula at the same time to use for later feeds (Supporting Document 4). Other studies reported it was common practice to prepare feeds in advance, however these did not specifically investigate the duration.

FSANZ has observed that infant formula product labels vary. Most products include the direction that made up formula can be stored up to 24 hours. Some New Zealand products have a shorter time period for storage (e.g. 4 hours). There were also products that did not include this direction at all, opting instead to focus on directions such as 'feed immediately' and 'do not store'. Only one product referred to the refrigeration temperature.

Based on the assessment and consumer evidence, FSANZ is proposing to retain the existing requirement. The intent of this requirement is to provide information on infant formula labels that a prepared infant formula product must be stored in a refrigerator and not beyond 24 hours. FSANZ is of the view that a label direction to this effect would provide clarity to caregivers that any formula made up in advance (irrespective of the brand) is safe for use if it has been refrigerated and used within 24 hours.

As noted above, prepared formula stored at or below 6°C for 24 hours has the same risk as formula stored for four hours at this temperature, if prepared with water at 20°C or less. FSANZ therefore considers there is no public health and safety risk associated with the recommended maximum storage time from 24 hours, noting the proposal in the following section to include a direction to prepare infant formula product using **cooled**, previously boiled water on the label.

Water used to reconstitute powdered infant formula

As noted above, FSANZ's risk assessment concluded that the temperature of the reconstitution water appears to have greater influence on microbiological risk than time spent under refrigerated storage. There is no difference in relative risk (i.e. when compared to reconstitution at 37°C with no storage time) for prepared infant formula stored under refrigeration (6°C) for 24 hours compared to 4 hours when reconstituted with water at a temperature of 20°C in both scenarios, however the relative risk increased for storage times of 2, 4, 12 and 24 hours when reconstituted at temperatures of 40 and 50°C. The relative risk when reconstituted at 37°C increased with a storage time of 24 hours but not when stored for 2 and 4 hours (Supporting Document 3).

The increase in relative risk is due to *Cronobacter* species being able to grow while the temperature of the reconstituted formula cooled to 6°C. Once the temperature of the reconstituted formula reaches refrigeration temperature, there will be no or limited further growth of the organism.

Consumer evidence shows that many caregivers either use cold pre-boiled water from the kettle or prefilled bottles with boiled water that were kept in the fridge or on the kitchen bench. Some caregivers reported using filtered tap water rather than boiled water. An online study of 1333 Australian and New Zealand caregivers found that 63% of respondents self-reported using boiled water to make up formula every time and 80% of respondents thought it was correct to let the boiled water cool down before mixing it with the formula powder, rather than mixing it when it is still hot. However, only 33% of respondents reported always using cool or lukewarm water to make formula. Caregivers in another study considered the use of cooled boiled water to be one of three key preparation instructions (the others were

how to sterilise bottles, and the powder to water ratio required) for ensuring the formula is safe for consumption (Supporting Document 4).

Current industry practice is to include directions to boil the water and the majority of product labels also specified cooling the water before use, with some instructing the water should reach 'room temperature' or be 'completely cooled' or 'lukewarm'. One manufacturer qualified lukewarm at 40ºC temperature.

Based on the risk assessment and the available consumer evidence, FSANZ considers the direction should be retained. All submitters to this topic supported the existing requirement although some submitters suggested certain additions (see Table 5.2). However, while caregivers understand there is a need to use cooled water to make up formula, the evidence suggests this practice is not always followed. Given the risk assessment findings indicate the use of warmer water represents a safety risk for stored infant formula, FSANZ considers there is scope to change the required direction so that it refers to the use of **cooled**, potable, previously boiled water. This approach would support best practice public health guidance in Australia and New Zealand and will not affect the majority of infant formula manufacturers that are already referring to use of cooled water on their product labels.

Discarding leftover formula

Consumer evidence indicates that some caregivers do not follow or understand the instruction to discard unfinished formula. In the FSANZ commissioned eye tracking study undertaken in Australia, most respondents understood the instruction to throw away any leftover feed immediately but many noted a timeframe for following the instruction is not specified and were uncertain as to how long after feeding they should dispose of leftovers.

Of the 30 study participants, 13 reported discarding unfinished feeds immediately after feeding, 12 usually waited between 30 and 60 minutes before discarding unused formula and five reported saving the leftover formula in the fridge for a few hours or a couple of days. The majority of the 12 participants who waited 30 to 60 minutes before discarding unused feeds reported not having seen the discard instruction.

A qualitative online survey of Australian and New Zealand caregivers found that 52% of respondents reported never saving unused formula in the fridge for later use, meaning nearly half of respondents had done so. Of concern is that six percent reported always saving left-over formula to reuse later, and 11% said they did this most times.

In another qualitative online survey, 62% of Australian and 71% of New Zealand respondents wanted to know if they could refrigerate unfinished formula and use for the next feed. A similar number of respondents were interested in how long leftover formula could be kept before it should be discarded (Supporting Document 4).

Infant formula labels commonly include the discard direction at the end of the step-by-step preparation instructions, instructing caregivers to 'discard any unfinished feeds', 'any formula left in the bottle after feeding must be discarded' or 'discard unused portions, do not keep for later feeding'. Some products specify a time by which unfinished feeds must be discarded (for example, ' any formula left after feeding must be discarded immediately' or 'discard any feed that has not been consumed within 1 hour').

The Australian Infant Feeding Guidelines specify any formula left at the end of the feed must be discarded and that any formula at room temperature for longer than one hour should be discarded (NHMRC 2012). In contrast, the New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers specify that formula not used after being at room temperature for two hours should be discarded (MoH 2008). The WHO PIF guidelines state prepared

feed should be discarded after two hours unless stored in the refrigerator, and leftover feed should never be saved for later or added to freshly prepared feed (WHO 2007).

Based on the assessment and consumer evidence, FSANZ considers there is sufficient evidence to support a change to the direction instructing that unfinished formula must be discarded within a specified time. The addition of a specified time is intended to address the public health and safety risk that can occur from bacterial contamination from the use of powdered infant formula (which is not sterile), or from the infants' mouth during feeding. Discarding formula leftover from a feed is therefore important as harmful bacteria may have increased to unsafe levels if the unfinished formula remains at room temperature over a period of time. Contaminated formula should also not be stored in the refrigerator for later use.

FSANZ is proposing the direction refers to a specified time period ('within 2 hours') noting this addition would provide greater clarity for consumers and would reflect best practice public health guidelines which include a specified time period (Australian Infant Feeding Guidelines, New Zealand infant feeding guidance, the WHO PIF guidelines and a Ministry for Primary Industries review of reconstituting infant formula that recommended formula should be kept for no more than two hours at room temperature (Campbell and Soboleva 2015)).

Application of preparation and use directions to concentrated and ready-to-drink formula

FSANZ understands that, unlike some overseas markets in which both ready-to-drink and concentrated infant formula products are sold (for example, in the United Kingdom and United States), ready-to-drink formulas are only available domestically through health professionals and concentrated formula products are not currently available (advice from submitters to the 2016 Consultation paper). However, FSANZ is aware the market may change in the future and therefore considers it appropriate to review the labelling provisions for directions for preparation as applies for these products.

The directions for preparation and use set out in subsection 2.9.1—19(3) apply to powdered, concentrated and ready-to-drink infant formula products. However, the nature of concentrated and ready-to-drink products is such that certain directions do not appear to be relevant for these products. FSANZ has considered whether or not the existing directions would apply to ready-to-drink and concentrated infant formula products.

The direction for each bottle to be prepared individually (paragraph 2.9.1—19(3)(a)) would apply to concentrated infant formula, given it must be reconstituted before use. As noted in section 5.3.1, the purpose of this direction is to address the public health and safety risk of incorrect proportions of formula to water being used during reconstitution. However, given there is no need for ready-to-drink products to be reconstituted FSANZ is therefore proposing not to apply this direction to these products.

Similarly, the direction to refrigerate formula and use within 24 hours if it is made up and stored prior to use would apply to concentrated formula products (paragraph 2.9.1—19(3)(b)), noting there is a potential risk of contamination during preparation. In contrast, ready-to-drink products do not require advance preparation when asceptically packaged, other than the need to transfer the liquid formula into a sterilised bottle for feeding. FSANZ is proposing not to apply this direction to ready-to-drink formula products.

It is appropriate for the direction to reconstitute formula with potable, previously boiled water (paragraph 2.9.1—19(3)(c)) to apply to concentrated infant formula products, for the same reasons described above for reducing the microbiological risk during preparation. However, FSANZ is proposing the direction does not apply to ready-to-drink products because they do not require reconstitution.

Given the risk of microbiological contamination from the bottle teat during feeding, FSANZ considers the direction to discard formula left in the bottle after a feed (paragraph 2.9.1—19(3)(e)) is as relevant to concentrated and ready-to-drink formulas as it is to powdered infant formula and is proposing the existing requirement remains for these products.

FSANZ reviewed Australian and New Zealand infant feeding guidelines for best practice public health guidance on the preparation and use of ready-to-drink and concentrated formula. The Australian infant feeding guidelines refer to ready-to-drink formula made available in aseptically packed glass bottles or tetra packs, for hospital or domestic use respectively. It is recommended to pour the liquid formula into a sterilised bottle just before feeding, or into numerous sterilised bottles for refrigeration below 5ºC and used within 24 hours. Unfinished formula left in the bottle after a feed must be discarded (NHMRC 2012). New Zealand infant feeding guidance recognises ready-to-drink formula may be available commercially, but does not include any specific recommendations for its use (MoH 2012). Neither guideline refers to concentrated formula.

Proposed approach

As discussed above, FSANZ's proposed approach 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)).

For the other two relevant directions, considering the principles of public health and safety, best practice guidance and clarity and the risk assessment conclusions and submitter comments, FSANZ is proposing the following amendments:

- revise the direction for water used to reconstitute powdered infant 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)).

FSANZ is also proposing not to apply the following directions to ready-to-drink infant 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)).

5.3.2 Standardised wording or pictures for directions for preparation and use

Previous consideration

In the 2016 consultation paper, FSANZ noted there was some variation in the wording and images used for directions on products marketed in Australia and New Zealand, as currently infant formula companies have flexibility in how they word and present this information on their products.

As FSANZ received little evidence to indicate that consumers are confused by presentation and information differences in directions between products, FSANZ's preliminary view in 2016 was to maintain the existing approach not to prescribe the exact words or pictures for the instructions required by subsection 2.9.1—19(3).

Stakeholder views

Six submitters (3 government, 2 industry, 1 consumer group) commented on FSANZ's preliminary view (Table 5.3).

Table 5.3: Submitter comments on standardised wording or pictures for directions for preparation and use

Comment	Submitter
Supported FSANZ' preliminary view. Reasons included: • no evidence to indicate caregivers are confused by differences in presentation between products. • noted difficulty in standardising advice due to differences in infant feeding guidelines between Australia and New Zealand and variation in ratio of scoops to water across brands.	Industry Government
Prescribing words and pictures has potential to benefit consumers by reducing safety risk associated with incorrect formula preparation.	Government
Supported flexibility for manufacturers but noted consideration should be given to clarifying instructions (which may include prescribed wording) noting a 2012 submitter comment that some consumers find the variety of instructions confusing (e.g. low socioeconomic, low literacy groups). The primary aim of instructions is to ensure all caregivers can safely prepare infant formula.	Government
Would like to see standardised directions based on evidence-based best practice. Supports *WHO Guidelines for the safe preparation, storage and handling of powdered infant formula* as a guiding document for instructions.	Consumer group

Discussion

There is little consumer research to indicate whether consumers would benefit from prescribed (standardised) text and pictures for directions on formula use and preparation. Research commissioned by FSANZ found that while most participants looked at the preparation instructions and indicated they understood and were confident using them, most participants did not follow the preparation steps as written. The three main parts of the instructions caregivers did not follow were hand washing, bottle sterilisation and water preparation, for reasons of wanting to increase preparation efficiency, having a low perceived risk from deviating from the instructions, and the infant's age (older infants were considered less vulnerable). FSANZ has not identified any evidence to indicate that caregivers are confused by presentation and wording differences in directions between products.

FSANZ notes the 2012 submitter referred to in Table 5.3 did not provide specific evidence that caregivers affected by socio-economic disadvantage or poor health literacy found the instructions confusing (rather they suggested it was unlikely these caregivers would follow instructions). In addition to recommending mandated consistent instructions, the submitter suggested educational material could assist and provided an example of the 'Guide to bottle feeding' prepared by the NHS in the UK.

Not prescribing exact wording or pictures allows infant formula product suppliers flexibility to word the required directions for preparation and use appropriately for their particular product, to align with infant feeding guidelines in the applicable country where possible, and to align with directions specific to their products where possible (e.g. to instruct caregivers to use prepared infant formula within 4 hours rather than 24 hours).

Not prescribing the exact words or pictures for these directions is consistent with Codex CXS 72-1981 (Codex 1981).

Proposed approach

Based on the discussion above, FSANZ proposes to maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions of use and preparation on infant formula products.

5.4 Other safe preparation and storage issues

5.4.1 Date marking

Current regulation

The 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. It is the responsibility of the food business attaching the label 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.

Previous consideration

FSANZ's preliminary view was to maintain the existing requirement for date marking on infant formula, and input was sought on whether there are any other issues associated with date marking for infant formula.

Stakeholder views

Eight submitters (4 government, 4 industry) commented on FSANZ's preliminary view with six supporting FSANZ's preliminary view to maintain existing date marking requirements (Table 5.4).

Table 5.4: Summary of submitter comments on dating marking requirements

Comment	Submitter
Suggested FSANZ considers whether a 'use-by' date should always be used for infant formula products rather than a 'best-before' date, noting the nutrient content could deteriorate over a certain time period, after which a 'best-before' would not be appropriate.	Government

Discussion

The existing date marking requirements ensure that all infant formula products must carry a date mark, regardless of whether it is a use-by date or a best-before date. This approach was introduced when Standard 2.9.1 was developed, because although powdered infant formula could have a long shelf life, nutrient content would diminish over time in the unopened product.

FSANZ noted in the 2016 Consultation paper that, although research shows high levels of reported use of date marking information on foods in general, there is some confusion about the purpose and meaning of use-by and best-before dates among consumers. While this confusion likely extends to infant formula, a change to date marking requirements for infant formula products is unlikely to resolve the general consumer confusion (see section 4.1 of

SD2 in the 2016 Consultation paper.

In the 2016 FSANZ-commissioned study, caregivers were found to have a good understanding that the use-by date is the date by which the formula should be used and any remaining formula should be discarded. Some caregivers also noted a use-by date would require stricter adherence than a best-before date (Malek 2016a).

FSANZ considers the existing requirement for infant formula manufacturers to determine whether to label with a use-by date or best-before date irrespective of the shelf life of the product continues to be appropriate, noting the Code specifies that a use-by date must be used if the formula should not be consumed past this date for health or safety reasons (which could include nutrient deterioration).

The use of a best-before date would be consistent with Codex, which specifies that the date of minimum durability (preceded by the words '*best before'*) shall be declared (Codex 2018).

Proposed approach

Based on the discussion above, FSANZ proposes to maintain existing date marking requirements for infant formula products.

5.4.2 Storage instructions for infant formula

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.

Previous consideration

In the 2016 consultation paper, FSANZ noted the existing approach aligns with Codex specifications for storage instructions (Codex 1981), and no submissions to the 2012 Consultation paper commented on the specific requirement in section 2.9.1 of the Code. FSANZ's preliminary view was therefore to maintain the existing requirement.

Stakeholder views

Eight submitters (4 government, 4 industry) supported FSANZ's preliminary view to maintain the existing approach as it aligns with Codex.

Discussion

The 2016 FSANZ-commissioned study found caregivers consider the storage instructions are generally straightforward and easy to understand. With respect to the instruction to use

formula within four weeks of opening, most caregivers either reported adhering to the instruction or 'not needing to' due to opened tins of formula lasting less than four weeks. The main drivers of adherence were the desire to prevent spoilage before end of shelf-life and risk aversion. Those caregivers that did not adhere to the instruction were either unaware of the duration or they knowingly continued to use the formula beyond the four weeks of opening (Malek 2016a).

FSANZ considers the existing requirements provide caregivers with clear instructions to ensure infant formula products retain safety and quality characteristics through appropriate storage. The approach aligns with Codex specifications for instructions for storage both before and after the powdered or liquid product has been opened (Codex 1981).

As noted above, all submitters to this topic supported the existing approach.

Proposed approach

FSANZ proposes 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.

5.4.3 Measuring scoop

Current regulation

There are three relevant requirements in Standard 2.9.1:

- Section 2.9.1—18 requires that a package of infant formula in powdered form (excluding single serve sachets) must contain a scoop to enable the use of the product in accordance with the directions for preparation on the label.
- Paragraph 2.9.1—21(1)(b) requires the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula).
- Paragraph 2.9.1—19(3)(d) requires a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.

Previous consideration

Some submitters to the 2012 Consultation paper suggested standardisation of scoop sizes and prescribing the wording of the labelling direction (refer to section 4.3 of SD2 of the 2016 Consultation paper). Anecdotal evidence was provided by health professionals, consumer groups and industry that caregivers did not realise scoop sizes differ. However anecdotal evidence was also cited of caregivers having a good awareness and understanding about the importance of using the correct scoop. Given the conflicting anecdotal evidence and little evidence in published literature to demonstrate a problem with the current regulatory requirements, FSANZ's preliminary view was that:

- standardising the scoop size would present technical challenges and require widespread reformulation of products
- prescribing the wording of the enclosed scoop direction in paragraph 2.9.1—19(3)(d) may not be justified.

Stakeholder views

Twelve submitters (3 government, 9 industry) commented on FSANZ's preliminary view

(Table 5.5).

Table 5.5: Submitter comments about the enclosed scoop direction and standardised scoop size

Comment	Submitter
Direction regarding using enclosed scoop	
Opposed prescription of wording because there is no evidence of problem or that benefit of change would outweigh costs. It was also noted that the direction was already used across the board.	Industry
FSANZ should consider mandating the wording, noting there is anecdotal evidence from paediatric dietitians that the wrong measuring scoop is used.	Government
Noted there is insufficient evidence of a problem and therefore considered there is no reason to mandate at this stage.	Government
Would like to see further consideration including consumer feedback on the differences between brands.	Government
Standardised scoop size	
Does not support standardised scoop size for the following reasons: • a standard reconstitution ratio can be applied (e.g. one scoop to each 50 ml water), but standard scoop volume is not possible due to different powder weights and bulk densities. • according to current Government regulatory policy, must first explore non-regulatory options such as health intermediary and maternal education. • mandating scoop size is not aligned with Codex or other international practice.	Industry
Scoop sizes and dilution recipes should be considered further noting: • issues relate to unintentional errors when changing formula (scoops from one brand used for another, incorrect ratio of scoop to water used as this differs across brands) • lack of formal evidence about misuse despite consistent anecdotal reports from health professionals • low socioeconomic/education background and low literacy groups should be considered to ensure safe and appropriate preparation by these groups • industry should provide more information to better understand the technical issues.	Government
Have been informed that clinical paediatric dietitians often use the same ratio of infant formula when fortifying breast milk as this is considered to provide similar nutrients regardless of brand.	Government
If standardised scoop size is not possible, suggests a consistent ratio of formula to water across all brands be considered (e.g. 1 scoop to 30 mL as seen in the UK) to simplify preparation and reduce risk of errors.	Government

Discussion

Direction regarding enclosed scoop

Consumer evidence found that most caregivers understood not all scoops are the same as the scoop that is provided in the tin and had a good understanding to reconstitute a certain volume of product using only the enclosed scoop in the amount stated in the directions. The majority of caregivers reported using the measuring scoop provided in the tin. It was unclear whether those caregivers using something other than the scoop provided were unaware of the direction or the risks associated with doing so (Supporting Document 4).

In 2019, FSANZ observed the majority of products on the Australian and New Zealand market used the exact wording *only the enclosed scoop should be used*.

FSANZ has no evidence that the existing requirement is unclear or not understood by caregivers. The direction is necessary to ensure caregivers are able to reconstitute

powdered formula safely. The direction also supports best practice guidance, noting the Australian infant feeding guidance recommends to always measure the amount of powder using the scoop provided in the can. FSANZ considers there is no need to prescribe the wording of the direction and notes the current regulatory approach provides the opportunity for infant formula product manufacturers to incorporate the instruction in a manner that they consider is best for their particular label and product.

Similar to section 5.3.1 above, FSANZ has considered whether this direction would apply to ready-to-drink and concentrated infant formula products. Although the current direction indicates it is subject to whether a package contains a measuring scoop, FSANZ considers the direction would not apply to these products.

Standardised scoop and ratio for preparation

FSANZ notes standardising the scoop volume would be difficult and costly to implement due to different powder weights required (according to product formulation) and bulk densities (affected by ingredients and manufacturing process). Some infant formula product companies would have to undertake significant reformulation of their products to achieve the uniform scoop size.

There are also few benefits to be obtained from introducing a standard scoop size or requiring a consistent reconstitution ratio of formula to water across all brands. The available consumer research shows that caregivers had a good understanding of the correct use of scoops and how to reconstitute a product. FSANZ has not identified any evidence to indicate that scoops are being incorrectly transferred from one product to use for another product, or that the incorrect use of a scoop is contributing to reformulation errors.

FSANZ also notes that neither Codex or any other overseas regulations mandate a standard scoop volume. If Australia and New Zealand were to implement a standard scoop volume, then it would likely result in a significant barrier to trade.

Proposed approach

Based on the discussion above, FSANZ proposes to maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used, without prescribing the exact wording for this direction.

FSANZ is also proposing not to apply this requirement to concentrated infant formula and ready-to-drink formula from the direction to only use the enclosed scoop

5.5 Warning statements

The term ‘warning statement’ in relation to a food for sale is defined in subsection 1.1.2—2(3) of the Code to mean “a statement about a particular aspect of the food that is required to be expressed in the words set out in the following provisions”. Paragraph 1.1.2—2(3)(c) refers to the provisions specific to infant formula in subsection 2.9.1—19(1) in relation to following preparation instructions and the ‘breast is best’ statement and section 2.9.1—13 in relation to products formulated for premature or low birthweight infants.

This section considers the aspect of Standard 2.9.1 that relate to warning statements for infant formula and the legibility requirements of such statements. The warning statement required for products formulated for premature or low birthweight infants (section 2.9.1—13) will be discussed in a future consultation.

Section 2.9.1—19 also sets out requirements for certain statements of an advisory nature

relating to the preparation and use of infant formula, and section 2.9.1—23 mandates statements that identify the protein source(s) in the product and the risk of dental fluorosis.

Generic requirements in Standard 1.2.3 Information requirements – warning statements, advisory statements and declarations of the Code apply to all food for sale including infant formula. Of these, the generic labelling requirements listed in section 1.2.3—4 relating to the declaration of certain allergenic substances apply to infant formula. These requirements are not part of the scope of this review and are therefore not discussed or considered in this report.

The consumer research referred to in this section of the report has been sourced from Supporting Document 4 unless stated otherwise.

5.5.1 Legibility requirements for warning statements

Current regulation

General legibility requirements for all foods, including infant formula, are set out in Division 6 of Standard 1.2.1 (Requirements to have labels or otherwise provide information). In general, 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—24). Section 1.2.1—25 mandates general requirements for the size of type for warning statements, based on the surface area of the package.

Section 2.9.1—20 sets out specific requirements for 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 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.

The intent of these general and specific requirements is to ensure prescribed information is readily accessible to the consumer before purchase and during the life of the product. The larger size of type is intended to be read more easily and alert consumers to important safety information.

Previous consideration

FSANZ noted that some stakeholders to the 2012 Consultation paper, including industry, government and a health professional organisation, considered existing legibility requirements were adequate for infant formula products. Other consumers and health professionals commented that bolding and capitalisation should be mandated for statements on infant formula labels, along with the placement and size, so that statements can be easily seen and read by consumers (many of these comments related to the ‘breast is best’ statement).

In 2016, FSANZ noted there was no evidence to indicate that the current legibility requirements are inadequate, and our preliminary view was to maintain the existing requirements.

Stakeholder views

Five submitters (1 government, 4 industry) commented on FSANZ’s preliminary view. All these submitters supported maintaining the current legibility requirements as there was no

evidence to indicate they are inadequate.

Discussion

Findings from a FSANZ commissioned study indicated some caregivers do not visually attend to the warning statement to follow instructions exactly, and some reported never having seen this warning statement (although most caregivers tend to follow the preparation instructions anyway). Neither of the two infant formula labels used in the formula preparation task had the warning statement co-located with the preparation instructions (Malek 2016a, Magill et al 2020, Supporting Document 4). A common response provided by caregivers was that they probably read the warning statement for the first time they used formula but had not noticed it since or felt a need to read it again (Malek 2016b). Other general literature about warnings have found that as consumers become more familiar with a product they are less likely to notice warnings on the product and are less likely to follow the precautions included in the warning (Supporting Document 4). There was also evidence that some caregivers avoided reading all warning and advisory statements after responding negatively to the 'breast is best' warning statement.

When asked how warning statements could be improved, caregivers in one study suggested they should be large and clear enough to be easily and quickly read (Malek 2016a).

In addition to existing print size requirements, FSANZ notes current industry practice is to present warning statements in capitalised format, often in a separate box or with an emphasis on the text (e.g. through colour or bolding).

Proposed approach

Based on the available evidence and stakeholder views, FSANZ does not propose to change the existing legibility requirements for generic or specific warning statements on infant formula labels. FSANZ considers the existing requirements are appropriate to ensure prescribed warning statements on infant formula product labels are able to be read by caregivers. These legibility requirements also afford industry some flexibility in how warning statements are presented.

5.5.2 Warning statements about following instructions exactly

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.*

Previous consideration

FSANZ noted the intent of these warning statements is to alert caregivers to the importance of following instructions about the essential hygiene measures for equipment (e.g. teats and bottles) and using the correct concentration.

Submitters to the 2012 Consultation paper raised concerns about anecdotal evidence of caregivers adding other foods, particularly baby cereal products, to bottles of infant formula. The basis of this practice was to delay hunger and prolong sleep, or reduce the cost of feeds. Submitters recommended additional instructions be included on the label to discourage this practice.

FSANZ noted no particular issues were raised about the existing warning statement for 'ready-to-drink' products, and assumed this was because the warning statement specifically instructs caregivers to not dilute or add anything to the product.

In the 2016 Consultation paper, FSANZ discussed the findings of a literature search which suggested the practice of adding other foods to infant formula may be common practice, including in Australia and New Zealand. However, it was not possible to estimate the prevalence of this behaviour, or determine whether this practice differs by product form (i.e. powdered, concentrated or ready-to-drink).

FSANZ noted that options to communicate to caregivers that other foods should not be added to infant formula may need to be considered (e.g. as a label statement or education material provided by health agencies).

FSANZ sought stakeholders comments on three questions to assist with the assessment of this issue. The questions sought evidence about: the prevalence of adding other foods to formula; whether this practice is more common with powdered, concentrated, or ready-to-drink products; and whether caregivers add other foods to formula to reduce the cost of the feed.

FSANZ's preliminary view was that the existing warning statements are effective and sought stakeholders' views on this preliminary view.

Stakeholder views

Five submitters (1 government, 4 industry) supported maintaining the current requirements. Eight submitters (2 government, 4 industry, 1 consumer and 1 health professional) provided comments to FSANZ's questions relating to adding other foods to formula (Table 5.6).

Table 5.6: Submitter comments about warning statements to follow instructions exactly and adding other foods to formula

Comment	Submitter
Prevalence of adding other foods to formula	
Referred to the 2010 Australian National Infant Feeding Study, which reported 9.7% of infants less than 3 months old had received soft/semi-solid/solid food in the previous 24 hrs. Although not questioned, it is possible some was added to infant formula.	Health professional
Suspected or became aware of this practice from care call lines, however, considered the prevalence is low.	Industry
Noted anecdotal evidence of this practice occurring in Australia and New Zealand, however there is international evidence of adding other food to formula (references provided). Consultation with State Maternal and Child Health Service (Victoria) indicated this practice is an ongoing issue.	Health professional Government Consumer

Comment	Submitter
There is substantial international evidence of this practice (references provided in submission).	Consumer
Evidence on whether the practice is more common with powdered, concentrated or ready-to-drink infant formula products	
Noted liquid concentrate or ready-to-drink products not presently widely available in the Australian or New Zealand market.	Industry Government Consumer
Evidence that caregivers add other foods to reduce the cost of the feed	
Provided anecdotal evidence of adding other foods for this reason. Comments included: • formula stretching to make the product last longer • food insecurity in certain population groups, but difficult to estimate prevalence as carers can be reluctant to offer information.	Government Consumer
Considered price is unlikely to be the key driver for such practice for the following reasons: • consumer survey showed eleven other factors ranked ahead of price; 16% of respondents looked at price (Jigsaw, 2015). • insights from international markets and cultural groups indicate reason for adding other foods is to settle infant at night. • as substantial market share in Australia and New Zealand is in the premium category, do not anticipate price to be a key driver.	Industry
Other comments	
Supported a warning statement similar to the ready-to-drink statement instructing caregivers not to add anything to formula.	Government
Did not support an additional labelling statement to manage a potentially limited practice. Comments included: • it may be appropriate to add to formula following advice of health professional. • current labelling statements are clear and adequate. • FSANZ should engage with health professionals to educate relevant groups.	Industry
Provided anecdotal reasons for adding other food to formula: • addition of brown sugar recommended by maternal nurses as one-off method to relieve constipation is sometimes continued by carers. • parents add cereal to formula to promote longer sleep. • can be due to tradition (e.g. beliefs about particular foods benefiting the baby) and family custom in addition to reasons provided in literature (e.g. reflux, early weight gain, reduce feedings).	Government Health professional Consumer

Discussion

Consumer evidence indicates that when asked about the level of importance of the warning statement to follow instructions exactly, most caregivers considered it to be important or very important, and only a small proportion considered it wasn't important to follow instructions exactly. Most caregivers stated they would comply with the advice in the warning statement and not deviate from the directions given. However they believed other formula users must be deviating from the advice and suggested a range of reasons including encouraging infants to feed, administering medicine (e.g. Panadol), adding vitamins and minerals if medically advised, adding cow's milk during weaning and adding substances if the baby is upset, to bulk up the formula or for financial reasons (Supporting Document 4, Malek 2016a).

In contrast, one recent study of 1333 Australian and New Zealand caregivers found only 75% of respondents self-reported never adding extra flavourings or foods to the bottle when

preparing powdered infant formula. The study found some caregivers were regularly adding extra flavourings or other foods, such as cereal to bottles. Five percent reported always doing this and six percent did this most times. In another study of 30 Australian caregivers, two participants reported adding foods such as chocolate powder, crushed biscuits, cinnamon and vanilla essence to the formula to encourage their infants to feed. Overseas studies report similar findings. There was no evidence of adding other foods or flavourings to ready-to-drink formula or when reconstituting liquid concentrate formula (Supporting Document 4).

When asked to consider the warnings on powdered versus ready-to-drink formula, the majority preferred the latter believing it was clearer and more direct, and more strongly conveyed the message that the formula should not be changed in any way. Some caregivers also noted that because the warning on infant formula powder does not specifically say 'do not add anything' and only mentions making changes to the amount of powder, it does not rule out other changes to the formula (Malek 2016a).

There is some evidence that caregivers' understanding that adding foods or flavourings is not recommended is improved when specific advice to this effect is explicitly stated on the label (see Supporting Document 4).

Infant feeding guidelines recommend that powdered infant formula is prepared according to the instructions on the product label and that it should not be concentrated, diluted or have any other foods added to it unless on the advice of a health practitioner (NHMRC 2012; MoH 2013). The addition of other foods to infant formula modifies its composition, and consequently it may not meet the nutritional requirements of the infant or may be too concentrated with adverse effects to health.

The WHO Code, Codex Standard and EU Regulations all specify the need for a warning about the health hazards of inappropriate preparation, storage and use, but do not prescribe or specify the wording of such warnings (WHO 1981, Codex 1981, Commission Delegated Regulation (EU) 2016/127). The Code requirements differ in that the wording of warning statements are prescribed, and must be used without modification (subsection 1.1.1—8(1)). As noted above, submitters supported the current requirements. However, when asked to provide evidence of adding other foods to formula, there was some support for changing the warning statements to make it clear not to add anything to powdered and concentrated infant formula.

Although evidence for Australian and New Zealand caregivers adding other foods to infant formula is still limited, the findings noted above and anecdotal reports provided in submissions suggest it may be a fairly common practice. FSANZ considers the potential risks to public health and safety (for example, choking) need to be addressed through clear instructions to caregivers to not add anything when preparing formula. Therefore, FSANZ proposes that additional text be required on the label of powdered and concentrated infant formula to advise caregivers not to add anything to the feed. Consistent with the existing 'ready to drink' warning statement, FSANZ proposes additional text to advise not to *add anything* to the formula*,* noting this would capture the addition of any other foods or flavourings. FSANZ is proposing the additional text should apply to the warning statement for concentrated infant formula for consistency with the warning statements for powdered and ready-to-drink formulas (noting that concentrated formulas are not currently available for sale in the domestic market and therefore cost impacts would be minimal).

FSANZ considers it appropriate for this additional text to be inserted into the existing warning statement about following instructions exactly (as required by paragraphs 2.9.1—19(1)(a) and (b)) rather than as a separate warning or instruction. This will reduce the additional text required on the label, noting also, the existing statement already informs caregivers that

incorrect preparation can make your baby ill which is applicable to the addition of other foods.

Inserting the new text before the existing text *except on medical advice* is consistent with best practice guidance that other foods should not be added to formula except on the advice of a health practitioner. This is also consistent with the existing 'ready to drink' warning statement (*Do not dilute or add anything…except on medical advice)* required by paragraph 2.9.1—19(1)(c).

Proposed approach

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

For the two remaining warning statements to follow instructions exactly (paragraphs 2.9.1—19(1)(a) and (b)), FSANZ has considered the principles of public health and safety, best practice guidance and clarity, and consumer evidence and submitter comments and is proposing to include new additional text that is bolded here for identification only and would not be required to be bolded on labels:

- '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'.

5.5.3 Warning statement that 'breast is best'

Current regulation

Paragraph 2.9.1—19(1)(d) requires the label on a package of infant formula product 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 statement is subject to the requirements for the size of type set out in section 2.9.1—20.

This required statement is often referred to as the 'breast is best' statement.

Previous consideration

In response to the 2012 Consultation paper, some stakeholders suggested amending the 'breast is best' statement to become a risk-based statement about the risks to infant health of *not* breastfeeding. The rationale for a risk-based statement was to strengthen the message about the superiority of breast milk compared to formula, with the primary purpose to promote breastfeeding and maintain (or increase) current breastfeeding rates. Submitters opposed to a risk-based statement approach considered the evidence to support effectiveness of such statements is inconclusive. They also noted that studies show that caregivers who formula feed their babies experienced negative emotions such as guilt, anger, worry, uncertainty and a sense of failure, and that this type of risk-based statement on formula products could amplify these feelings.

In 2016, FSANZ noted information about the advantages and disadvantages of breastfeeding and formula feeding is available for caregivers from multiple information sources, particularly in the prenatal period, to assist in their decision about whether to breastfeed or formula feed. It was also noted that the current statement aligns with the WHO Code principles and the corresponding Australian and New Zealand agreements, the Codex

infant formula standard (Codex 1981) and public health messages about the superiority of breastfeeding compared to formula feeding. In addition, there was insufficient information to determine whether either gain-framed (messages emphasising the benefits of breastfeeding) or loss-framed messages (emphasising the risks of formula feeding) would have an impact on caregivers' breastfeeding intentions or outcomes (refer to Appendix A2.2 of SD2 of the 2016 Consultation paper).

FSANZ sought views on its preliminary position that the existing 'breast is best' statement is appropriate and that the existing requirement should be maintained.

Stakeholder views

Seven submitters (3 government, 3 industry, 1 consumer) provided comments about this labelling requirement. Six submitters supported the current requirement (Industry and government) (Table 5.7).

Table 5.7: Submitter comments regarding the 'breast is best' warning statement and FSANZ response

Comment	Submitter	FSANZ Response
Did not support a statement about the risks of not breastfeeding. Reasons provided: • risks are clearly communicated by health professionals. • do not necessarily agree with reasons provided by FSANZ, but insufficient evidence at this time to support changing the statement.	Industry, Government	A risk-based statement could be considered contrary to infant feeding guidelines that state that infant formula is the only suitable and safe alternative when infants are not breastfed. A risk-based statement is therefore not supported.
Statement should be revised to 'breastfeeding is best for babies' as the current statement is inaccurate, misleading and inadequate for informed choice. 'Breastfeeding' is not the same as 'breast milk' feeding.	Consumer	The current statement aligns with the WHO Code principles and the corresponding Australian and New Zealand agreements, Codex Standard (CXS 72-1981) and public health messages about the superiority of breastfeeding compared to formula feeding.

Proposed approach

Based on the above, FSANZ proposes to retain the existing 'breast is best' warning statement as currently required by paragraph 2.9.1—19(1)(d).

5.6 Product identification

5.6.1 Prescribed name

Current regulation

The product name 'Infant formula' is a prescribed name in the Code as follows. Standard 1.2.1 requires a food to be labelled with the name of the food. Paragraph 1.2.2—2(1)(a) states 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' is a prescribed name.

Previous consideration

In the 2016 Consultation paper, FSANZ's preliminary view was to maintain the requirement for the prescribed name 'Infant formula'.

Stakeholder views

Three industry and two government submitters that commented on this issue supported the use of the prescribed name being maintained.

Discussion

The requirement to use the prescribed name 'Infant formula' was put in place to alert consumers to the appropriate formula choice for infant age and stage (compared to Follow-on formula). This is particularly important from a health and safety perspective for formula-fed infants who may be reliant on infant formula as the sole source of nutrition.

The prescribed name 'Infant formula' is consistent with Codex, where section 9.1.2 specifies the name of the product shall be either 'Infant Formula' or any appropriate designation indicating the true nature of the product, in accordance with national usage (Codex 1981).

Proposed approach

FSANZ proposes to maintain the requirement to use the prescribed name 'Infant formula' as the name of the food on the labels of infant formula, based on the above discussion.

5.6.2 Statement that infant formula product may be used from birth

Current regulation

Paragraph 2.9.1—19(4)(a) requires a statement indicating that the infant formula product may be used from birth, in the case of infant formula. The statement applies to both general infant formula and IFPSDU (e.g. pre-term formulas). 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.

Previous consideration

FSANZ's preliminary view was that the existing statement remains relevant and should be maintained.

Stakeholder views

Five submitters (2 government, 3 industry) commented on FSANZ's preliminary view, and all supported maintaining the statement in its current form.

Discussion

FSANZ considers the existing statement meets the public health and safety principle because it enables caregivers to correctly identify the appropriate formula for their infants aged from birth. The statement also meets the clarity principle by providing clear information to caregivers about the appropriate use of the infant formula. No issues have been raised by submitters about this statement.

The existing statement is consistent with CXS 72-1981 which specifies that products shall be

labelled in such a way as to avoid risk of confusion between infant formula, follow-up formula and formula for special medical purposes.

Proposed approach

FSANZ proposes to maintain the requirement for the existing statement indicating that the infant formula product may be used from birth, in the case of infant formula.

5.6.3 Statement about age to offer foods in addition to formula

Current regulation

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

Previous consideration

FSANZ's preliminary view was that this labelling statement is appropriate and should be maintained without change.

Stakeholder views

Five submitters (2 government, 3 industry) commented on FSANZ's preliminary view. All submitters supported the requirement.

Discussion

The requirement in Standard 2.9.1 for a statement about offering foods in addition to infant formula product provides advice to the consumer that additional foods should be included in the diet, in order to reduce the risk of ill health due to poor nutrition (thus meeting the public health and safety principle).

The current labelling statement 'from the age of 6 months' is consistent with Codex[27], noting the exact wording of the statement is not prescribed in the Code. Given most submitters supported the current labelling requirement and FSANZ is not aware of any evidence of harm or issues with the existing requirement, FSANZ does not consider an amendment to the existing labelling statement is warranted.

Proposed approach

Noting the discussion above, FSANZ proposes to maintain the existing labelling statement indicating that infants from the age of 6 months should be offered foods in addition to infant formula as currently required by paragraph 2.9.1—19(4)(c).

5.6.4 Statement on protein source

Current regulation

Paragraph 2.9.1—23(1)(a) requires infant formula labels to contain a statement of the specific source, or sources, of protein in the product. Standard 2.9.1 specifies requirements

[27] Part 9.6.4 of CXS 72-1981 states: *information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months* (underline added by FSANZ).

for the quality and quantity of protein in infant formula but does not prescribe the protein source.

Previous consideration

In 2016, FSANZ noted the practice of infant formula companies was to be very specific about the source of protein used (e.g. soy, cow's milk, goat milk).

FSANZ's preliminary view was to maintain the current requirement to label the protein source as it ensures correct identification of products suitable for infants with particular dietary requirements and sought stakeholders' views.

Stakeholder views

Twelve submitters (6 industry, 4 government, 1 consumer group and 1 consumer) commented on FSANZ's preliminary view (Table 5.8).

Table 5.8: Summary of submitter comments about the statement on protein source

Comments	Submitter
Supported maintaining the current requirement to state the specific source(s) of protein for the following reasons: • assists consumers to make an informed choice • enables caregivers of infants with allergies, intolerances or particular dietary requirements to identify suitable products • no evidence of issues with current labelling.	Industry Government
Suggested prescribing the protein source using primary protein source words (e.g. cow's milk, goat's milk, soy milk), or clarifying the existing requirement, so that subgroups of protein are not declared. Considered protein source statements that referred to subgroups of protein (e.g. 'casein/whey dominant') could be considered nutrition content claims.	Government
There is anecdotal evidence that caregivers are unaware most infant formula is cows' milk and therefore 'dairy' based.	Consumer group
Labelling requirements should advise parents that current research does not support concerns over soy-based formula and reproductive health, nor effectiveness of hydrolysed formula in reducing rates of allergy.	Consumer

Discussion

The original intent of the protein source statement was to provide clarity for consumers to be able to make informed choices. The statement was also introduced for consistency with Codex, which requires the sources of protein to be clearly shown on the label (Codex 2018).

The findings from the consumer evidence indicates there is variability in consumers' use of protein source statements and in their understanding of the protein source that is declared. One qualitative study of 136 Australian and New Zealand caregivers found protein source information is of most value to caregivers of infants with known health conditions such as allergies and intolerances. There was a general lack of understanding of the term 'whey dominant', with views that whey protein is harder to digest, or that it is the 'clearer' part of milk (compared to curds as a solid). Caregivers reading the protein source statement who did not have an infant with an allergy or intolerance were mainly interested in whether the formula was based on cow's milk, soy or goat's milk (Malek 2016b).

In an online study of 626 Australian and New Zealand caregivers, participants ranked the type of protein as the third most important product characteristic when making an infant

formula purchase decision, after nutrition information and whether the product was recommended by health professionals (Supporting Document 4).

A study commissioned by the New Zealand Ministry for Primary Industries also found protein source information is useful to caregivers of children with allergies or intolerances. A few caregivers believed whey protein was easier to digest (Supporting Document 4).

FSANZ has observed significant variability in protein source statements displayed on 16 stage 1 infant formula products found in the Australian market in 2018. These included the protein source (e.g. 'cow's milk', 'goat milk') and in some cases, additional references to a specific protein fraction (e.g. 'casein dominant', 'A2 Beta-casein protein', 'whey protein source').

Codex states the sources of protein in the product shall be clearly shown on the label and that the name of the product shall be *Infant Formula* or an appropriate designation indicating the true nature of the product. In addition, for the situation that cows' milk is the only source of protein, it is stated that the product may be labelled *Infant Formula Based on Cows' Milk* (Codex 1981).

There was general stakeholder support to retain the requirement, although some government submitters suggested either prescribing the protein source using primary protein source words (e.g. cow's milk, goat's milk, soy milk), or clarifying the meaning of protein source excludes protein fractions. FSANZ considers a more pragmatic approach would be to clarify that protein 'source' as the origin of the protein, rather than include an exhaustive list of primary protein sources for labelling purposes in the Standard.

A government submitter commented that protein source statements referring to subgroups of protein (e.g. 'casein/whey dominant') could be considered nutrition content claims. FSANZ is proposing to address issues relating to the provision of nutrition information in a future paper.

One consumer submitter suggested IFP labels should advise caregivers that concerns over soy-based formula and reproductive health, and the efficacy of hydrolysed formula in reducing allergy rates, are not supported by current research. FSANZ considers these advisory statements are unnecessary because infant formula products are already required to carry a warning statement for caregivers to consult their doctor or health worker for advice before deciding to use the product (in accordance with paragraph 2.9.1—19(1)(d)).

Based on the evidence and stakeholder views, FSANZ considers the requirement to display a statement on the protein source should refer to 'source' being the origin of the protein, and not the protein fraction. This information is used by caregivers more generally to make informed purchase decisions and by caregivers who have infants with certain allergies (in addition to allergen information appearing elsewhere on the label). The consumer evidence suggests this information would be provide greater clarity for caregivers, particularly where there is a public health need to seek alternatives to general purpose formulas based on mammalian milk.

Given the protein quantity and quality of infant formula products are regulated, and the consumer understanding of protein fractions is varied, FSANZ considers there is the potential for consumer confusion if the specific protein fraction (e.g. whey or casein) is included as part of the protein source statement.

Proposed approach

Based on the discussion above, the principles of public health and safety and clarity, the risk

assessment conclusions and submitter comments, FSANZ is proposing to clarify the 'source' of protein in section 2.9.1—23 refers to the origin of the protein (e.g. cows' milk) and not the protein fractions (e.g. whey protein or casein).

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

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 product 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. Paragraph 2.9.1—17(a) states that 'Infant formula' is a prescribed name.

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. As a result, the prescribed name and protein source statement may be separate from, and less prominent than, the brand name of the product.

Previous consideration

FSANZ noted in the 2016 Consultation paper that the location of the protein source statement varied among products. Some products included the statement on the front but separate from the prescribed name, some with the prescribed name, others included the statement on the back of the product. Products made from protein sources other than cows' milk (e.g. soy) were generally marketed to highlight the protein source, for example the protein source information was displayed together with the brand or product name (which may include the prescribed name) in a prominent position, and in large font, on the front of the label.

At the time of the 2016 consultation there was no evidence available to determine whether caregivers had trouble finding the protein source statement.

FSANZ considered there was a lack of regulatory clarity regarding the requirement to co-locate the protein source statement with the name of the product as the prescribed name and the position of this information on the label. FSANZ's preliminary view was to maintain the existing requirement that the protein source statement must be immediately adjacent to the prescribed name. FSANZ also noted it would consider how to make it clearer that the name of the food is the prescribed name.

Stakeholder views

Sixteen submitters (5 government, 8 industry, 1 health professional, 1 consumer group, 1 consumer) provided comments to FSANZ's questions seeking evidence on caregivers having difficulty in locating protein source information and whether consistent placement of the protein source statement would provide a benefit to caregivers. Nine submitters supported or agreed the protein source statement must be immediately adjacent to the name of the food (Table 5.9).

Table 5.9: Summary of submitter comments regarding the location of the protein source statement

Comments	Submitter
Considered clarity is needed that • the name of the food is the prescribed name and not the brand name. • the protein source should be stated immediately adjacent to the prescribed name every time this occurs.	Government
Evidence of difficulty finding protein source/making informed choice	
Had no evidence or only anecdotal evidence that consumers have difficulty finding the statement.	Health professional Industry Government
Evidence that consistent placement would benefit caregivers	
Had no evidence or anecdotal evidence, but considered a consistent location would: • make it easier for caregivers to understand labels and easily find this information. • be useful for health professionals.	Consumer Health professional Consumer group Government
Suggested FSANZ undertake: • further consultation with caregivers • research, subject to there being insufficient evidence.	Government
Should the location on the label be prescribed (e.g. front of pack)?	
Supported information to be on front of pack, however had no evidence or only anecdotal evidence to support this view. Comments provided: • should only appear once on the label provided the statement is in a prominent place, such as the front of pack. • should be in consumer friendly language (e.g. 'infant formula based on milk from cows'). • consistent with Codex General Standard for Food Labelling which requires the name of the food to be in a prominent position. • line marketing on labels refer to other products, so a prominent name on the front will help avoid confusion. • the source of protein being dairy milk should be prominently labelled on the front as numerous sources report parent confusion that formula is human milk, or not dairy food.	Health professional Consumer group Consumer
Cost and trade implications of prescribing the location on the label	
The following implications of prescribing the location were noted: • cost of packaging changes, noting changes involve significant lead time. • it would be inconsistent with other international jurisdictions • prescription would present a barrier to trade for imported products, and potentially jeopardise supply (e.g. IFPSDU). Noted additional requirements need to be based on strong evidence, and considered it was unlikely that benefits would outweigh costs.	Industry
Considered trade implications as secondary to the health of infants and supported parents need for information when making purchase decisions.	Consumer

Discussion

In relation to the co-location requirement, FSANZ notes the original intent for the statement to be immediately adjacent to the name of the product was clarify the true nature of the food and enable caregivers to make appropriate food choices for their infants.

The Codex Infant Formula standard does not prescribe the location of the protein source statement, however section 8.1.4 of the Codex General Standard for the Labelling Of

Prepackaged Foods (Codex 1985) requires the name of the food to appear in a prominent position.

As outlined in section 5.6.4.4 above, research suggests that protein source information is of most value to caregivers with infants with known health conditions, such as allergies and intolerances. Caregivers with infants with such conditions report sometimes looking for allergen (e.g. specific proteins) information in the protein source statement and the statement of ingredients.

In the qualitative study by Malek, focus group participants generally had no issues with the location of the protein source statement (Malek 2016b). Some New Zealand-based participants expressed a preference for the statement to appear on the front of pack.

Similar to FSANZ's previous observations reported in 2016 (see section 5.6.5.2 above), FSANZ observed significant variability in the location of the protein source statements on infant formula labels in 2019, with some statements appearing on the front of pack and others appearing below the statement of ingredients, the nutrition information statement or adjacent to the feeding guide. Several products had multiple protein source statements made on their labels.

The majority of the stage 1 products surveyed had a protein source statement co-located with the name of the product, although this was not always the prescribed name (in some cases it was the brand name). The remaining products had either protein source statements separate from the name of the product or no statement at all.

A number of submitters were supportive of retaining the requirement for the source of protein statement to be immediately adjacent to the name of the food. FSANZ agrees with submitters that the intent of the requirement for the statement to be immediately adjacent to the 'name of the product' could be clarified (i.e. that this is the prescribed name) to ensure greater consistency between products and assist consumers to make an informed choice.

Several submitters suggested the protein source statement should only appear once on the label, or that the Code should be clarified as to whether the protein source should be stated immediately adjacent to the prescribed name every time this occurs. FSANZ does not consider it necessary to state the protein source adjacent to the prescribed name every time that name occurs on the label and proposes to clarify this intent.

Proposed approach

FSANZ is proposing to maintain the requirement for the co-location of the protein source statement and the name of the product. Considering the principles of public health and safety and clarity, the risk assessment conclusions and submitter comments, FSANZ is also proposing to:

- clarify the 'name of the product' in paragraph 2.9.1—23(1)(a) is the prescribed name ('Infant formula')
- clarify the protein source adjacent to the prescribed name is not required every time that prescribed name occurs on the label.

5.7 Summary of the proposed labelling risk management approach

Based on FSANZ's assessment, the proposed labelling risk management approach is

summarised below.

Amend the Code to -

- revise the direction for water used to reconstitute powdered infant 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 infant 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)).

- not apply the direction to only use the enclosed scoop (paragraph 2.9.1—19(3)(d)) to concentrated infant formula and ready to drink infant formula

- revise the warning statements to follow instructions exactly for infant formula product in powdered form (paragraph 2.9.1—19(1)(a)) and for concentrated infant formula product (paragraph 2.9.1—19(1)(b)) to include text about not adding anything to the formula as follows:
    - ‘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’.

- clarify the ‘source’ of protein in paragraph 2.9.1—23(1)(a) refers to the origin of the protein (e.g. cows’ milk) and not the protein fractions (e.g. whey protein or casein).

- clarify the ‘name of the product’ in paragraph 2.9.1—23(1)(a) is the prescribed name (‘Infant formula’)

- clarify the protein source adjacent to the prescribed name is not required every time that prescribed name occurs on the label.

6 Issues that will not be considered further

The following issues related to safety and technology will not be considered further in Proposal P1028 (reasons as indicated).

Issue	Details	FSANZ Response
Inaccurate volume indicators on infant feeding bottles	In 2016 FSANZ acknowledged the issue of inaccurate volume measure indicators on some infant feeding bottles sold in Australia and New Zealand. This had been raised in submissions to the 2012 Consultation paper. As infant feeding bottles are regulated as consumer goods and not covered in the Code, and are not solely for the purpose of feeding infant formula to infants, FSANZ considered the issue is outside the scope of this Proposal and will not be considered further by FSANZ. Two industry submitters agreed that this issue is beyond the scope of the Code, FSANZ and of infant formula manufacturers. Two government submitters commented on the FSANZ conclusion, suggesting that consideration should be given to the inclusion of an accurate measuring container for water in the package of infant formula powder (similar to the scoop).	FSANZ considers that mandating inclusion of a vessel to measure water would be difficult to justify given the availability of other measurement containers such as cups and jugs. This approach would be inconsistent with other countries. In addition there would be challenges for manufacturers to fit a measurement container in a packaged infant formula product.
Microbiological criteria	As microbiological criteria for infant formula was considered in P1039, this issue will not be considered further as part of this Proposal. Further information about P1039 is available on the FSANZ website.	
Food additives		
Gellan Gum	In 2017 industry requested FSANZ consider permitting gellan gum (INS 418) for use in infant formula. There are no equivalent permission in Codex of the EU.	Consideration of new food additive permissions is outside of the scope of the Proposal. An application could be made to amend the Code to permit use.
Acetylated distarch adipate	In 2017 FSANZ noted industry had requested FSANZ consider a list of food additives that were permitted in Codex and the EU, acetylated distarch adipate was included in this list. As the additive was not permitted in either the EU or Codex FSANZ did not consider it further. In response to 2017 paper industry argued the case to align with Codex, as well as it having a history of safe use. It is stated to be used in follow-up formula at 25,000 mg/L (singly or in combination in hydrolysed protein and/or amino acid-based liquid products).	The industry request for permission to use acetylated distarch adipate in follow-up formula is outside the scope of this proposal, so it is not proposed to permit its use for infant formula.
Contaminants		
Location of the ML for aluminium	The ML for aluminium is listed in Standard 2.9.1—8. Under proposal P1025 – Code Revision (in effect March 2016) MLs for all foods were moved from Standard 1.4.1 to Schedule 19. This is consistent with the approach used by Codex. In line with this	Based on unanimous stakeholder support over several consultations rounds, the proposed approach is to consolidate all MLs for contaminants in Schedule 19 including those set for infant formula.

Issue	Details	FSANZ Response
	approach, the ML for aluminium should also be transferred to Schedule 19.	
Processing aids		
	In 2012 no issues had been identified with processing aids. In response to the paper, submitters noted CAC/GL 10-1979 listed substances which function as 'nutrient carriers' that were not captured in the Code. The 2016 paper discussed the five substances (gum arabic, silicon dioxide, mannitol, starch sodium octenyl succinate and sodium ascorbate); noting the substances are all "additives permitted at GMP" (table in section S16—2), so are generally permitted processing aids due to subsection 1.1.2—11(3) and repeated in paragraph 1.3.1—4(2)(a). No changes were proposed to processing aid requirements. Two submitters commented on this approach and supported it.	FSANZ is not aware of any issues relating to the permissions for processing aids in the Code for the manufacture of infant formula. As no issues have been identified we are not considering any changes to Standard 1.3.3, Schedule 18 or processing aids in the manufacture of infant formula under this Proposal.

7 List of questions for submitters

FSANZ invites stakeholders to provide comment on the proposed approaches as outlined in this paper. To facilitate this feedback, FSANZ has proposed a series of questions for consideration. As noted in relevant sections, some of these questions pertain to a lack of information that will be needed to support proposed options in the 1st Call for Submissions paper.

In addition, the purpose of some of these questions will be to inform a CRIS should one be required. Additional information on costs and benefits would also be useful to help us consider cost/benefit in accordance with the FSANZ Act.

Questions for submitters
Questions about food additives and contaminants (Section 2, Section 3)
1. FSANZ has proposed two options in relation to the ML for cadmium (Section 3.3.4). FSANZ ask stakeholders for views on these options. 2. Table 2.17 lists the proposed approach for food additives. It includes some food additives where it is proposed to align with EU regulations but FSANZ has noted that there is a lack of safety information and therefore, it is not possible to draw a conclusion on the safety of these substances at the proposed levels in the target population. In these cases (all relate to IFPSDU which are generally imported into the Australian and New Zealand market), we request further information from health professionals about the need to permit addition of these food additives to IFPSDU and information from manufacturers about industry use of these food additives in Australian and New Zealand. The food additives that this question pertains to are: • Locust bean gum • Pectins

Questions for submitters
• Xanthan gum • Sodium alginate • Sodium carboxymethylcellulose • Sucrose esters of fatty acids For health professionals, please provide information to the following questions: 3. In addition to the above list, what new evidence (if any) do you have for the potential health impacts for infants of changing any of the current permissions for any other food additives, discussed in this paper? 4. In addition to the list above, can you provide any further examples of lack of alignment with EU regulations delaying important formula from reaching vulnerable infants? 5. To what extent would proposed changes to current permissions and limits for Special formula address any perceived delays to vulnerable infants accessing the imported formula that they need? Please provide evidence where possible. For industry, please provide information to the following questions: 6. Would there be any practical barriers to complying with new permissions and limits as proposed in this document for any formula products that have not yet been identified? How might such barriers be overcome? 7. What (if any) implications might overcoming any practical barriers have for production costs per product line? Please quantify where possible. 8. Might smaller or else larger businesses be disproportionately impacted if a new permission does not align with international regulations or standards? ? If so can you specify how by providing quantitative evidence where possible? 9. Are any food additive preparations (food category 0 in Schedule 15) used in infant formula products? If so, how? The following questions are targeted mainly to industry and relate to carry over provisions (Section 2.3) 10. What would be the practical steps involved in ensuring compliance of your products with the carry over provisions proposed in this paper? 11. Do you have any more information on how much ensuring compliance would cost per effected product? 12. Would different sized businesses be generally equally impacted from our proposed changes to the carry-over principle?
Questions about L(+) lactic acid producing microorganisms (Section 4)
13. 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 non-pathogenic specifically permitted) or is the base ‘safe and suitable’ requirement considered sufficient to manage this risk?
Questions about labelling (Section 5)

Questions for submitters
14. Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach? 15. Are you aware of any further data on infant illnesses that can be attributed to incorrect preparation as a result of unclear labelling or warning statements on products? 16. How often do you change labels on your products voluntarily for marketing or other purposes? 17. If the proposed changes were made at the same time as a voluntary label change, how much extra would it cost to change each product's labels (on average)? 18. If the proposed changes could not be made at the same time as a voluntary change, how much extra would it cost to change each product's labels (on average)? 19. Apart from any costs, would there be any other practical challenges of changing your products' labels as proposed?
General question related to the Consultation paper
20. In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence and quantify impacts where possible.

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Supporting Documents

SD1 – Food additives safety assessment

SD2 – Microbiology risk assessment: L-lactic acid producing microorganisms

SD3 – Microbiological safety of powdered infant formula: Effect of storage temperature on risk

SD4 – Consumer research in relation to safe preparation and use of infant formula