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Supporting document 1

Food technology for Infant Formula Products

Proposal P1028 – Infant formula 2nd CFS

Executive summary

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

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products and Schedule 29 – Special Purpose Foods in the Australia New Zealand Food Standards Code (the Code). Other standards in the Code also contain provisions related to the food technology for infant formula products, such as Standards 1.3.1 – Food Additives (and related Schedule 15) and 1.4.1 – Contaminants and Natural Toxicants (and related Schedule 19).

The protection of public health and safety is the primary objective for FSANZ in developing or reviewing food standards. Infant formula must be safe for formula-fed infants to consume.

This Supporting Document (SD) considers permissions for food additives, processing aids and contaminants for infant formula products and SMPPi.

FSANZ had proposed a number of approaches to such permissions during the 1st Call for Submissions (CFS) and its SD1 of April 2022, which built on the consideration of stakeholder views expressed in response to FSANZ's 2021 Consultation Paper 1 – Safety and Food Technology (FSANZ 2021 CP1), as well as previous consultations.

FSANZ is now proposing a number of regulatory/risk management amendments to the various standards in this 2nd CFS. Proposed amendments 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.

This supporting document addresses submitter comments from the FSANZ 2022 1st CFS SD1 (FSANZ 2022). There was significant stakeholder interest in the food technology for infant formula products. Overall, a total of 32 submissions were received to the 1st CFS representing all stakeholder groups. Of these, nine commented on issues related to food additives, nine commented on issues related to chemical contaminants and five commented on processing aids.

Food additives

Nine submissions were received to the 1st CFS on issues relating to food additive permissions. The major issues raised by submitters related to the:

- technological justification for the use of the additive
- carry-over principle[1], and
- international alignment of permissions to Codex and European (EU) Regulations.

FSANZ considered the technological justification for food additives in IFP where there was no existing:

- permission in the Code
- provisions in relevant Codex standards, or
- EU Regulations for equivalent products to SMPPi.

Applying these criteria, only phosphoric acid required a separate assessment of technical function. FSANZ concluded that the use of phosphoric acid is technologically justified as an acidity regulator, to assist in preventing aggregation and coagulation of milk proteins used as an ingredient in IFP.

FSANZ maintains its preferred proposal is to remove carry-over permissions for food additives so as to be consistent with Codex and the EU regulations. This position is consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population. FSANZ will propose an appropriate transitional period that ensures continuous supply of these products.

FSANZ is proposing to update the food additive permissions for IFP to align as best as possible with relevant international regulations, especially Codex standards and EU Regulations. As a part of the harmonisation process, FSANZ has considered the available evidence on safety and technological function of the food additives. Table 1 below summarises FSANZ's proposed amendments to permissions for food additives and Maximum Permitted Level (MPL) for the different food classes. Information provided in parentheses relates to how the permissions align with relevant international standards.

A complete table of the proposed food additive permissions for IFP is provided in the body of this SD. The proposed drafting is at Attachment A of the 2nd CFS.

Table 1 – P1028 proposed MPL for infant formula products and SMPPi

Food additive (INS #)	FSANZ proposed MPL (mg/L)	
	Infant Formula Products (includes follow-on formula, FOF)	SMPPi
Calcium carbonates (170)	NP	GMP (EU 13.1.5.1)
Ascorbic acid, L- (300)	50 (Codex FUF)	NP
Sodium ascorbate (301)	50 (Codex FUF)	NP
Calcium ascorbate (302)	50 (Codex FUF)	NP

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

Ascorbyl palmitate (304)	50 (Codex FUF)	100 (EU 13.1.5.1)
Tocopherols concentrate, mixed (307b)	30 (Codex FUF)	unchanged (10)
Gamma-tocopherol (308)	10 (EU 13.1.1)	
Delta-tocopherol (309)	10 (EU 13.1.1)	
Calcium citrates (333)	NP	GMP (EU 13.1.5.1)
Phosphoric acid (338) Sodium phosphates (339) Potassium phosphates (340)	450 (aligns EU 13.1.1)	-
Phosphoric acid (338) Sodium phosphates (339) Potassium phosphates (340) Calcium phosphates (341)	-	450 (EU 13.1.5.1)
Sodium alginate (401)	NP	1000 (EU 13.1.5.1)
Locust bean (carob bean) gum (410)	Unchanged (1000)	5000 (reduced cf EU 13.1.5.1)
Guar gum (412)	Unchanged (1000)	10,000 (EU 13.1.5.1)
Xanthan gum (415)	NP	1000 (Codex) 1200 (EU 13.1.5.1)
Pectins (440)	10000 (Codex FUF)	2000 (Codex) 5000 (reduced cf EU 13.1.5.1)
Citric and fatty acid esters of glycerol (CITREM) (472c)	9000 for liquid products, 7500 for powdered products, (Codex and EU).	
Diacyltartaric and fatty acid esters of glycerol (472e)	Remove the permission in the Code (Codex and EU).	
Sucrose esters of fatty acids (473)	NP	120 (EU 13.1.5.1)
Sodium carbonates (500)	2000 (Codex)	
Potassium carbonates (501)	2000 (Codex)	
Sodium hydroxide (524)	2000 (Codex)	
Potassium hydroxide (525)	2000 (Codex)	
Calcium hydroxide (INS 526)	2000 (Codex and EU)	
Silicon dioxide (amorphous) (551)	10 (EU)	
Acetylated distarch adipate (1422)[1]	5000 (Codex FUF)	25,000 (Codex FUF)
Starch sodium octenylsuccinate (1450)	NP	20,000 (Codex and EU 13.1.5.1)

Notes
1 Linked to INS 1412, 1413, 1414 (for FOF)
NP = Not Permitted
FUF = Codex Follow-Up Formula
GMP = Good Manufacturing Practice
EU 13.1.1 = EU Regulation food category 13.1.1 (comparable to IFP)
EU 13.1.5.1 = EU Regulations food category 13.1.5.1 (comparable to SMPPi)

Processing aids

No changes to the Code related to processing aids is required. The FSANZ position is unchanged from the 1st CFS.

Contaminants

Standard 1.4.1 – Contaminants and natural toxicants and Schedule 19 – Maximum levels of contaminants and natural toxicants as well as Standard 2.9.1 – Infant Formula specify the maximum levels (MLs) of a number of contaminants for infant formula products. Previous consultations for P1028 outlined the principles that underpin the approach to setting MLs in the Code. It is important to note that the ML listed in Schedule 19 for IFP apply to the products as 'ordinarily consumed' (see paragraph 1.4.1—2(1)).

Nine submissions were received to the 1st CFS on issues relating to chemical contaminants. The major issue raised related to having a single ML for aluminium of 0.05 mg/100 mL for infant formula, including soy-based. FSANZ remains of the view that, in the absence of any new data or information, the rationale presented in FSANZ 2016 CP, FSANZ 2021 CP1 and the 1st CFS is still valid. Specifically:

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

Therefore FSANZ's preferred option is to progress with the FSANZ 2021 CP1 approach, which is to retain a single ML of 0.05 mg/100 mL for aluminium in infant formula products including soy-based formula. FSANZ remains of the view that having only one ML for aluminium, which is lower than the current one for soy-based IFP, will help ensure the safety of IFP.

FSANZ has again carefully considered other issues raised in all the submissions related to contaminants noting that no new issues were raised in response to the 1st CFS.

The summary of FSANZ proposed amendments for the MLs for the thirteen chemicals or chemical group contaminants is provided in Table 2 below. No changes are proposed to the current MLs for three contaminants, no MLs are proposed for eight contaminants, and changes for the MLs for aluminium and lead are proposed consistent with the 1st CFS and FSANZ 2021 CP.

Table 2 P1028 proposed MLs for infant formula products and SMPPi

Contaminant	FSANZ draft decision
Acrylonitrile	No change to the ML of 0.02 mg/kg for all foods including infant formula products.

Aluminium	Move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19. Retain single ML of 0.5 mg/kg for aluminium for IFP including soy based.
	Retain ML of 0.2 mg/kg in SMPPi formulated for pre-term infants
Arsenic	No ML for infant formula products. Monitor and review (for rice that may be used as an ingredient in infant formula).
Cadmium	No ML to be established.
Lead	Lower ML from 0.02 mg/kg to 0.01 mg/kg in IFP
Melamine	No ML to be established.
Tin & inorganic tin	No change to the ML of 250 mg/kg.
Vinyl chloride	No change to the ML of 0.01 mg/kg.
Aflatoxins B1 and M1	No ML to be established.
Ochratoxin A	No ML to be established.
Polycyclic aromatic hydrocarbons (PAH)	No ML to be established.
Perchlorate	No ML to be established.
Chloropropanol, glycidol and their esters	No MLs to be established.

Table of contents

1 Introduction

All infant formula must be safe for formula-fed infants to consume. This supporting document covers the assessment of requirements that relate to the food technology and safety of infant formula products.

The specific issues in this paper cover food additives, contaminants and processing aids.

The assessment aimed to determine whether amendments to the Code were needed to apply or revise current risk management measures, align requirements with international regulations, and/or improve regulatory clarity. Within each section, FSANZ has provided further summarised consideration of the issue, the proposed amendment to the Code and the rationale for the amendment.

As presented in the 2nd Call for Submissions (CFS) document, FSANZ's proposed revised regulatory framework will set in place a category of infant formula intended for infants with serious illness or conditions. The category is defined as Special Medical Purpose Products for infants (SMPPi). Products under this category are intended to be restricted from sale to healthy infants (i.e. through pharmacies) and for use under medical supervision (see section 2 – Regulatory Framework in the 2nd CFS).

It is noted that these products are generally not produced in Australia and New Zealand, but mainly imported from Europe in small quantities as specialised products. Consistency with European regulations is therefore critical to ensure a continued supply of essential products for vulnerable infants as they are often the infant's sole source of nutrition. Discussion of food additive permissions in this supporting document is presented using this terminology[2].

FSANZ 1st CFS and its SD1 (FSANZ 2022) provided FSANZ's detailed regulatory/risk management approaches to the various issues identified and consulted on earlier. Further background on the regulatory approach to developing or varying food standards, international and overseas regulations, and application of Ministerial Policy Guidelines (MPG) was covered in FSANZ's 2021 Consultation Paper 1 – Safety and Food Technology (FSANZ 2021).

This 2nd CFS SD1 document does not repeat the consideration and analysis of information already considered and resolved.

2 Previous consultations

Previous consideration and preliminary views on the topics covered in this supporting document are listed below.

- Consultation paper on infant formula products excluding follow on formula and special infant formulas (FSANZ 2016 CP, SD2)
- Consultation paper on infant formula products for special dietary use (FSANZ 2017 CP)
- Consultation paper covering safety and food technology, addressing submitter comments from the 2016 and 2017 papers (FSANZ 2021 CP1)
- 1st CFS, Supporting Document 1 – Safety and food technology, 2022 (FSANZ 2022 1st CFS, SD1)

This supporting document addresses submitter comments from the FSANZ 2022 1st CFS

[2] Standard 2.9.1 currently categorises these products under the heading Infant Formula for Special Dietary Use (IFPSDU).

SD1 (FSANZ 2022). There was significant interest from stakeholders on the food technology and safety issues for infant formula products.

Overall, a total of 32 submissions were received to the 1st CFS representing all stakeholder groups: of these, 9 commented on issues related to food additives, 9 commented on issues related to chemical contaminants and 5 commented on processing aids.

3 Food additives

Food additives have a range of functional properties, some of which are very important for ensuring the safety and quality of infant formula products. A food additive may only be added to infant formula products if permitted in the Code and it complies with a relevant specification.

Standard 1.3.1 – Food additives and Schedule 15 – Substances that may be used as food additives of the Code specifies which food additives are permitted, including maximum permitted levels (MPLs) for use in different food products. For a food additive to be permitted, FSANZ must ensure that it is safe at the permitted level in that particular food and is technologically justified.

The relevant schedules for labelling of food additives in the statement of ingredients are Schedule 8 - food additive names and code numbers and Schedule 7 - food additive class names. 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 1999).

Proposal P1028 is reviewing existing permissions to improve harmonisation with Codex food standards and European regulations to, where possible, facilitate the importation of infant formula products, especially special infant formulas[3], which generally are not manufactured in Australia and New Zealand.

- The relevant Codex standards include the infant formula standard (CXS 72-1981) and the General Standard for Food Additives (GSFA) (CXS 192-1995).

- The EU regulations of relevance include Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008, which provides a Union list of permitted food additive permissions for different food categories in Annex II, and Commission Regulation (EU) 231/2012, which contains the specifications for food additives listed in Annexes II and III to Regulation (EC) 1333/2008.

For further information regarding Codex standards and EU regulations related to food additive permissions in infant formula products, please refer to the 1st CFS SD1 (FSANZ 2022) and the FSANZ 2021 CP1 (FSANZ 2021) as several permissions have since been updated.

This section will address the following issues relating to reviewing food additive permissions, as covered in the 1st CFS SD1, specifically including responses to submissions raised on these topics:

1. Technological justification of food additives
2. Carry-over principle for food additives in infant formula products
3. Harmonisation of food additive permissions with international regulations

[3] Which fall under the IFPSDU category in the current Standard 2.9.1, and which are now been referred to as SMPPi for the 2nd CFS and this SD1.

A number of matters were resolved through CP1 2021 and 1st CFS, so they are not considered further here. Those are:

- Clarifications to the Code, addressing what have been agreed to be errors that are appropriate to be readily corrected.
- Food class (category) system for food additive permissions, where there has been general agreement to minimise the number of food classes and to differentiate permissions using condition statements linked to permissions. The proposed food class system is provided in the proposed drafting of permissions within the Table to section S15—5 of Schedule 15. FSANZ has proposed only one food class being 13.1 *Infant formula products* and its subclass 13.1.1 *Special Medical Purpose Products for infants*.

For most issues, a summary of submitter comments to the 1st CFS, a discussion (where relevant), and FSANZ's proposed amendment to the Code is presented. For further details regarding previous FSANZ considerations please refer to FSANZ 2021 CP1, which includes the outcomes of FSANZ's risk assessments; and the 1st CFS.

3.1 Consideration of technological justification (need) for food additives in infant formula

A number of jurisdictions requested that FSANZ evaluate the efficacy/need/technological justification for permitting new food additives to be added to infant formula products. A summary of those comments and FSANZ responses is provided in the relevant sections of submissions dealing with food additives in Appendix 1. This section provides a more detailed explanation of FSANZ responses.

Where there is already a permission of the food additive in the Code for any form of infant formula, FSANZ has not performed a technological justification for its use, as it has already been conducted or can be presumed to perform that function. Retrospectively assessing current permissions is not within the scope of the Proposal.

Similarly where the food additive has provisions in Codex infant formula standards, which includes follow-on formula (called 'follow-up formula' by Codex) for the appropriate age limit of up to 12 months, FSANZ has not performed a technological justification assessment. FSANZ considers this to be justified on the basis of MPG 'Regulation of Infant Formula Products' which states that:

The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:

- *Relevant World Health Organization agreements; and*
- *Relevant World Trade Organization agreements, Codex standards and guidelines.*

The third category involves food additives that are permitted in the EU Regulation (EC) No 1333/2008 for food category (FC) 13.1.5.1 – *Dietary foods for infant for special medical purposes and special formulae for infants* have been aligned with the new food category added to the Code as SMPPi.
These products are restricted, specialised infant formula produced for infants with specific medical conditions that are not produced in Australia and New Zealand but need to be imported, usually from the EU. To ensure there are no supply issues for infants with specific medical conditions FSANZ has aligned the permissions as well as the condition requirements of the EU Regulations with the Code, almost without exception. A technological function assessment was not considered warranted on the basis of the risk benefit considerations for this population group.

Taking these three criteria into account the list of food additives that require an assessment of their technological justification is limited to phosphoric acid (Table 3 summarises the assessment of each food additive that has been considered by FSANZ to be permitted in infant formula products).

In addition it is noted that the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), developed a framework to evaluate the technological justification for use of food additives in infant formula products[4]. CCNFSDU used this framework to conclude that the following two food additives were technologically justified for addition to infant formula products for special medical purposes[5]:

- xanthan gum (INS 415)
- pectins (INS 440)

The detailed consideration of the technological justification of these two food additives following the framework is provided in a CCNFSDU document considered at the 40th CCNFSDU meeting of 2018[6].

It is further understood that the CCNFSDU will consider the technological justification of other relevant food additives permitted or proposed to be permitted in IFP at future meetings using this same framework. Sodium and potassium phosphates were considered at the CCNFSDU43 meeting proposed held in March 2023 as explained in the CCNFSDU Circular Letter[7] with the conclusions summarised in the report[8].

Information received in confidence from industry that may be provided to the CCNFSDU has been received, for sodium and potassium phosphates. The detail of this information will not be provided in this report but some of the important high-level conclusions are shared. The group of sodium and potassium phosphates have the technological function of 'acidity regulator' when used and added to IFP. These food additives cover a range of different substances that represent a wide range of pH values, buffering capacity and pH modification for the stabilisation of the IF matrix, as required. For milk based IF the buffering action stabilises the pH to keep the calcium micelle intact to assist in preventing curdling/precipitation, especially during heat treatment. Stabilisation of the pH of the IF also prevents degrading of nutrients during processing as well as during the shelf life of the product. These properties of sodium and potassium phosphates make them better acidity regulators compared to some others that are also permitted, for use in certain IFP.

[4] https://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_NFSDU20_e.pdf
[5] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FReport%252FAdoption%252FREP20_NFSDUe_Rev.pdf
REP20/NFSDU, para 155
[6] CX/NFSDU 18/40/11, Annex D, https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-40%252FWD%252Fnf40_11e.pdf
[7] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FCircular%252520Letters%252Fcl%2525202022-80%252Fcl22_80e.pdf
[8] The REP23/NFSDU was not finalised at the time of writing, but the draft report conclusions were that they are both technologically justified for their use (checked late March 2023).

Table 3 - Summary of whether a technological justification assessment of food additives for IFP is required

INS	Description	In Code[1]	Proposed, General (G includes FOF[2]), SMPPi	Codex/EU	Tech just[3] needed	Reason for decision[4]
170	Calcium carbonates	N	SMPPi	EU	N	SMPPi, EU Regs
270	Lactic acid	Y	G	Codex (FOF)/EU	N	In Code
300	Ascorbic acid, L-	N	FOF	Codex	N	Codex FUF
301	Sodium ascorbate	N	FOF	Codex	N	Codex FUF
302	Calcium ascorbate	N	FOF	Codex	N	Codex FUF
304	Ascorbyl palmitate	Y	G	Codex/EU	N	In Code
307b	Tocopherols concentrate, mixed	Y	G	Codex/EU	N	In Code
308	Gamma-tocopherol	N	G	EU	N	EU Regs (including SMPPi)
309	Delta-tocopherol	N	G	EU	N	EU Regs (including SMPPi)
322	Lecithin	Y	G	Codex/EU	N	In Code
330	Citric acid	Y	G	Codex/EU	N	In Code
331	Sodium citrates	Y	G	Codex/EU	N	In Code
332	Potassium citrates	Y	G	Codex/EU	N	In Code
333	Calcium citrates	N	SMPPi	EU	N	SMPPi, EU Regs
338	Phosphoric acid	N	G&SMPPi	EU	Y	G use, EU Regs; SMPPi, EU Regs CCNFSDU has NOT conducted tech just yet.
339	Sodium phosphates	N	G&SMPPi	Codex/EU	N	Codex & SMPPi
340	Potassium phosphates	N	G&SMPPi	Codex/EU	N	Codex & SMPPi
341	Calcium phosphates	N	SMPPi	EU	N	Codex & SMPPi
401	Sodium alginate	N	SMPPi	EU	N	SMPPi, EU Regs
407	Carrageenan	Y	G&SMPPi	Codex/EU	N	In Code
410	Locust bean (carob bean) gum	Y	G&SMPPi	Codex/EU	N	In Code (G), SMPPi (EU Regs)
412	Guar gum	Y	G&SMPPi	Codex/EU	N	In Code (G), SMPPi (EU Regs)

INS	Description	In Code[1]	Proposed, General (G includes FOF[2]), SMPPi	Codex/EU	Tech just[3] needed	Reason for decision[4]
415	Xanthan gum	N	SMPPi (conditions, MPL 1000 & 1200 mg/L)	Codex & EU (SMPPi)	N	SMPPi (Codex & EU Regs) Codex CCNFSDU agreed tech just via framework (at lower MPL of 1000 mg/L)
440	Pectins	N	FOF & SMPPi	Codex/EU	N	Codex & SMPPi, EU Regs, Codex CCNFSDU agreed tech just via framework (at lower MPL of 2000 mg/L)
471	Mono- and diglycerides of fatty acids	Y	G	Codex/EU	N	In Code
472c	Citric and fatty acid esters of glycerol	Y	G	Codex/EU	N	In Code
472e	Diacetyltartaric and fatty acid esters of glycerol	Y	remove	None	N	N/A since removing
473	Sucrose esters of fatty acids	N	SMPPi	EU	N	SMPPi, EU Regs
500	Sodium carbonates	N	G	Codex	N	Codex
501	Potassium carbonates	N	G	Codex	N	Codex
524	Sodium hydroxide	N	G	Codex	N	Codex
525	Potassium hydroxide	N	G	Codex	N	Codex
526	Calcium hydroxide	Y	G	Codex	N	Codex
551	Silicon dioxide	N	G	Codex	N	Codex
1412	Distarch phosphate	Y	G&SMPPi	Codex/EU	N	In Code
1413	Phosphated distarch phosphate	Y	G&SMPPi	Codex/EU	N	In Code
1414	Acetylated distarch phosphate	Y	G&SMPPi	Codex/EU	N	In Code
1422	Acetylated distarch adipate	N	G (FOF)	Codex/EU	N	Codex FUF
1440	Hydroxypropyl starch	Y	G&SMPPi	Codex/EU	N	In Code
1450	Starch sodium octenyl succinate	N	G (condition, Codex) & SMPPi	Codex/EU	N	Codex & SMPPi, EU Regs

Notes:

1 N: No; Y: Yes

2 The Code uses the term follow-on formula (FOF) while the relevant Codex standard is called follow-up formula (FUF) (for older infants)

3 Technological justification

4 The MPG 'Regulation of Infant Formula Products', under Additional Policy Guidance includes the words copied below. Therefore, for these reasons, FSANZ does not consider that additional assessment including technological justification is required.

Relevant international agreements

The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:

- *Relevant World Health Organization agreements; and*
- *Relevant World Trade Organization agreements, Codex standards and guidelines.*

3.1.1 Phosphoric acid (INS 338)

FSANZ notes that the use of phosphoric acid is already permitted in EU Regulations for FC 13.1.5.1, so SMPPi. The use in general IFP is due to EU Regs FC 13.1.1, MPL 450 mg/L as phosphorus (equivalent to 1000 mg/L as P_2O_5), linked to limits on ions, i.e. sodium, potassium and phosphorus. Two phosphates, sodium phosphates (INS 339) and potassium phosphates (INS 340) are also permitted in FC 13.1.1 at the MPL of 450 mg/L as phosphorus, singly or in combination, but not linked to the permission for phosphoric acid.

CP1 2021 provided a summary of the information provided by industry submitters on the technological justification and history of use of a number of food additives used in IFP. The information on phosphoric acid was provided in Table 2.9 and has not been reproduced here.

In brief, the conclusion was that phosphoric acid has the technological purpose (function) as an acidity regulator, to reduce the pH of the solution during manufacturing. The technological justification is that using acids (e.g. phosphoric acid) to reduce the pH of solutions containing milk protein ingredients before heat treatment prevents the aggregation and coagulation of the milk proteins during the heat treatment (Bernal and Jelen 1985).

Additional confidential information on the technological function and justification has been provided by industry that provides further information which has been summarised below.

Phosphoric acid is used to normalise the pH after the protein hydrolysis step at the beginning of the manufacturing process. During the protein hydrolysis, the pH is artificially kept high to remain in a pH range where the enzyme activity is optimum. It also naturally increases during the protein hydrolysis process. Once the protein hydrolysis is completed, mineral salts are added and then the phosphoric acid is added to neutralize the basic calcium hydroxide and potassium hydroxide used during the hydrolysis step, and to lower the pH.

Phosphoric acid is a stronger acid (to function as an acidity regulator) compared to other acids such as lactic or citric acids. Phosphoric acid also has a lower molecular weight, compared to the other acids so less acid is required to reduce the pH to the required level. Citric acid provides significant buffer capacity to the mix requiring the addition of higher amounts of alkali substances for pH readjustment after the heat treatment. This would lead to higher and possibly unacceptable levels of sodium or potassium in the final formula depending on which alkali substance (sodium hydroxide or potassium hydroxide) is used.

FSANZ is satisfied that phosphoric acid is technologically justified for its use in IFP, with the technological purpose as an acidity regulator, to assist in preventing aggregation and coagulation of milk proteins used as ingredients in producing IFP. It is also the preferred acid used in the manufacturing of IFP containing hydrolysed protein for special dietary purposes.

3.2 Carry-over principle

3.2.1 Background and earlier assessments

FSANZ has continued to maintain the preferred option that it has proposed since early consideration of the proposal to remove carry-over provisions of food additives for infant formula products to align with the requirements of Codex and EU regulations.

This was fully explained in section 3.3 of the 1st CFS, where responses to objections from stakeholders were addressed. This was earlier addressed in section 2.3 of 2021 CP1. FSANZ's preliminary view in section 8.3 in SD2 for the 2016 CP was that it would be appropriate to restrict carry-over of food additives in IFP. There were different

understandings in submissions to the 2016 CP whether carry-over of food additives was permitted for IFP.

This information has not been repeated here. But to ensure clarity some summary statements explaining the carry-over principle are provided.

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

It is proposed that the carry-over of food additives should NOT be permitted in IFP unless a specific permission exists in the Code for that food additive in the final food (i.e. IFP). This proposed approach is consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population. Currently, subsection 1.3.1—3(2) of the Code allows for the carry-over of food additives for all food classes; there is no exemption for infant formula products.

For the proposed situation for IFP the following summary statements are relevant.

> *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 IFP 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 IFP standard.*

From earlier industry submissions on this issue FSANZ had concluded that it is not the proposed changes to carry-over provisions per se that are of most concern, rather, that the changes will not result in complete alignment with Codex and the EU Regulations. The concern is that there will be gaps in permissions for certain food additives which need to be addressed to prevent impacts on cost and supply (including impacts on trade). FSANZ continues to aim to ensure alignment with relevant Codex and EU regulations, while always ensuring safety, especially for SMPPi to ensure there is not an impact in the trade of products from the EU for specific infants with specific conditions (i.e. SMPPi products).

3.2.2 Stakeholder views

The same concerns as earlier submissions to consultation papers were expressed by some industry submitters to the 1st CFS. Additionally, an industry submitter requested that if the carry-over of food additives for IFP is removed then they request that new permissions be added to Schedule 29—7 to allow permitted forms of vitamins, minerals and electrolytes.

3.2.3 FSANZ response

FSANZ's preferred option remains unchanged. That is, the carry-over of food additives should not be permitted unless a specific permission exists for that food additive in the final food (i.e. IFP). This aligns with relevant international regulations for IFP, being Codex and EU Regulations as well as being consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population.

It is important to note that permissions for nutritive substances (being vitamins, minerals and electrolytes) is not a permission for food additives, even if they are the same substances. This is also further explained in the relevant section of Appendix 1.

The consideration of permitted forms of nutritive substances is separately considered in the

nutrition assessment SD2. In particular see Table 2 with a list of permitted forms and equivalents of nutritive substances, Table 7 of summary of submitter comments and responses on nutritive substances plus Table 11 discussion of submitter comments on SMPPi.

FSANZ repeats its comments in the SD1 for the 1st CFS that it will aim to ensure consistency of food additive permissions with Codex and EU Regulations, as much as possible along with ensuring safety of products, so that carry-over and compliance is not of concern for infant formula products. FSANZ will also propose an appropriate transitional period that ensures continuous supply of these products.

3.3 Proposed food additive permissions

FSANZ is proposing to update the food additive permissions for IFP to align as best as possible with relevant international regulations, especially Codex standards and EU Regulations. As a part of the harmonisation process FSANZ has considered the available evidence on safety and technological function of the food additives.

The proposed amendments to food additive permissions are based on work conducted as a part of the 1st CFS sections 3.4 – Harmonisation of food additive permissions and 3.5 – Food additive permissions by type of substance. They recognise submissions to the 1st CFS, and include some corrections and further clarifications. This section of the report includes more detail to the summary responses to submitter comments, including those for specific food additives in Appendix 2.

A summary of only the amended proposed food additive permissions for infant formula products is provided in Table 4.

Table 4 - Proposed MPL for infant formula products and SMPPi

Food additive (INS #)	FSANZ proposed MPL (mg/L)	
	Infant Formula Products (includes follow-on formula, FOF)	SMPPi
Calcium carbonates (170)	NP	GMP (EU 13.1.5.1)
Ascorbic acid, L- (300)	50 (Codex FUF)	NP
Sodium ascorbate (301)	50 (Codex FUF)	NP
Calcium ascorbate (302)	50 (Codex FUF)	NP
Ascorbyl palmitate (304)	50 (Codex FUF)	100 (EU 13.1.5.1)
Tocopherols concentrate, mixed (307b)	30 (Codex FUF)	unchanged (10)
Gamma-tocopherol (308)	10 (EU 13.1.1)	
Delta-tocopherol (309)	10 (EU 13.1.1)	
Calcium citrates (333)	NP	GMP (EU 13.1.5.1)
Phosphoric acid (338) Sodium phosphates (339) Potassium phosphates (340)	450 (aligns EU 13.1.1)	-

Phosphoric acid (338) Sodium phosphates (339) Potassium phosphates (340) Calcium phosphates (341)	-	450 (EU 13.1.5.1)
Sodium alginate (401)	NP	1000 (EU 13.1.5.1)
Locust bean (carob bean) gum (410)	Unchanged (1000)	5000 (reduced cf EU 13.1.5.1)
Guar gum (412)	Unchanged (1000)	10,000 (EU 13.1.5.1)
Xanthan gum (415)	-	1000 (Codex) 1200 (EU 13.1.5.1)
Pectins (440)	10000 (Codex FUF)	2000 (Codex) 5000 (reduced cf EU 13.1.5.1)
Citric and fatty acid esters of glycerol (CITREM) (472c)	9000 for liquid products, 7500 for powdered products, (Codex and EU).	
Diacyltartaric and fatty acid esters of glycerol (472e)	Remove the permission in the Code (Codex and EU).	
Sucrose esters of fatty acids (473)	NP	120 (EU 13.1.5.1)
Sodium carbonates (500)	2000 (Codex)	
Potassium carbonates (501)	2000 (Codex)	
Sodium hydroxide (524)	2000 (Codex)	
Potassium hydroxide (525)	2000 (Codex)	
Calcium hydroxide (INS 526)	2000 (Codex and EU)	
Silicon dioxide (amorphous) (551)	10 (EU)	
Acetylated distarch adipate (1422)[1]	5000 (Codex FUF)	25,000 (Codex FUF)
Starch sodium octenylsuccinate (1450)	NP	20,000 (Codex and EU 13.1.5.1)

Notes:
1 Linked to INS 1412, 1413, 1414 (for FOF)
NP= Not Permitted
FUF= Codex Follow-Up Formula
GMP= Good Manufacturing Practice
EU 13.1.1 = EU Regulation food category 13.1.1 (comparable to IFP)
EU 13.1.5.1 = EU Regulations food category 13.1.5.1 (comparable to SMPPi)

Discussion of food additives have been provided below only where it was considered there was a need, either due to differences in submissions or where it was thought an explanation was helpful to explain proposed amendments. They have been added in numerical order of their INS numbers.

3.3.1 Ascorbic acid, L- (300), sodium ascorbate (301) and calcium ascorbate (302)

Ascorbic acid and the sodium and potassium ascorbates are proposed in the draft Codex standard for follow-up formula, section A, for older infants (6-12 months) as antioxidants at the MPL of 50 mg/L, expressed as ascorbic acid, singly or in combination. There is also a condition statement relating to limits for sodium. There are no permissions for these food additives in other IFP, including SMPPi, in the Code, Codex or the EU Regulations.

FSANZ has performed a risk assessment of these three food additives (see Appendix 4) and

concluded that permitting L-ascorbic acid, sodium ascorbate and calcium ascorbate as food additives in follow-on formulas at GMP, and within the range of vitamin C indicated by the maximum and minimum concentrations of vitamin C in Schedule 29 of the Code, does not pose safety concerns.

Therefore, FSANZ proposes to align permissions with the draft Codex FUF standard, using the same condition statement. The proposed amendment is considered to be consistent with the MPG.

3.3.2 Ascorbyl palmitate (304), tocopherols concentrate, mixed (307b), and other tocopherols (308 & 309)

Ascorbyl palmitate (304) and tocopherols concentrate, mixed (307b) are already permitted in the Code for IFP. They both have higher MPLs in the draft Codex standard for follow-up formula, section A, for older infants (6-12 months) than in the Code.

Two other forms of tocopherols, gamma-tocopherol (308) and delta-tocopherol (309) are also permitted in EU Regs for IFP and SMPPi, also at 10 mg/kg. Both these food additives are already permitted in the Code, for food class 0 (food additive preparations) and 2 (edible oils and oil emulsions) at GMP. The EU Regs also permit both tocopherols in preparations of nutritive preparations added to IFP. FSANZ proposes to permit both for IFP along with the current permission for tocopherols concentrate, mixed (307b) to ensure alignment with EU Regs, so IFP from EU that contain them are permitted to be imported into Australia and New Zealand. A risk assessment for tocopherols is at Appendix 4.

Ascorbyl palmitate also has a higher MPL of 100 mg/L in the EU Regulations FC 13.1.5.1 (SMPPi) compared to the Code, Codex and EU Regulations FC 13.1.1 for IFP which has the MPL of 10 mg/L. FSANZ proposes to add the higher MPL for SMPPi to align with EU Regulations for SMPPi to ensure the importation of such products from the EU for specific infants with specific medical conditions.

Ascorbyl palmitate is linked with the three ascorbates above (INS 300, 301 and 302), at the MPL of 50 mg/L, expressed as ascorbic acid, singly or in combination, with the same condition statement relating to limits for sodium as above for the draft Codex FUF standard. The MPL for ascorbyl palmitate in the Code for IFP is 10 mg/L.

Tocopherols concentrate, mixed (307b) has the higher MPL of 30 mg/L for the draft Codex FUF, compared to 10 mg/L in the Code. The draft Codex FUF standard also is linked to two other tocopherols – tocopherol, d-alpha (307a) and tocopherol, dl-alpha (307c) – singly or in combination. But neither of these tocopherols are permitted in the Code for any food classes so they are not considered further for permissions for IFP. If specific permission is sought for these alternative forms of tocopherols they will require separate assessment outside of this proposal, i.e. an application.

FSANZ proposes to align permissions with the draft Codex FUF standard, using the same condition statement, to ensure alignment with Codex standards therefore consistency with the MPG.

3.3.3 Calcium citrates (333)

Unlike sodium citrates (331) and potassium citrates (332), calcium citrates are not permitted in the Code for IFP. However, they are permitted in the EU Regulations FC 13.1.5.1 (equivalent to SMPPi) at quantum satis (meaning ‘no maximum level is specified’ and is equivalent to GMP). Calcium citrate is permitted for various food classes since it is listed as a GMP food additive in S16—2.

FSANZ's safety assessment in SD1 of CP1 (2021) concluded that permitting calcium citrates as food additives in SMPPi at GMP does not pose toxicological concerns.

Calcium citrate, also called tricalcium citrate, is the only calcium citrate that has a Joint FAO/WHO Expert Committee on Food Additives (JECFA) specification, so the entry in the Code will be singular 'calcium citrate' like the entry in S16—2. JECFA specifications are one of the primary sources of specifications for food additives in Schedule 3 – Identity and purity.

FSANZ therefore proposes to add permission for the additive at GMP to align with EU Regulations for SMPPi to ensure the importation of such products from the EU for specific infants with specific medical conditions.

3.3.4 Phosphoric acid (338), sodium phosphates (339), potassium phosphates (340) and calcium phosphates (341)

Phosphoric acid and the three phosphates are not permitted in the Code for IFP. Sodium, potassium and calcium phosphates however are GMP food additives being listed in S16—2, so are permitted to be added to many food classes. There are no provisions for phosphoric acid, but there are provisions for sodium phosphates and potassium phosphates in Codex standards for all infant formula products (i.e. includes SMPPi). There are also permissions in EU Regulations for both FC 13.1.1 (phosphoric acid, sodium phosphates and potassium phosphates) and 13.1.5.1 (phosphoric acid, and sodium, potassium and calcium phosphates) at the MPL of 1000 mg/L as P_2O_5 (equivalent to 450 mg/L as phosphorus). For Codex and the EU Regulations FC 13.1.1 (IFP) the permission is linked to limits for sodium, potassium and phosphorus.

For EU Regulations FC 13.1.5.1 (SMPPi) the permission for phosphoric acid is linked directly to three other phosphates, sodium phosphates (339), potassium phosphates (340) and calcium phosphates (341), singularly or in combination with the same MPL of 450 mg/L as phosphorus. But the permission also has a condition that it is only for pH adjustment.

FSANZ's safety assessment in SD1 of CP1 (2021) concluded that permitting the use of phosphoric acid, sodium phosphates, potassium phosphates and calcium phosphates as food additives in IFP does not raise toxicological concerns provided the limits on calcium, sodium, potassium and phosphorus provided in the Code for IFP are met.

A consideration of the technological justification for phosphoric acid is provided in section 3.1.1. This supports the conclusion that use of phosphoric acid is technologically justified for addition to IFP at the MPL of 450 mg/L as phosphorus, singularly or in combination with sodium phosphates and potassium phosphates, with the condition statement relating to limits for sodium, potassium and phosphorus. FSANZ therefore proposes to add permissions for phosphoric acid, sodium phosphates and potassium phosphates, singularly or in combination at the MPL of 450 mg/L as phosphorus to align with EU Regulations. It is further noted that Codex permits sodium phosphates and potassium phosphates as acidity regulators for all IFP at the same MPL so the permission for these additives ensures alignment with Codex standards due to consistency with the MPG.

FSANZ also proposes to add permissions for phosphoric acid, sodium, potassium and calcium phosphates, singularly or in combination at the MPL of 450 mg/L as phosphorus to align with EU Regulations for SMPPi to ensure the importation of such products from the EU for specific infants with specific medical conditions. The permissions have the same condition statements as the EU Regulations.

3.3.5 Sodium alginate (401)

Sodium alginate is not permitted in the Code for IFP, nor is it permitted by Codex standards. Sodium alginate is a GMP food additive since it is listed in S16—2, so permitted for use in many food classes. However, it is permitted by EU Regulations for use in FC 13.1.5.1 (equivalent to SMPPi). FSANZ proposed in the 1st CFS, following on from its recommendation in the 2021 CP to align with EU Regulations by proposing permission for SMPPi at the same MPL and with the same condition statement. That is, to permit at 1000 mg/L for products suitable for infants from four months onward in products for dietary management of metabolic disorders and for general tube-feeding.

The permission for use of sodium alginate in the EU Regulations for Foods for Special Medical Purposes for Infants and Young Children was supported by the Scientific Committee on Food in March 1997 (SCF, 1997). It had been requested and supported as a stabiliser for use in Foods for Special Medical Purposes for products for infants from 4 months onwards, for the infants with metabolic disorders and for general tube-feeding. The justification for its use is to be used in combination with other stabilisers and emulsifiers which reduces the overall intake of any food additive for products for metabolic disorders. Its purpose in tube feeds is to use in combination with other thickeners and gelling agents to prevent separation of fibre in the liquid feed.

The position at the 1st CFS (and earlier 2021 CP1) is unchanged. That is, FSANZ proposes to add permission for the additive at 1000 mg/L to align with EU Regulations for SMPPi with a consistent condition statement to ensure the importation of such products from the EU for specific infants with specific medical conditions. A risk assessment for sodium alginate is at Appendix 4.

3.3.6 Locust bean (carob bean) gum (410)

Locust bean (carob bean) gum (LBG) is already permitted in the Code for all IFP with a MPL of 1,000 mg/L. This is also consistent with Codex standards.

It is permitted in EU Regulations in FC 13.1.5.1 (equivalent to SMPPi) at an MPL of 10,000 mg/L with a condition statement for use from birth onwards in products for reduction of gastro-oesophageal reflux. The technological purpose of the food additive is as a thickener.

There are a number of specific references addressing the use of LBG in IFP. JECFA's Chemical and Technical Assessment (CTA) report of 2016 contains a section dealing with its use in IFP and the Codex Food Category 13.1.3 – Formulae for Special Medical Purposes for Infants, equivalent to SMPPi (JECFA 2016). The gum is used as a thickener in powdered infant Foods for Special Medical Purposes (FSMP) and follow-on FSMP formula for the prevention and therapeutic dietary management of gastro-oesophageal reflux (GER). Its advantages are that it forms adequate viscous solutions at relatively low concentrations, that are relatively unaffected by pH, salts or temperature. The viscous solution it forms in the bottle of the IFP is maintained in the stomach of the infant. It also does not alter the taste of the IFP and being composed of non-digestible polysaccharides it does not add calories.

Updated FSANZ risk assessment

FSANZ's previous evaluation of LBG was primarily based on the most recent JECFA assessment.

At that time JECFA concluded the available data were not sufficient for the evaluation of LBG for use in infant formula at the proposed use level of 10,000 mg/L, due to the absence of toxicological studies in neonatal animals. JECFA noted that while human infant feeding

studies did not report any serious adverse effects and support tolerability up to 6000 mg/L, these studies were not designed to evaluate effects on infant gut morphology of health.

In FSANZ's last call for submissions it was proposed to maintain the current permission to align with Codex (MPL 1000 mg/kg), and to permit in SMPPi at a lower MPL of 5,000 mg/L, which was indicated by an industry submitter as the upper level required for the technological purpose.

A recent reevaluation of LBG has been published by the European Food Safety Authority (EFSA) in February 2023 (EFSA 2023) which FSANZ has assessed and provides its summary of the assessment below.

EFSA reevaluation 2023

EFSA noted in its recent reevaluation that the available clinical studies provided only limited information and none could be taken into account in assessing the safety of LBG because of their methodological limitations. However, post-marketing data provided by an interested business operator (IBO) did not show serious adverse events among over 50 million units sold except for a single case of allergic reaction.

A new study in neonatal piglets was submitted for review. Doses of 0, 1050, 1500 or 2400 mg/kg bw/day were administered (corresponding to formula containing 0, 3.5, 5.0 or 8.0 g/L LBG, respectively).

EFSA concluded that there were no adverse effects on clinical appearance, defecation, formula consumption, body weight, and weight and morphology of the small and large intestines in this study. Decreased blood zinc concentration was observed, and considered of toxicological importance as zinc deficiency is known to correlate with a number of biological effects including increased risk of anaemia. Increases in blood glucose were also observed, considered likely to be secondary to decreased zinc levels (zinc is involved in blood sugar regulation). Some changes in red blood cell parameters were also observed and considered possibly related to the decreased zinc levels.

For the risk assessment, benchmark dose (BMD) modelling was conducted to calculate a $BMDL_{20}$ of 1400 mg/kg bw/day LBG. The $BMDL_{20}$ represents the lower confidence limit on the dose of LBG associated with a 20% decrease in blood zinc concentration compared with controls. It was considered a margin of exposure (MOE) greater than 1 would not indicate a safety concern.

Reported use levels of LBG in infant formula ranged from 650 – 10,000 mg/L, with a mean level of 4347 mg/L. Dietary exposure assessments were conducted based on the maximum use level and the average typical level.

Results of the exposure assessment were as follows:

Age group	Mean use level (4347 mg/L)		Maximum use level (10,000 mg/L)	
	Mean consumption	High consumption	Mean consumption	High consumption
Infants < 16 weeks of age	MOE > 1 No safety concern	MOE > 1 No safety concern	MOE < 1 Potential safety concern	MOE < 1 Potential safety concern
Infants > 16 weeks up to 1 year (consumers	Not assessed	Not assessed	MOE > 1 No safety concern	MOE < 1 Potential safety concern

only of FSMP)				
Toddlers (consumers only of FSMP)	Not assessed	Not assessed	MOE > 1 No safety concern	MOE > 1 No safety concern

FSANZ dietary exposure assessment

A dietary exposure assessment was conducted to assess whether FSANZ's proposed MPL of 5000 mg/L LBG in SMPPi would be a safety concern for the appropriate target populations. Dietary exposures to LBG were estimated using model diets for infants aged 3 months and 9 months, assuming 100% of energy requirements are met by SMPPi. For 9 month old infants, this excludes exposure to LBG from general purpose foods or foods for infants.

A set of model diets for infant formula consumption based on the energy content of infant formula, the recommended energy intakes for infants, and infant body weights, are commonly used by FSANZ for risk assessments (methodology explained further in the risk assessment for A1155[9]). A set of model diets was not established for infants consuming SMPPi as the energy, fluid and nutrient requirements can vary depending on the medical conditions of the infant, therefore for this assessment the standard model diets have been used to approximate consumption amounts. Additionally, the energy content of the various SMPPi can be variable. If an infant consuming SMPPi has similar energy requirements to those used in the model infant diets and their specific formula has a similar energy content to that used in the model diets, then their exposure to LBG is anticipated to be similar to that outlined in the assessment below. If their specific formula has a higher energy content to that used in the model diets, then their intake of LBG is anticipated to be similar to or lower than that outlined in the assessment below.

The estimated mean and 90th percentile[10] dietary exposures to LBG are 620 mg/kg bw/day and 1240 mg/kg bw/day for 3 month old infants, and 600 mg/kg bw/day and 1190 mg/kg bw/day for 9 month old infants. Comparison of the $BMDL_{20}$ (1400 mg/kg bw/day) with all estimated exposures results in MOEs greater than 1, therefore these do not indicate a safety concern.

Infants consuming SMPPi are generally under medical and dietetic supervision given their specific needs. Short term dietary exposures to food additives in excess of those estimated may be of a lesser priority than medical and dietetic considerations in their overall case management.

Summary

Based on the results for infants < 16 weeks of age consuming IFP containing 4347 mg/L LBG, it can be inferred that exposures for infants consuming IFP containing LBG at the current MPL in the Code of 1000 mg/L would not be a safety concern.

A dietary exposure assessment conducted to assess FSANZ's proposed MPL of 5000 mg/L LBG in SMPPi indicated that this would also not be a safety concern for the appropriate target populations.

[9] https://www.foodstandards.gov.au/code/applications/Pages/A1155.aspx

[10] Mean consumption multiplied by two to obtain 90th percentile amounts. World Health Organization (1985) Guidelines for the study of dietary intakes of chemical contaminants. WHO offset publication, no.87. World Health Organization, Geneva

The position at the 1st CFS, which had been further consolidated from its 2021 CP1 position, is unchanged. That is, to permit the use of the food additive in SMPPi but to reduce the EU Regulation MPL from 10000 mg/L to 5000 mg/L due to it being the upper level required for the technological purpose as provided by an industry submitter. The recent EFSA re-evaluation provides additional confidence that the proposed MPL of 5000 mg/L for SMPPi would not be a safety concern. FSANZ considers that it is important that permission is provided for SMPPi products to ensure the importation of such products from the EU for specific infants with specific medical conditions. The EU Regulation condition statement is also added to ensure consistency.

3.3.7 Guar gum (412)

Guar gum is already permitted in the Code for all IFP with a MPL of 1000 mg/L. This is also consistent with Codex standards, but with a condition statement that it is used in liquid formula products containing hydrolysed protein. The condition statement is also linked to the same MPL in EU Regulations for FC 13.1.1 (general IFP). FSANZ proposes to add this condition statement to the current permission to ensure alignment.

Guar gum is permitted in EU Regulations in FC 13.1.5.1 (equivalent to SMPPi) at an MPL of 10000 mg/L with a condition statement for use from birth onwards in products in liquid formulae containing hydrolysed proteins, peptides or amino acids. The technological purpose of the food additive is as a thickener.

The position at the 1st CFS, which had been further consolidated from its 2021 CP1 position, has been slightly amended. That is, FSANZ proposes to add the Codex and EU Regulations condition statement (only for use in liquid formula containing hydrolysed protein) to the current permission for use in IFP at the MPL of 1000 mg/L to ensure alignment of permissions with Codex and EU Regulations. It maintains its 1st CFS proposed position to add permission for the additive at 10000 mg/L to align with EU Regulations for SMPPi with a consistent condition statement to ensure the importation of such products from the EU for specific infants with specific medical conditions. A risk assessment for guar gum is included at Appendix 4.

3.3.8 Xanthan gum (415)

Xanthan gum is not currently permitted in the Code for IFP, which is consistent with both Codex and EU Regulations. However, it is permitted in both Codex and EU Regulations for products equivalent to SMPPi, but with different MPLs and different condition statements.

Codex permits it at MPL of 1000 mg/L with the condition statement of use in powdered hydrolysed protein and/or amino acid based infant formula only. The EU Regulations permit it in FC 13.1.5.1 at a slightly higher MPL of 1200 mg/L with the condition statement of from birth onwards for use in products based on amino acids or peptides for use in patients who have problems with impairment of the gastrointestinal tract, protein mal-absorption or inborn errors of metabolism.

FSANZ's safety assessment in SD1 of CP1 (2021) concluded that permitting xanthan gum in all IFP at concentrations up to 1000 mg/L, the maximum level assessed by JECFA, does not raise safety concerns.

The position at the 1st CFS, which varied from its 2021 CP1 position, is unchanged. That is, to have two permissions for its use in SMPPi products; one to align with Codex and a second to align with EU Regulations. The two permissions have different MPLs and different condition statements.

Aligning SMPPi permissions with Codex, including using the same condition statement, ensures consistency with the MPG. Also having the higher MPL and consistent condition statement to align with the EU Regulations for SMPPi ensures the importation of such products from the EU for specific infants with specific medical conditions.

3.3.9 Pectins (440)

The food additive pectins is not currently permitted in the Code for IFP, which is consistent with both Codex and EU Regulations. However, it is permitted in the draft Codex FUF standard at 10000 mg/L. It is also permitted in both Codex and EU Regulations for products equivalent to SMPPi, but with different MPLs and different condition statements.

FSANZ's safety assessment in SD1 of CP1 (2021) concluded that permitting pectins as a food additive in all IFP at 2000 mg/L does not raise any safety concerns.

Codex permits it at MPL of 2000 mg/L with the condition statement of use in liquid hydrolysed protein infant formula only. The EU Regulations permit it in FC 13.1.5.1 at a higher MPL of 10000 mg/L with the condition statement of from birth onwards in products used in case of gastrointestinal tract disorders. The technological purpose of the food additive is as a thickener.

The position at the 1st CFS, which had been further consolidated from its 2021 CP1 position, is unchanged. That is, to propose two separate and different MPLs and condition statements for SMPPi to align with both Codex and EU Regulations. The permission aligning with Codex is for a MPL of 2000 mg/L with a condition statement only for liquid hydrolysed protein infant formula. It is to also reduce the EU Regulation MPL from 10000 mg/L to 5000 mg/L due to EFSA 2021 opinion that use levels of the food additive in FC 13.1.5.1 were up to a maximum of 4170 mg/L. This proposed reduction in the MPL is in response to the lack of risk assessment data for the safety of the food additive in IFP at the higher permitted use level in EU Regulations for SMPPi.

What has changed from the 1st CFS is the proposal to add a permission explicitly for follow-on formula to align with the draft Codex FUF standard with an MPL of 1000 mg/L. Aligning permissions with the draft Codex FUF standard ensures alignment with Codex standards and therefore consistency with the MPG.

Aligning SMPPi permissions with Codex, including using the same condition statement, ensures consistency with the MPG. Also having the higher MPL and consistent condition statement to align with the EU Regulations for SMPPi ensures the importation of such products from the EU for specific infants with specific medical conditions.

3.3.10 Diacetyltartaric and fatty acid esters of glycerol (472e)

Diacyltartaric and fatty acid esters of glycerol is currently permitted in the Code as a food additive for FC 13.1.3 (Infant formula products for special dietary use based on a protein substitute). However, it is not permitted in any infant formula product in Codex standards or EU Regulations.

The position at the 1st CFS, which had been earlier proposed in both the 2017 CP and 2021 CP1 documents, is unchanged. That is, to remove permission in the Code on the basis that there are no equivalent permissions in Codex or the EU. Consistent with earlier industry submissions to the 2017 and 2021 CPs industry submissions to the 1st CFS opposed the removal. It noted that the food additive is permitted in the USA due to section 184.1101 of the USA Code of Federal Regulation (CFR), chapter 21 (Food). This section does not specifically reference infant formula but has permissions for use in fats and oils. It is possible

such fats and oils could be ingredients in IFP but that is not an appropriate reason for FSANZ to not remove the permission. Industry has also noted that the food additive has been permitted in the Code for use in IFP for many years. However, there has been a lack of actual use or justification of use of the food additive in IFP provided by industry stakeholders for FSANZ to change its proposal to remove permission from the Code.

3.3.11 Sucrose esters of fatty acids (473)

Sucrose esters of fatty acids is not currently permitted in the Code for IFP, which is consistent with Codex standards. However, it is permitted in EU Regulations for FCs 13.1.1 (IFP) and 13.1.5.1 (equivalent to SMPPi). Both permissions have a MPL of 120 mg/L and the same condition statement of only for products containing hydrolysed proteins, peptides and amino acids. Due to the condition statement FSANZ has concluded the permission is appropriate to SMPPi and not general IFP.

The position at the 1st CFS (and earlier 2017 CP and 2021 CP1) is unchanged. That is, FSANZ proposes to add permission for the additive at 120 mg/L to align with EU Regulations for SMPPi with a consistent condition statement to ensure the importation of such products from the EU for specific infants with specific medical conditions.

3.3.12 Acetylated distarch adipate (1422)

The four starches: distarch phosphate (1412), phosphate distarch phosphate (1413), acetylated distarch phosphate (1414) and hydroxypropyl starch (1440) are currently permitted in the Code for use in FC 13.1.1 – Soy-based infant formula at the MPL of 5000 mg/L; and separately in FC 13.1.3 – Infant formula products for specific dietary use based on a protein substitute at the MPL of 25000 mg/L. These permissions are consistent with Codex and EU Regulations.

The draft Codex FUF standard has slightly different permissions where INS 1440 is replaced by acetylated distarch adipate (1422). The MPLs for the approvals of the four starches is comparable to those for IFP and SMPPi for the above list of four starches. That is 1412, 1413, 1414 and 1422 have the MPL of 5000 mg/L in soy-based products and 25000 mg/L in hydrolysed protein and/or amino acid-based products only.

Acetylated distarch adipate is not permitted in the Code for any IFPs. It is however a food additive permitted at GMP, being listed in S16—2 of the Code, so permitted in many food categories. FSANZ conducted a risk assessment for use of the food additive in IFP (see Appendix 4) and concluded that permitting acetylated distarch adipate as a food additive in follow-on formulas, in alignment with Codex provisions, does not pose toxicological concerns.

FSANZ proposes to permit acetylated distarch adipate (1422) along with 1412, 1413 and 1414 for use in soy-based follow-up formula at the MPL of 5000 mg/L, and for SMPPi products containing hydrolysed protein and/or amino acid-based for follow-on formula at the MPL of 25000 mg/L. Adding these permissions will align with the draft Codex FUF standard. Aligning permissions with the draft Codex FUF standard ensures alignment with Codex standards and therefore consistency with the MPG.

3.3.13 Starch sodium octenylsuccinate (1450)

Starch sodium octenylsuccinate is not currently permitted in the Code for IFP, which is consistent with both Codex and EU Regulations. However, it is permitted by Codex standards and EU Regulations for use in comparable products to SMPPi. Both permissions are with the MPL of 20000 mg/L and with Codex having the condition statement for use in

hydrolysed protein and/or amino acid based infant formula only.

The position at the 1st CFS (and earlier 2021 CP1) is unchanged. That is, FSANZ proposes to add permission for the additive at 20000 mg/L to align with both Codex standards and EU Regulations for SMPPi with a condition statement of use in hydrolysed protein and/or amino acid based infant formula only.

Aligning SMPPi permissions with Codex, including using the same condition statement, ensures consistency with the MPG. Also aligning with the EU Regulations for SMPPi ensures the importation of such products from the EU for specific infants with specific medical conditions.

3.3.14 Silicon dioxide (amorphous) (551)

The Codex Guideline CXG 10-1979 – Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children contains section D – Advisory list of food additives for special nutrient forms. It is stated here that the five food additives listed may be used as nutrient carriers. One of these food additives is silicon dioxide (INS 551) with a ML of 10 mg/kg (L) in ready to use products. An infant formula manufacturer communicated that a nutrient preparation used by them includes silicon dioxide in small amounts but not specifically as a nutrient carrier but as an anti-caking agent, which is a food additive function (listed in Schedule 14). For regulatory certainty it was important that alignment of the Codex provision is reflected within the Code.

Silicon dioxide (amorphous) is a GMP food additive, being listed in the table of section 2 of Schedule 16 (S16—2), so it is a safe and suitable food additive. It also has Codex provision for a similar use as noted above. It is well known to also have the technological function as an anti-caking agent (as well as carrier). Therefore, FSANZ proposes to add permission in the Code for this use, but only for use in nutrient preparations added to IFP.

A summary of the proposed food additive permissions for infant formula products is provided in Table 5. This includes all the current permissions in the Code, and those that are proposed to be added or amended as part of the proposal. The consequential draft variation in Appendix A of the 2nd CFS provides the current proposed complete draft variation including proposed condition statements.

Table 5 - Summary of proposed permissions of all food additives for infant formula products

INS	Description	Proposed MPL (mg/L)			Condition[4]
		General[1]	FOF[2]	SMPPi[3]	
170	Calcium carbonates	-	-	GMP	N
270	Lactic acid	GMP	GMP	GMP	N
300	Ascorbic acid, L-	-	50	-	Y
301	Sodium ascorbate	-	50	-	Y
302	Calcium ascorbate	-	50	-	Y
304	Ascorbyl palmitate	10	50	100	Y
307b	Tocopherols concentrate, mixed	10	30	10	N
308	Gamma-tocopherol	10	10	10	N
309	Delta-tocopherol	10	10	10	N
322	Lecithin	5000	5000	5000	N
330	Citric acid	GMP	GMP	GMP	N
331	Sodium citrates	GMP	GMP	GMP	Y
332	Potassium citrates	GMP	GMP	GMP	Y
333	Calcium citrate	-	-	GMP	N
338	Phosphoric acid	450	-	450	Y
339	Sodium phosphates	450	-	450	Y
340	Potassium phosphates	450	-	450	Y
341	Calcium phosphates	-	-	450	Y
401	Sodium alginate	-	-	1000	Y
407	Carrageenan	300	300	1000	Y
410	Locust bean (carob bean) gum	1000	1000	5000	Y
412	Guar gum	1000	1000	10000	Y
415	Xanthan gum	-	-	1000 (Codex)	Y

INS	Description	Proposed MPL (mg/L)			Condition[4]
		General[1]	FOF[2]	SMPPi[3]	
				1200 (EU)	Y
440	Pectins	-	10000	2000 (Codex)	Y
				5000 (EU)	Y
471	Mono- and diglycerides of fatty acids	4000	4000	5000	Y
472c	Citric and fatty acid esters of glycerol	7500 (powder) 9000 (liquid)	7500 (powder) 9000 (liquid)	7500 (powder) 9000 (liquid)	N
~~472e~~	~~Diacetyltartaric and fatty acid esters of glycerol~~ (remove permission)	-	-	-	N
473	Sucrose esters of fatty acids	-	-	120	Y
500	Sodium carbonates	2000	2000	2000	Y
501	Potassium carbonates	2000	2000	2000	Y
524	Sodium hydroxide	2000	2000	2000	Y
525	Potassium hydroxide	2000	2000	2000	Y
526	Calcium hydroxide	2000	2000	2000	Y
551	Silicon dioxide (amorphous)	10	10	10	Y
1412	Distarch phosphate	5000	5000	25000	Y
1413	Phosphated distarch phosphate	5000	5000	25000	Y
1414	Acetylated distarch phosphate	5000	5000	25000	Y
1422	Acetylated distarch adipate	-	5000	-	Y
1440	Hydroxypropyl starch	5000	-	25000	Y
1450	Starch sodium octenyl succinate	-	-	20000	Y

Notes:

1 General relates to the proposed new high level food class of 13.1 – Infant formula and related products, that captures all infant formula products including follow-on formula and SMPPi

2 FOF stands for follow-on formula, being comparable to the draft Codex Follow-up Standard for older infants (6-12 months)

3 Stands for the sub food class of 13.1.2 – Special medical purpose products for infants
4 Yes (Y) or No (N) whether condition statements are proposed to be linked to the permission

3.4 Consideration of aligning with draft Codex FUF standard

FSANZ very briefly mentioned the draft Codex standard for Follow-Up Formula within section 3.1.1 of SD1 of the 1st CFS. However, at that stage it had not considered in any detail the food additive permissions for this draft standard. It is important to note that the current Codex Standard for Follow-Up Formula, CXS 156-2006-1987 is being reviewed by the CCNFSDU and split into two sections, with section A – Follow-up formula for older infants[11] (6-12 months) now relevant for this proposal. The current CXS 156-1987 applies for infant and young children aged between 6 to 36 months which is outside the age limit for follow-on formula products of the Code, which is between 6-12 months.

The report of the 42nd session of the CCNFSDU of Nov-Dec 2021[12] provided some discussion of the review of the Standard for follow-up formula. Appendix III provided the scope, description, essential composition and quality factors and labelling held at step 7. Of particular relevance to this proposal, Appendix IV contains the proposed food additive provisions for section A – Follow-up formula for older infants, which is held at step 4. CCNFSDU agreed that the provisions are ready for adoption at step 5/8 but in order to advance the entire Standard to Codex Alimentarius Commission (CAC) for adoption, the provisions would be held at Step 4 on the understanding that all issues on the remaining sections of Sections A and B had been addressed and no further discussion was needed. These have essentially not been changed from the current CXS 156-1987, noting that flavourings and lactic acid producing cultures (which are not food additives) are not proposed to be permitted.

REP22/NFSDU also agreed to making the section relating to carry-over for food additives more explicit in the draft FUF standard by copying the relevant section from CXS 72-1981, rather than mention the carry-over section in the preamble to the GSFA as in the current CXS 156-1987.

A number of industry submitters to the 1st CFS requested that FSANZ also align the provisions of the draft Codex FUF standard for section A as part of the proposal work on updating food additive provisions. FSANZ notes that the draft standard has not been formally presented to and adopted by the CAC yet. However, it does note that the food additive provisions are very similar to the current CXS 156-1987 and the changes supported by the CCNFSDU do not change FSANZ's consideration.

FSANZ has made the amendments to the Code aligning with the draft Codex FUF standard via the consequential draft variation in Attachment A of the 2nd CFS, so that all stakeholders can identify what is being proposed and how permissions for FOF are added into the proposed changes for IFP and SMPPi. Obviously, FSANZ will need to ensure that the proposed changes to the Code are consistent with the adopted new Codex FUF standard once that occurs, which is predicted to be before or around the same time as the final drafting in the Approval Report of the proposal is produced.

FSANZ notes that the proposed food additive provisions in the draft FUF standard was provided to the Codex Committee on Food Additives (CCFA), CCFA53 meeting 27-31 March 2023 for its alignment. FSANZ understands that the CCNFSDU43 meeting (held 7-10 March 2023) will provide the draft FUF standard to the CAC46 meeting in late November/early

[11] **older infant** means a person from the age of 6 months and not more than 12 months of age, in Appendix III of REP22/NFSDU, Nov-Dec 2021, held at step 7

[12] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-44%252FFINAL%252520REPORT%252FRep21_CACe.pdf

December 2023 for adoption. The CCFA53 meeting will prove the aligned food additive provisions for this same draft FUF to the same CAC46 meeting in parallel so the standard can be fully adopted if agreed. FSANZ staff have been part of the Australian delegations to both these Codex meetings.

4 Contaminants

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

Standard 1.4.1 – Contaminants and natural toxicants and Schedule 19 – Maximum levels of contaminants and natural toxicants as well as Standard 2.9.1 – Infant Formula specify the maximum levels (MLs) of a number of contaminants for infant formula products. Previous consultations for P1028 outlined the principles that underpin the approach to setting MLs in the Code (1st CFS 2022, CP1 2021, FSANZ 2017, FSANZ 2016, FSANZ 2012). Comparison between the requirements in the Code and international regulations and standards were also reviewed. Further details are provided in the 1st CFS and FSANZ 2021 CP1.

MLs will be specified in the Code:

- only for those contaminants that present a significant risk to public health and safety
- only for those foods that are major contributors to total dietary exposure of the contaminant
- where those MLs are practically achievable
- to be consistent with Codex levels, where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.

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

The 1st CFS built on the FSANZ 2021 CP1 proposed approaches on three issues:

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

Nine submissions were received to the 1st CFS on issues relating to chemical contaminants. The major issue raised related to having a single ML for aluminium of 0.05 mg/100 mL for infant formula, including soy-based. This issue had been raised previously in response to FSANZ 2021 CP1 and is discussed in detail in the 1st CFS.

FSANZ remains of the view that, in the absence of any new data or information, the rationale presented in FSANZ 2016 CP, FSANZ 2021 CP1 and the 1st CFS remains valid. Specifically:

- The HBGV established by JECFA in 2011 is relatively low and remains unchanged.
- Occurrence data from the 23rd and 24th ATDSs indicated that the upper range for aluminium approached the ML of 0.05 mg/100 mL (23rd ATDS). As such, retaining the ML will keep dietary exposure within safe levels those contaminants that present a significant risk to public health and safety.

- Whilst the 2016 risk profile calculated exposures as less than 40-50% of the PTWI (in 9-month olds), it concluded that the maximum limits in Standard 2.9.1 were protective (i.e. removal of the MLs could lead to higher exposures).
- Lowering the ML for soy-based infant formula and having a single ML for aluminium in the Code is protective and FSANZ has received no indication that this level cannot be met by manufacturers.

Overall, in the absence of any further information, FSANZ's preferred option is to progress with the FSANZ 2021 CP1 approach, which is to retain a single ML of 0.05 mg/100 mL for infant formula products including soy-based formula. FSANZ is of the view that having only one ML for aluminium, which is lower than the current one for soy-based IFP will help ensure the safety of IFP.

FSANZ has again carefully considered all the submissions related to contaminants noting that no new issues were raised in response to the 1st CFS. Detailed responses are provided in Appendix 3.

The summary of FSANZ proposed amendments for the maximum levels (MLs) for the thirteen chemicals or chemical group contaminants is provided in the Table below. No changes are proposed to the current MLs for three contaminants, no MLs are proposed for eight contaminants, and changes for the MLs for aluminium and lead are proposed consistent with the 1st CFS and FSANZ 2021 CP.

Table 6 - Proposed MLs for infant formula products and SMPPi

Contaminant	FSANZ draft decision
Acrylonitrile	No change to the ML of 0.02 mg/kg for all foods including infant formula products.
Aluminium	Move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19. Retain single ML of 0.5 mg/kg for aluminium for IFP including soy based.
	Retain ML of 0.2 mg/kg in SMPPi formulated for pre-term infants
Arsenic	No ML for infant formula products. Monitor and review (for rice that may be used as an ingredient in infant formula)
Cadmium	No ML to be established.
Lead	Lower ML from 0.02 mg/kg to 0.01 mg/kg in IFP
Melamine	No ML to be established.
Tin & inorganic tin	No change to the ML of 250 mg/kg.
Vinyl chloride	No change to the ML of 0.01 mg/kg.
Aflatoxins B1 and M1	No ML to be established.
Ochratoxin A	No ML to be established.
Polycyclic aromatic hydrocarbons (PAH)	No ML to be established.
Perchlorate	No ML to be established.
Chloropropanol, glycidol and their esters	No MLs to be established.

5 Consideration of processing aids

FSANZ had a short section on processing aids related to IFP in the 1st CFS. It had earlier written a similar short section in the 2016 CP. FSANZ proposed in the report that it will not consider the issue of processing aids further as part of the proposal.

Two submissions to the 1st CFS did not support the proposed approach. This issue has been responded to within Appendix 1. All assessment and approvals of processing aids are considered for their specific purpose and use in specific food categories, which is no different to IFP, which is how the Code operates and is considered by FSANZ as appropriate.

FSANZ confirms its earlier conclusion that it will not consider processing aids further as part of this proposal.

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Appendix 1

Summary of submitter comments and FSANZ responses for: FOOD ADDITIVES

Issue	Comment	Submitter(s)	FSANZ Response
Removal of carry-over principle for food additives in infant formula products (consistent with Codex and EU Regs)			
Yes, the preferred option is supported.	These submitters supported for the following reasons: • FCG can support to align with Codex but would prefer the status quo. But doing this requires FSANZ to add new permissions to ensure smooth transition for industry (see comment below). • NSWFA notes this aligns with the Ministerial Policy Guideline – Regulation of Infant Formula Products (it abbreviated it as MPGI) that provides for a pre-market safety assessment of all food additives in IFP. • NZFS supports the proposed approach to be consistent with international regulations and standards, i.e. Codex and EU. This serves to both support NZ IFP exports and maintain importation of IFP, especially SMPPi which are generally not manufactured in Australia or New Zealand. • DA supports clearer restrictions for carry-over of food additives, which should not be permitted in IFP, as they may represent a risk to infants.	FCG NSWFA NZFS DA	These comments are noted. As detailed in FSANZ's reports the intent is to restrict the carry-over of food additives for IFP consistent with Codex and EU. This will be made clear in the proposed drafting.
No, the preferred option is not supported.	These submitters did not support for the following reasons: • DAN did not support the proposal as it will be a major change from the status quo and will require substantial work with suppliers. • INC and DAN reiterates their earlier opposition to the proposal as it seeks the maintenance of the status quo. However, if it is removed then INC requests that new permissions be added to allow substances (permitted forms of vitamins, minerals and electrolytes) to be listed in Schedule 29—7. • INC requests that the new permissions be included in the 2nd CFS [assumed to mean in the proposed drafting] so that amendments to food additive permissions can be made concurrently with the removal of the carry-over principle to allow a smooth transition.	DAN INC	These comments are noted. However, these comments do not promote consistency with international regulations and standards, specifically Codex IFP standards, and the EU Regulations for IFP. They are also not consistent with the agreed principle that food additive use should be minimised for IFP, as they are often the sole source of nutrition, and infants are a vulnerable population. The consideration of permitted forms of nutrients are considered in the Nutrient Composition SD2.

Issue	Comment	Submitter(s)	FSANZ Response
			This is not something that can be done via consideration of food additive permissions, since a permission for a nutritive substance is not a permission for its use as a food additive. The 2nd CFS contains the proposed drafting for food additives in Schedule 15 within the consequential draft variation in Attachment A.
International alignment of food additives in IFP with Codex and EU Regulations			

Yes, the preferred option is supported.	These submitters supported for the following reasons:
	• FCG notes there is support for harmonisation with relevant Codex standards as a means of reducing trade barriers, unless there is strong scientific justification for a different approach.
	• NZFS supports the proposed permissions for:
	  • Acidity regulators
	  • Citric and fatty acid esters of glycerol (472c)
	  • Starch sodium octenylsuccinate (1450)
	  • Locust bean (carob bean) gum (410) in IFP at 1000 mg/L
	  • Guar gum (412), maintain in IFP at 1000 mg/L
	  • Remove permission of diacyltartaric and fatty acid esters of glycerol (472e)
	  • Make additional clarifications as noted in the report
	  • Retain current INS names and numbers, not change them
	• DA supports not to permit adding these food additives to general IFP (excluding SMPPI):
	  – Pectins (440)
	  – Xanthan gum (415)
	  – Sodium alginate (401)
	  – Sucrose esters of fatty acids (473)
		FCG
		NZFS
		DA
			These comments are noted.

Issue	Comment	Submitter(s)	FSANZ Response
	The INC supports the proposed amendments: • Citric and fatty acid esters of glycerol (472c) • Starch sodium octenylsuccinate (1450) • Xanthan gum (415) • Guar gum (412) • Sodium alginate (401) • Sucrose esters of fatty acids (473) • Make additional clarifications as noted • Retain current INS names and numbers	INC	These comments are noted
	VIC supported the following proposed permissions, with additional comments as noted: • Acidity regulators, but with appropriate condition statements as FSANZ has proposed re maximum limits within Schedule 29 • Sodium, potassium and calcium phosphates, but with appropriate condition statements as FSANZ has proposed re maximum limits within Schedule 29 • Citric and fatty acid esters of glycerol (472c) • Starch sodium octenylsuccinate (1450) • Locust bean (carob bean) gum (410), MPL of 5000 mg/L in SMPPi, with condition statement but not increasing to 10000 mg/L VIC supports not permitting the following food additives: • Sodium carboxymethylcellulose (466) • Diacyltartaric and fatty acid esters of glycerol (472e)	VIC	These comments are noted
No, the preferred option is not supported.	This submitter did not support for the following reasons: • NES noted that the description of SMPPi is broader than IFPSDU and so food additive permissions need to also align with Codex Standard GSFA (CXS 192-1995) FC 13.1.3 for Formulae for Special Medical Purposes for Infants, and EU Reg 2008/1333 FC 13.1.5.2 from 6 months to 3 years.	NES	FSANZ can only consider aligning food additive provisions/permissions in Codex and EU Regulations that are appropriate for IFP up to 12 months, and certainly not foods for infants older than 12 months within the scope of P1028. It is aware of the current draft Codex Standard for Follow-Up Formula for Older Infants, section A for infants 6 to 12 months (see below).
	INC reiterates its (CP1 2021) view that food additives that also contribute essential nutrients should not have food additive MPLs above the maximum levels specified for nutrition compositional requirements.	INC	The assessment examines the purpose and function the substance is performing in the IFP. The answer to that assessment determines the appropriate MPL for the particular purpose sought.

Issue	Comment	Submitter(s)	FSANZ Response
			A food additive is added to perform a technological purpose (as listed in Schedule 14). A food additive needs to comply with one of these purposes to be a permitted food additive. It is therefore assessed (by JECFA and the relevant Codex Commodity Committee) for that technological purpose, as well as by FSANZ. An assessment is required for the minimal use level required to perform that technological purpose in the food category by an assessment of technological need and justification. A nutrient is added to a food to provide a nutritional benefit, which needs to be understood and assessed. In this situation a nutritional risk/benefit assessment is required. Therefore, there is a fundamental difference in how substances used as nutrients compared to food additives are considered, related to their purpose and assessment of such. This means there is likely to be different MLs for the same substance used as a food additive compared to it used as a nutrient. Both the EU Regs and Codex have over-arching total limits for substances when they can be used as both nutrients and food additives which have to be complied with. FSANZ has incorporated these limits in condition statements with permissions to ensure better consistency of the Code with Codex and EU.
	INC raised issues related to a number of proposed permissions: • Pectins (440), for SMPPi, at 2 different MPLs, 2000 mg/L and 5000 mg/L. It notes the different MPL for 2nd MPL which is misaligned compared to the EU Regs FC 13.1.5.1 with MPL of 10000 mg/L. • Plus, pectins has MPL of 10000 mg/L for draft Codex FUF. • There are a number of additional antioxidants for the draft FUF, or	INC	These comments are noted. A detailed response to each of the issues listed against the individual food additives is provided in Appendix 2.

Issue	Comment	Submitter(s)	FSANZ Response
	at different MPL compared to Codex IFP and proposed for the Code: ○ These are for different tocopherols (307a & 307c) combined with 307b at higher MPL, as well as different ascorbates, 300, 301 & 302, combined with ascorbyl palmitate (304), again at higher MPLs • Ascorbyl palmitate has a higher MPL for EU Reg FC 13.1.5.1 (SMPPi) of 100 mg/L (compared to 10 mg/L in the Code for IFP) • Additional tocopherols (308 & 309) to be considered for SMPPi (EU Regs FC 13.1.5.1) • Calcium citrates (333), propose should be permitted for all IFP since it is a permitted nutrient (mineral) • It does not support specific permissions provided for substances as nutrient carriers since these already have permissions as processing aids, Code needs to be consistent: comment relates to calcium citrates (333), tricalcium phosphate (341(iii)) • Acidity regulators: proposes these should have a MPL of GMP for all IFP, consistent with Codex draft FUF and EU Regs FC 13.1.5.1. Plus, the MPL proposed are often in conflict with use and MPL as nutrients • Phosphoric acid (338), supports but like for other acidity regulators does not consider a MPL is required. • Why has FSANZ removed the permission for calcium phosphates (341) linked with sodium phosphates (339) and potassium phosphates (340) for all IFP when it proposed this in the CP1 2021 which INC supported? • Permission is needed for 339, 340 & 341 for SMPPi to align with EU Regs FC 13.1.5.1. • Locust bean (carob bean) gum (410) supports permission for IFP but notes MPL for SMPPi (5000 mg/L) is not consistent with EU Regs FC 13.1.5.1 (10000 mg/L), noting EFSA is re-evaluating it; INC supports aligning with EFSA opinion once finalised. • Pectins (440), as above, plus supports MPL for IFP, requests review also for Codex draft FUF. • Sodium carboxymethylcellulose (466) it does not support the proposal to not permit for SMPPi, as this does not align with EU		

Issue	Comment	Submitter(s)	FSANZ Response
	Regs FC 13.1.5.1, which permits for use in SMPPi for disorders, MPL 10000 mg/L • Diacyltartaric and fatty acid esters of glycerol (472e) it does not support removal of permission from Code; it is permitted in US for some use in IFP under 21 CFR 184.1101. No risk assessment justification of risk has been provided to remove; it has been present in products sold globally for decades.		
	VIC does not support the following permissions: • Locust bean (carob bean) gum (410), at MPL of 1000 mg/L in IFP without technological need • Pectins (440), not a MPL of 5,000 mg/L in any IFP • Xanthan gum (415), not a MPL of 1200 for SMPPi, prefer 1000 mg/L, plus concerned having 2 products within SMPPi with different MPLs, cause uncertainty • Guar gum (412), require technological need and safety assessment at MPL of 10000 mg/L in SMPPi, plus require technological need in IFP • Sodium alginate (401), require technological need and safety assessment at MPL of 1000 mg/L in SMPPi • Sucrose esters of fatty acids (473), at MPL of 120 mg/L in SMPPi, require safety assessment or medical justification	VIC	These comments are noted. A detailed response to each of the issues listed against the individual food additives is provided in Appendix 2.
Other issues raised.	Seek further advice on efficacy of food additives performing the function of thickeners to be used in IFP for 'anti-reflux'. Questions whether there is 'generally accepted scientific data' for this claimed effect [technological purpose and technological justification]	NSWFA	The comment is noted and addressed via the general discussion of technological justification in section 3.1. Additional discussion is provided for some of the individual food additives within section 3.3 addressing this question.
	Technological purpose [and justification] for permission of: • Citric and fatty acid esters of glycerol (472c); broaden permission from SMPPi to all IFP • Locust bean (carob bean) gum (410) 1,000 mg/L for IFP & 5,000 mg/L SMPPi as thickener for 'anti-reflux' products, safety and efficacy • Pectin (440) 5,000 mg/L SMPPi for treating gastro-intestinal disorders • Xanthan gum (415), 1,200 mg/L for SMPPi, for GI tract problems, protein mal-adsorption or inborn errors of metabolism, safety, noting JECFA safety assessment at 1,000 mg/L	NSWFA	These comments are noted. A detailed response to each of the issues listed against the individual food additives is provided in Appendix 2.

Issue	Comment	Submitter(s)	FSANZ Response
	• Guar gum (412), advice re EFSA re-evaluation compared to 10,000 mg/L SMPPi, products containing hydrolysed proteins, peptides or amino acids • Sodium alginate (401) 1,000 mg/L SMPPi, metabolic disorders and for general tube-feeding • Sucrose esters of fatty acids (473) 120 mg/L SMPPi, products containing hydrolysed proteins, peptides or amino acids		
	Starch sodium octenylsuccinate (1450): Questions statement on page 28 of SD1 that 'no changes to the Code are required' [to permit its continued use for this purpose].	NSWFA	This statement refers explicitly to its use as a carrier processing aid (see section 2.3 of SD1 of 1st CFS), not adding a specific permission as proposed to SMPPi at 20,000 mg/L consistent with Codex and EU Regs, which is stated in the paragraph above in SD1, page 28. FSANZ notes that the paragraph under previous consideration at the bottom of page 27 of SD1 is an error as that applies to the food additive above it, i.e. citric and fatty acid esters of glycerol (472c).
	Will consider when the issue is discussed in the 2nd CFS, noting FSANZ's request for further information for the following: • Safety, technological justification and need of adopting Codex and EU permissions for hydrolysed protein within SMPPi. • Locust bean (carob bean) gum (410) at 5000 mg/L in SMPPi • Pectins (440) in SMPPi at 2000 mg/L for hydrolysed protein, and 5000 mg/L for GI disorder • Xanthan gum (415), SMPPi products, 1000 mg/L for hydrolysed protein and/or amino acid; 1200 mg/L for GI tract and other problems • Guar gum (412), SMPPi, 10000 mg/L for hydrolysed protein, peptides or amino acids • Sodium alginate (401), SMPPi 1000 mg/L • Sodium carboxymethylcellulose (466), not to permit in any IFP or SMPPi • Sucrose esters of fatty acids (473), SMPPi at 120 mg/L, hydrolysed proteins, peptides or amino acids	NZFS	These comments are noted.
	FSANZ needs to consider and align the food additive provisions in the draft Codex FUF standard. Its consideration should be similar to that already	DAN INC	FSANZ has been made aware of this draft Codex Standard, which is directly relevant to the scope of

Issue	Comment	Submitter(s)	FSANZ Response
	completed for IFP and IFPSDU [SMPPi]. The INC notes that provisions for acidity regulators in the draft Codex Standard for Follow-Up Formula for Older Infants is at GMP rather than a numerical MPL. This is also consistent with the EU Regs for food category 13.1.5.1 [but not for Codex provisions for IFP]. The INC notes that permission be provided for follow-on formula for a number of additional food additives and at different MPLs to align with the draft Codex standard for Follow-Up Formula for Older Infants, to ensure consistency.	NES FCG	P1028, but not in time for it to conduct an assessment for the 1st CFS. Its consideration is provided in section 3.4 of this SD1. FSANZ understands that at this current time it is still a draft Standard as it has not been formally endorsed by the CAC. However, it is further understood that the food additive provisions have not been changed (very minor differences mainly related to the structure and separation into 2 different parts for different age groups) for when it will be formally endorsed. This draft Codex standard has been considered and added into the draft consequential variation for the 2nd CFS for information and so it is not lost. FSANZ will ensure it checks that the food additive provisions for the finalised Codex FUF for consistency and alignment before this Proposal is finalised. The comments related to having a MPL for various acidity regulators of GMP to be consistent with various standards is noted. However, the proposed alignment is to Codex standards for IFP, which has numerical MPLs.
Other issues raised.	Questioned the inconsistency of FSANZ approach to addressing permissions for food additives in nutrient preparations. It is noted that if the substances are either functioning as a processing aid carrier and is already permitted or is a permitted form of vitamins, minerals or electrolytes than it is already permitted and so no additional permission for use in nutritive preparations is required. It notes that FSANZ has explicitly proposed permissions for use of INS 333 [calcium citrates] and INS 341 [actually only 341(iii), tricalcium phosphate] in nutrient preparations, when both these food additives are generally permitted processing aids (carriers). It has noted that FSANZ has explicitly not permitted a number of such food additives (e.g. INS 414, 551, 421, 1450 and 301) [listed in section D – Advisory list of food additives for special nutrient	DAN INC FCG	The reason for adding permissions for these two specific food additives with very specific condition statements was to ensure consistency with the EU Regulations 1130/2011 (amending (EC) 1333/2008, Annex III, part 5, section B), as explicitly requested by industry submitters including INC to the CP1 2021. This was to ensure regulatory certainty for use of food additives in nutrient preparations and alignment with the EU Regulations, including using the same condition statements. FSANZ is also proposing to add permissions for the use of sodium ascorbate (INS 301) for use in nutrient preparations to be consistent with EU

Issue	Comment	Submitter(s)	FSANZ Response
	forms within Codex CAC/GL 10-1979] since they are also generally permitted processing aids.		Regulations and CXG 10-1979 since its technological purpose appears to be most appropriate as an antioxidant food additive (due to Codex Guideline CXG 36-1989) and not as a processing aid carrier. However, if industry agree that there is no need to add such permissions for substances performing the technological purpose as processing aid carriers into the Code then FSANZ is comfortable removing them. It notes that permission has been added for use of silicon dioxide (also listed in CXG 10-1979) as an anti-caking agent food additive (not carrier) for nutrient preparations to ensure regulatory certainty.
	Noted that CCNFSDU have recently developed a framework for appraising the technological need/justification for foods additives in IF.	NZFS	FSANZ was aware of it and has made mention of it and the CCNFSDU conclusions for different food additives as part of its further evaluation of technological justification of food additives in IFP (see section 3.1), as well as in Appendix 2.
	Further investigations into the efficacy and safety of thickeners in IFP marketed as 'anti-reflux' is requested as it considers there is insufficient evidence to support their addition to prevent or reduce the impacts of reflux. If food additives do not provide a benefit infants should not be exposed to them. If there is a medical need to use such thickeners, then products should be categorised as SMPPI and only administered under medical supervision.	DA	The comment is noted and addressed via general discussion of technological justification in section 3.1. Additional discussion is provided for some of the individual food additives within section 3.3 addressing this question.
	Request that FSANZ evaluate the technological justification for permitting any new food additive into IFP, including SMPPi. It notes that technological justification is not the same as technological purpose and requires a conclusion of need and benefit to be made.	SAH	The comment is noted and addressed via general discussion of technological justification in section 3.1.
Processing aids: maintain status quo, no change to current approach, not to be considered further within P1028			
Yes, the preferred option is supported.	These submitters supported for the following reasons: • Support status quo	NZFS DAN INC	These comments are noted.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters did not support for the following reasons: • SAH noted that as IFP are a special food category they should require a specific assessment of processing aids used in their production, not a general assessment that applies across all food categories. • VIC considers the current treatment of processing aids for IFP has not considered the specific risks in infants, which is not consistent with the policy guideline. It requests that further work is undertaken to determine appropriate controls and assessment of processing aids used in the manufacture of IFP.	SAH VIC	This is the current situation; all assessment and approvals of processing aids are considered for their specific purpose and food categories, including infant formula products.

Appendix 2

More detailed summary of submissions and FSANZ responses for: SPECIFIC FOOD ADDITIVES

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
Infant formula products				
Calcium carbonates (170)	No permissions (NP), align Codex & EU	VIC		These comments are noted.
Delta-tocopherol (308) and gamma-tocopherol (309)	Had not been proposed	INC and industry		FSANZ is proposing to add permissions at 2nd CFS to be consistent with EU Regs for IFP, including SMPPi. These are alternative forms of tocopherols permitted in EU. See further explanation in section 3.3.2.
Calcium citrate (333)	Permit in nutrient prep, align EU, condition statement	VIC	INC, DAN & FCG: do not support need to have specific permission for nutrient carriers as already permitted as processing aid. Noted that proposed permissions are not consistent as some other carriers are not explicitly permitted. INC also propose should be permitted in all IFP since is a permitted mineral (nutrient).	Initial industry requests in submissions to CP1 2021 made to explicitly permit nutrient carriers to align with EU Reg. However, FSANZ is now comfortable not to include if industry state not needed. A permission as a nutrient is not a reason to permit a substance as a food additive since the technological purpose is also relevant, not just safety and presence (see fuller explanation in Appendix 1).
Phosphoric acid (338)	450 mg/L, align EU, condition statements	Acidity regulators: NZFS	Acidity regulators: INC support permissions but considers MPL of GMP appropriate for all IFP, consistent with EU Regs FC 13.1.5.1 (and draft Codex FUF std) VIC: support for SMPPi to align	Proposed MPL is consistent with EU Regs FC 13.1.1, which is not GMP. Note: EU MPL of 1000 mg/L as P_2O_5 is equivalent to 450 mg/L as phosphorus. It is included in the general discussion of technological justification in section

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
			EU and safety data. Seek technological justification for use in IFP, cf other acidity regulators	3.1.
Sodium phosphates (339) Potassium phosphates (340)	450 mg/L, align Codex, condition statements	Acidity regulators: NZFS VIC, with condition statements	Acidity regulators: INC support permissions but considers MPL of GMP appropriate for all IFP, consistent with EU Regs FC 13.1.5.1 (and draft Codex FUF std)	Consistent with EU Regs FC 13.1.1, singly or in combination, MPL is not GMP. FC 13.1.5.1 relevant for SMPPi not general IFP.
Calcium phosphates (341)	NP, align Codex & EU		INC: Why has permission for calcium phosphates (341), linked with sodium phosphates (339) and potassium phosphates (340) proposed in CP1 2021, which INC supported been removed in 1st CFS	Re-checking identified that 341 is not linked to 339 & 340 for EU Regs FC 13.1.1, but they are for FC 13.1.5.1 (relevant for SMPPi, see below).
Tricalcium phosphate (341 (iii))	70 mg/L, permit in nutrient prep, align EU, condition statement	VIC	INC, DAN & FCG: do not support need to have specific permission for nutrient carriers as already permitted as processing aid. Noted that proposed permissions are not consistent as some other carriers are not explicitly permitted.	Initial industry requests in submissions to CP1 2021 made to explicitly permit nutrient carriers to align with EU Reg. However, FSANZ is now comfortable not to include if industry state not needed.
Sodium alginate (401)	NP, align Codex & EU	DA, INC		The support for the proposed MPL is noted.
Locust bean (carob bean) gum (410)	Maintain, 1000 mg/L, align Codex	NZFS	NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. Plus,	Permission is already provided in the Code and no change is proposed, plus it is aligned to Codex. Therefore, no further assessment is required for use in IFP. See below for SMPPi discussion.

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
			question on safety. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision. VIC: unable to support unless clear technological justification is provided.	
Guar gum (412)	Maintain, 1000 mg/L, align Codex & EU, condition statement	DA, INC, NZFS	NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision. VIC: Do not support permission in IFP unless a clear technological justification is provided.	Permission is already provided in the Code and no change is proposed, plus it is aligned to Codex and EU. Therefore, no further assessment is required for use in IFP. See below for SMPPi discussion.
Xanthan gum (415)	NP, align Codex & EU	DA, INC		The support for the proposed MPL is noted.
Pectins (440)	NP, align Codex & EU	DA		The support for the proposed MPL is noted.
Sodium carboxymethylcellulose	NP, align Codex & EU	NSWFA, VIC		The support for the proposed MPL is noted.

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
(466)				
Citric and fatty acid esters of glycerol (472c)	7 500 mg/L (powder), 9 000 mg/L (liquid), align Codex & EU	DA, INC, NZFS, VIC, based on safety data and aligns with Codex & EU	NSWFA: what is the technological purpose for its use in IFP [and justification]	Aligns with Codex and EU Regs (Policy guidelines) for all IFP. Codex (CCNFSDU) permitted the food additive after considering safety and technological need (justification) at its 36th (2014) meeting (REP15/NFSDU)[13], for use in all IFP, with subsequent inclusion in CXS 72-1981. The technological justification for use as an emulsifier was that it retains homogeneity of the IFP.
Diacyltartaric and fatty acid esters of glycerol (472e)	Remove permissions, align Codex & EU	NZFS, NSWFA, VIC, consistent with Codex and EU, and due to lack of technological justification/need.	INC: It is permitted in US for some use in IFP, under 21 CFR 184.1101. No risk assessment justification of risk has been provided to support removal; it has been present in products sold globally for decades.	As noted in 1st CFS it is not permitted in Codex & EU for IFP. Plus, no technological justification or use levels have been provided supporting the case that it is required to be permitted in IFP for international trade (as was requested in 1st CFS). Section 184.1101 in the US CFR does not specifically reference IFP, but fats and oils, which may be an ingredient in IFP but that is no justification for FSANZ to change its proposal to remove permissions for IFP, due to lack of information provided to support permission.
Sucrose esters of fatty acids (473)	NP, align with Codex & EU	DA, INC		The support for the proposed MPL is noted.
Sodium carbonates (500)	2 000 mg/L each, align Codex, condition statements	VIC, including condition statements		The support for the proposed MPL is noted.
Potassium carbonates (501)				The support for the proposed MPL is noted.

[13] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-36%252FREP15_NFSDUe.pdf

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
Sodium hydroxide ((524)				
Potassium hydroxide (525)				
Calcium hydroxide (526)				
Starch sodium octenylsuccinate (1450)	NP, align with Codex & EU	DA, INC, NZFS VIC, support based on safety data and aligns Codex & EU		The support for the proposed MPL is noted.
Special Medical Purpose Products for infants (SMPPi)				
Calcium carbonates (170)	GMP, align EU Regs			
Phosphoric acid (338)	450 mg/L, align EU Regs, for pH adjustment only			
Sodium phosphates (339)	450 mg/L, align EU Regs, condition statements	INC, permission needed for three, 339, 340 & 341 to align with EU Regs FC 13.1.5.1.		This was identified and is proposed, see proposed drafting.
Potassium phosphates (340)				
Calcium phosphates (341)				
Sodium alginate (401)	1000 mg/L, align EU Regs, condition statement		NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP, and evidence of safety. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision.	SMPPi product, aligning with EU Regs to ensure import of products from EU for specific infants with specific conditions. The proposed permission is consistent with the DA request.

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
			VIC: Do not support permission in SMPPi without appropriate safety data and technological justification of need.	
Locust bean (carob bean) gum (410)	5000 mg/L, reduced cf EU Regs, condition statement	VIC, support at revised MPL of 5000 mg/L with condition statement for particular products. This aligns with safety data. Do not support FSANZ seeking industry information to justify increasing to higher MPL of 10000 mg/L consistent with EU, as safety data only provide evidence of tolerance up to 6000 mg/L.	INC: notes EU Regs FC 13.1.5.1 MPL is 10000 mg/L. It supports aligning with EFSA opinion once finalised. NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision.	SMPPi product, aligning with EU Regs (but with half the MPL i.e. 5000 mg/L; MPL for EU FC 13.1.5.1 is 10000 mg/L) to ensure import of products from EU for specific infants with specific conditions. Noted: FSANZ will aim to align with EFSA opinion once finalised. Safety concerns, lack of RA conclusions that MPL of 10000 mg/L is safe for infants. An industry submitter to CP1 2021 indicated 5000 mg/L was the upper level required for the technological purpose. The proposed permission is consistent with DA request. More detailed explanation on the technological purpose (as a thickener) and technological justification was provided within section 2.4.5 of CP1 2021 including the history of safe use provided by an industry submission.

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
Guar gum (412)	10000 mg/L, align EU Regs, condition statement		NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. It notes EFSA is re-evaluating its use for infants under 16 weeks, so seeking an update on safety evaluation. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision. VIC: do not support MPL of 10000 mg/L in the absence of safety assessment and evidence of technological need (justification).	SMPPi product, aligning with EU Regs (MPL for EU FC 13.1.5.1 is 10000 mg/L) to ensure import of products from EU for specific infants with specific conditions. The proposed permission is consistent with DA request.
Xanthan gum (415)	1000 mg/L, align Codex, condition statement 1200 mg/L, align EU Regs, condition statement		VIC: do not support MPL of 1200 mg/L, without evidence of use and safety in EU. Prefer single MPL of 1000 mg/L, where there are technological and trade harmonisation requirements. Having two categories could produce regulatory overlap and uncertainty. NSWFA: general request for further advice on food additives with technological purpose as	The MPL of 1200 mg/L is to ensure permission is consistent with EU for SMPPi to ensure import of products from EU for specific infants with specific conditions. The two different permissions are to ensure alignment with both Codex and EU so consistent with Policy Guidelines. They have been written for two specific types of SMPPi, but if there is an appropriate way of combining them into one single product that would be preferable.

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
			thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision.	FSANZ notes that Codex (CCNFSDU) developed the Information Document "CCNFSDU Framework for Appraising the Technological Need for Food Additives"[14]. It used this framework to assess and conclude the use of xanthan gum as a thickener in infant formulas for special medical purposes with the MPL of 1000 mg/L, for powdered hydrolysed protein and/or amino acid-based formula was technologically justified[15] .This provision was added into the Codex standard CXS 72-1981. The proposed permission is consistent with DA request.
Pectins (440)	2000 mg/L, align Codex, condition statement 5000 mg/L, align EU Regs, but with half the MPL, condition statement		NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. INC: notes the MPL in EU is 10000 mg/L, plus MPL of 10000 mg/L in draft Codex FUF std	FSANZ notes that Codex (CCNFSDU) developed the Information Document "CCNFSDU Framework for Appraising the Technological Need for Food Additives"[16]. It used this framework to assess and conclude the use of pectins as a thickener in infant formulas for special medical purposes with the MPL of 2000 mg/L, for liquid infant formula containing hydrolysed protein was technologically justified[17].

[14] https://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_NFSDU20_e.pdf
[15] REP20/NFSDU_Rev, paragraph 155, https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FReport%252FAdoption%252FREP20_NFSDUe_Rev.pdf
[16] https://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_NFSDU20_e.pdf
[17] REP20/NFSDU_Rev, paragraph 155, https://www.fao.org/fao-who-codexalimentarius/sh-

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
				This provision was added into the Codex standard CXS 72-1981. The 1st CFS noted EFSA 2021 information that the maximum use levels were below 5000 mg/L. Plus safety concerns, lack of RA conclusions that MPL of 10000 mg/L is safe for infants. FSANZ requested information on actual use levels in 1st CFS for FSANZ to change proposed MPL; this has not been received.
				SMPPi product, aligning with EU Regs (but with half the MPL; MPL for EU FC 13.1.5.1 is 10000 mg/L) to ensure import of products from EU for specific infants with specific conditions, but with lower MPL in response to safety concerns. Permissions are consistent with Codex and EU (with half of MPL) for SMPPi so consistent with Policy Guidelines. The proposed permission is consistent with DA request.
Sodium carboxymethylcellulose (466)	NP, align Codex	NSWFA, VIC		1st CFS requested industry information on current use and usage levels to consider changing its proposal not to permit. This has not been received. EFSA's re-evaluation in 2018 noted that no data were submitted for FC 13.1.5.1 and 13.1.5.2, thus it was concluded that sodium carboxymethylcellulose is not currently used in such products (cf SMPPi).

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FReport%252FAdoption%252FREP20_NFSDUe_Rev.pdf

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
				There is currently a lack of safety or technological justification information on use of the food additive in IFP, on which FSANZ can base proposing a permission on. The only justification we have is to align with EU Regs for SMPPi. Without justification for actual need and use this is not considered a reason to propose adding a permission. FSANZ is therefore not proposing to permit. EFSA was undertaking an assessment of use of the food additive in infant formula, infants under 16 weeks but this has not yet been reported. The 2014 CCNFSDU (36th) meeting concluded there was limited technological need for using the food additive in IFP, so it has not been considered further within Codex.
Mono- and diglycerides of fatty acids (471)	Was not discussed in 1st CFS, but proposed 5 000 mg/L to align EU Regs, with condition statement			
Sucrose esters of fatty acids (473)	120 mg/L, align EU Regs, condition statement		NSWFA: request for information on the technological purpose for its use in IFP [and justification] and evidence of safety, noting EFSA is evaluating use for infants under 16 weeks. VIC: does not support due to lack of safety assessment or technological justification.	SMPPi product, aligning with EU Regs to ensure import of products from EU for specific infants with specific conditions. More detailed explanation on the technological purpose (as an emulsifier) and technological justification was provided within section 2.4.11 of CP1 2021 including

Food additive (INS #)	Proposed MPL and conditions (1st CFS)	Support	Not support, comments	FSANZ response
				the history of safe use provided by an industry submission.
Starch sodium octenylsuccinate (1450)	20000 mg/L, align Codex and EU Regs, with condition statement	VIC, support based on safety data and aligns Codex & EU	NSWFA: general request for further advice on food additives with technological purpose as thickeners, so technological justification for efficacy to achieve the effect, specifically for anti-reflux IFP. DA: similar comments to NSWFA, with additional comment that if there is a medical need for using such thickeners the products should be SMPPi and only administered under medical supervision.	The proposed permission aligns with Codex and EU so consistent with Policy Guidelines. SMPPi product, aligning with EU Regs to ensure import of products from EU for specific infants with specific conditions. The proposed permission is consistent with DA request. Codex (CCNFSDU) permitted the food additive after considering safety and technological need (justification) at its 36th (2014) meeting (REP15/NFSDU[18]), for hydrolysed protein and/or amino acid based informal formula only, with subsequent inclusion in CXS 72-1981. The technological justification for use as a thickener was that it retains homogeneity of hydrolysed protein and/or amino acid based infant formula only (SMPPi).

[18] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-36%252FREP15_NFSDUe.pdf

Appendix 3

Summary of submitter comments & FSANZ response related to: CONTAMINANTS

Issue	Comment	Submitter(s)	FSANZ Response
List the contaminant MLs for infant formula products as consumed, and as mg/kg for consistency			
Yes, the preferred option is supported.	These submitters supported for the following reasons: • Supported for reasons outlined in 1st CFS, noting it is consistent with international requirements/regulations. • FCG and INC prefers MLs applied on a powder basis for more practical implementation, however, they can support aligning with Codex, being mg/kg as consumed. INC uses the units mg/L and notes inconsistent units are listed in the report. • Support since it is consistent with Codex.	SAH DAN FCG NZFS INC VIC	These comments are noted. The comments about consistency of units are noted and have been corrected in the 2nd CFS and this report. As drafting was being considered it was realised that the term 'as consumed' is not required as MLs for contaminants are written for the food 'that is ordinarily consumed' due to subsection 1.4.1—2(1). This same intent is explicitly listed for infant formula products by paragraph 2.9.1—4(1)(a), where 'compositional requirements in this standard apply to a powdered or concentrated form of infant formula product that has been reconstituted with water according to directions'.
Other issues raised.	There was support for the preferred option to change the units of ML to mg/kg as consumed, but with questions and comments. It queried the technical justification for changing the units of liquid (usually mg/L, i.e. mass/volume) IFP prepared from powder (mg/kg, mass/mass), without considering technical matters: – Density or dilution factor to convert mass/volume to mass/mass – Has a density of the liquid prepared IFP been assumed to be 1 kg/L (1 g/mL)? – 'Wet weight' used as a unit qualifier in EU Reg No 2021/1323.	QLDH	These comments are noted. For the purposes of MLs noting the lack of required accuracy of such figures FSANZ notes that a simple approximation of the density of the prepared liquid IFP of 1 g/mL is appropriate as further accuracy is not necessary or required. The units in the Code for MLs in Schedule 19 are mg/kg and there is a need to maintain consistency by using these same units and not as 'wet weight' as per the EU Regulations.

Issue	Comment	Submitter(s)	FSANZ Response
	Consistency of units within the report and therefore future drafting has been identified and noted.		The comments about consistency of units are noted and have been corrected in the 2nd CFS and this report and already changed in the proposed drafting for Schedule 19 (default units are mg/kg). This applies to the removal of the aluminium ML from Standard 2.9.1 to Schedule 19.
Support the amendments proposed for MLs, for lead and aluminium only			
Yes, the preferred option is supported.	These submitters supported the reduction in the ML for lead for the following reasons: • DAN and INC supports reducing the lead ML from 0.02 mg/kg down to 0.01 mg/kg [listed as mg/L in submissions] • QLDH supports revising the ML for lead [incorrectly listed as 20 to 10 mg/L, this may have been a transcription error of using mg rather than µg] as this is consistent with EU Commission Regulation (EC) No 2021/1317	DAN NZFS QLDH INC VIC	These comments are noted.
No, the preferred option is not supported.	These submitters did not support a single ML for aluminium including for soy based IF for the following reasons: • DAN and INC do not support reducing the aluminium ML for soy down from 0.1 mg/100 mL to 0.05 mg/100 mL [1 mg/kg to 0.5 mg/kg]. This is because the reduced ML may not always be met due to varying natural levels in soy ingredients. Soy being a plant takes up aluminium from the soil and natural levels may vary, more so than in cow's milk where the aluminium level in the plant feed can be reduced by the cow's liver. • This could produce an availability issue for caregivers wishing to source a plant based IFP, such as from soy. • FCG and INC reaffirms its previous position which is to align with Codex which has not set an ML for aluminium in IFP, which is also consistent with the EU and USA regulations.	DAN FCG DA INC	These comments are noted. FSANZ had considered the issue and these same arguments from industry in its discussion in section 5.2.3 of the 1st CFS. No new information has been provided to require it to change its original proposal, which is to retain a single ML for aluminium of 0.5 mg/kg for IFP including soy-based products.
The submitter provides a new	These submitters proposed alternative changes (i.e. other than status quo or the proposed option) for the following reasons:	QLDH	FSANZ notes there appears to be a units issue, where the MLs as listed are out by a factor of 1000. It is possible that the units were

Issue	Comment	Submitter(s)	FSANZ Response
proposed option.	• QLDH proposed that some additional MLs needed for inorganic arsenic (iAs, being the sum of As III and As V) (for hydrolysed rice protein based IFP) and cadmium. • The justification for establishing iAs MLs is for rice-based products due to the higher levels in rice compared to cow's milk or other grain-based infant formula, and potential safety concerns due to inorganic arsenic. The same safety concerns were raised for cadmium (references provided). • It proposes adopting a cadmium ML comparable to Europe due to Commission Regulation (EU) No 2021/1323. It mentioned 40 mg/kg wet weight for processed cereal-based foods and baby foods for infants and young children [listed as 0.04 mg/kg wet weight]. But these are not IFP or SMPPi. The more comparable MLs are within food category 3.2.1.16 with MLs of units of mg/kg wet weight for cow's protein or milk hydrolysates, as powder (0.01 mg/kg) or liquid (0.005 mg/kg); or soya protein alone or with cow's milk protein as powder (0.02 mg/kg) or liquid (0.01 mg/kg). • It proposes an iAs ML of 100 mg/kg (wet weight) as consumed for IFP, follow-on formula and SMPPi. It is thought that the proposed units may actually be 0.1 mg/kg as consumed due to the differences noted in earlier figures. It notes the proposed ML is comparable to the Codex recognition of increased risk presented by rice-based foods and the 200 mg/kg ML [incorrectly written, it is actually 0.2 mg/kg for polished rice], along with the USFDA for rice-based formula (from 2021 Baby Food Safety Act) ML of 10 µg/kg or 0.01 mg/kg [not as written as 10 mg/kg] for infant and toddler food (not cereal based). • DA supports considering requiring a ML for arsenic, especially for rice based IFP due to the popularity of such products and the higher levels of arsenic in rice and the safety concerns (references provided). It recommends FSANZ carefully monitor trends in rice based IFP and take a conservative approach to arsenic ML for IFP to protect infant health and safety.	DA	meant to be written as µg/kg (ppb) not as mg/kg (ppm). The US Baby Food Safety Act of 2021 has not yet been gazetted, but it does include infant formula. In addition, the US FDA is undertaking work on MLs for arsenic, lead, cadmium and mercury on 'foods eaten by babies and young children' but this work has not been completed. This work does apply to IFP and SMPPi. FSANZ has information on inorganic arsenic in a selection of foods including white rice in its 25th Australian Total Diet Study (foodstandards.gov.au). FSANZ also contributed to targeted analytical survey work coordinated by the NZ MPI on inorganic arsenic in rice-based products commonly consumed by infants and children. The results of this work were published in the report 'Inorganic Arsenic in Rice and Rice Products in New Zealand and Australia' https://doi.org/10.1080/19393210.2019.1651403. Three Australian samples of rice-based infant formula were analysed with levels of inorganic arsenic below the limit of detection (0.02 mg/kg). Therefore, at this stage FSANZ does not have any evidence to support requiring a ML for iAS in IFP. FSANZ addressed the issue of the EU establishing a ML for cadmium in the 1st CFS and it re-affirms its proposed option not to apply a ML for cadmium. Evidence from Australian and New Zealand total diet studies

Issue	Comment	Submitter(s)	FSANZ Response
			indicates that levels of cadmium in infant formula (non-soy-based) are low. In particular, for the 25th ATDS, 4 samples of infant formula were analysed for cadmium with nil detections. There is no Australian or New Zealand data available for cadmium in soy-based products to inform the establishment of an appropriate ML. Codex does not have a ML for inorganic arsenic (or cadmium) for IFP or SMPPi. Therefore, at this stage FSANZ does not propose to require a ML for cadmium and inorganic arsenic. However, it will continue to monitor contaminants work for IFP at Codex and in the USA.
Other issues raised.	It noted the lack of evidence to support MLs in IFP for cadmium, aflatoxin B1 & M1, ochratoxin A, polycyclic aromatic hydrocarbons, perchlorate, chloropropanol and glycidol and their esters. It noted this might raise concerns and public perceptions that Australia [and New Zealand] would accept IFP rejected by other countries where such MLs exist.	NSWFA	This is the same issue raised in earlier submissions and addressed in SD1 of 1st CFS. FSANZ repeats its response, which is to have regard to the guiding principles for setting MLs (discussed in section 4.2.5 of SD1 of 1st CFS). FSANZ has not received any advice from NSWFA or other enforcement agencies indicating that the importation of rejected EU IFP is occurring.
	It supported FSANZ's proposed approach for MLs for acrylonitrile, aluminium, arsenic, lead, melamine, tin and vinyl chloride. However, it did not support the proposal not to establish MLs for aflatoxin B1 & M1 [listed as B2], ochratoxin A, polycyclic aromatic hydrocarbons, perchlorate, chloropropanol and glycidol and their esters. The concern was that doing so does not anticipate or address future challenges or emerging safety concerns. It mentions the likely increase in aflatoxin contamination linked to climate change and rising temperatures, and the potential increase in use of plant proteins as sources of IFP, and the increased risk of mycotoxins. It suggests aligning with EU MLs for these substances. It also suggests aligning with EU MLs for powdered IFP for glycidyl esters, based on JECFA work and FSANZ analytical results.	VIC	This is the same issue raised in earlier submissions and addressed in SD1 of the 1st CFS. FSANZ repeats its response, which is to have regard to the guiding principles for setting MLs (discussed in section 4.2.5 of SD1 of 1st CFS). FSANZ's repeats it responses to consideration of MLs for these contaminants as provided within the relevant sections of SD1 of the 1st CFS. It has not changed its conclusions and approach.

Appendix 4

Risk Assessment of additional food additives

Introduction

The purpose of this appendix is to assess the safety of four additional food additives, that do not currently have specific permissions in the Code for use as food additives in Follow-on Formulas for infants. These additions are required because Codex has split the Follow-Up Formula (FUF) standard into 2 parts; Part A older infants 6-12 months (which is within scope of Proposal P1028), and Part B older children (outside the scope of P1028). The food additives are:

- ascorbic acid, L (L-ascorbic acid) (INS No. 300)
- sodium ascorbate (INS No. 301)
- calcium ascorbate (INS. No. 302)
- acetylated distarch adipate (INS No. 1422)

In addition, a risk assessment has been conducted for:

- gamma-tocopherol (INS 308) and delta-tocopherol (INS 309) are currently permitted in the Code for food class 0 (food additive preparations) and 2 (edible oils and oil emulsions) at GMP. They are not currently permitted for addition to infant formula products and SMPPi. FSANZ is proposing to permit both gamma-tocopherol (308) and delta-tocopherol (309) for addition to IFP, follow-on formula and SMPPi along with the current permission for tocopherols concentrate, mixed. An MPL of 10 mg/L is proposed for gamma-tocopherol and delta-tocopherol.

- Guar gum is listed in Schedule 15 of the Code for use as a food additive in infant formula products at an MPL of 1000 mg/L. It is also a permitted food additive at GMP in Section 16—2. FSANZ is proposing to permit guar gum for use in SMPPi at a maximum permitted level of 10,000 mg/L for extensively hydrolysed protein formulas, to align with the EU.

- Sodium alginate is not permitted in the Code for infant formula products, nor is it permitted for use in infant formula by Codex. It is permitted as a food additive at GMP in Section 16—2 of the Code. FSANZ is proposing to align with EU regulations and permit sodium alginate in the Code for SMPPi at a MPL of 1000 mg/L, specifically for products suitable for infants from four months onward in special food products with adapted composition, required for metabolic disorders and for general tube-feeding.

Ascorbic acid and ascorbates

L-Ascorbic acid, sodium ascorbate and calcium ascorbate are approved in the Code as forms of Vitamin C for infant formula products and food for infants, together with potassium ascorbate and L-ascorbyl palmitate (Section 29—7).

Codex permissions

L-Ascorbic acid is permitted in the Codex General Standard for Food Additives (GSFA) as an acidity regulator, antioxidant, flour treatment agent and sequestrant. Sodium ascorbate and calcium ascorbate are permitted as antioxidants. For most food classes for which these additives are permitted the maximum level is GMP; that is, limited only by Good Manufacturing Practice. The lowest maximum level specified in the GSFA for the three additives, singly or in combination with each other or with ascorbyl palmitate (INS No. 304),

is 50 mg/kg ascorbic acid equivalent (on a ready-to-eat basis) in follow-up formulae, and only as antioxidants. L-ascorbic acid is permitted at up to 500 mg/kg in complementary foods for infants and young children, again only as an antioxidant. Sodium ascorbate is also permitted at up to 500 mg/kg (as ascorbic acid) in complementary foods for infants and young children, subject to limits on sodium specified in other standards for canned baby foods and processed cereal-based foods for infants and young children. Calcium ascorbate is permitted at up to 200 mg/kg ascorbic acid-equivalent in complementary foods for infants and young children, excluding products conforming to the Standard for Canned Baby Foods (Codex Alimentarius GSFA Online, 2019).

Other numerical maximum levels for L-ascorbic acid in the GSFA are for fresh pasta, noodles and like products (200 mg/kg); flours (300 mg/kg); and Untreated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses, and legumes [(including soybeans)], and aloe vera), seaweeds, and nuts and seeds (500 mg/kg). Other numerical limits for sodium ascorbate in the GSFA are 200 mg/kg in dried pastas, noodles and like products, and 300 mg/kg in flours. Another numerical maximum limit for calcium ascorbate in the GSFA is 200 mg/kg in dried pastas, noodles and like products (Codex Alimentarius GSFA Online, 2019).

JECFA evaluations

The most recent JECFA evaluation of ascorbic acid and some salts of the acid as antioxidants was in 1981. At this time, the Committee concluded that the ADI for ascorbic acid and its potassium and sodium salts should be changed from 0-15 mg/kg bodyweight to “not specified” and that calcium ascorbate should be included in this acceptance. While noting that the use of the calcium salt in large amounts could increase the risk of crystalluria and formation of calcium oxalate stones, the Committee concluded that the use of calcium ascorbate for food-additive and nutritional use would represent only a small fraction of the total dietary calcium intake and therefore the use of calcium ascorbate does not require any special restriction (JECFA 1981).

Additional reviews

A recent review (Doseděl et al. 2021) notes that ascorbic acid is of low toxicity in humans. A single oral dose of ascorbic acid of 5–10 g may be associated with transient effects of osmotic diarrhoea, abdominal bloating with pain, and/or polyuria.

Assessments by other regulatory agencies

EFSA published a re-evaluation of ascorbic acid, sodium ascorbate, and calcium ascorbate as food additives in 2015. They noted that ascorbic acid and its salts are of very low acute toxicity and had negligible effect in short-term animal studies, and only at high doses; that there are no concerns for genotoxicity; that long-term carcinogenicity assays in animals showed no evidence of chronic toxicity or carcinogenicity; and that there was no evidence of developmental effects. The Panel concluded that there is no need for a numerical ADI for ascorbic acid and its salts as food additives (EFSA 2015a).

The Cosmetic Ingredient Review (CIR) Expert Panel conducted a safety assessment of L-ascorbic acid, calcium ascorbate, magnesium ascorbate, magnesium ascorbyl phosphate, sodium ascorbate, and sodium ascorbyl phosphate for use in cosmetics. They noted that ascorbic acid at up to 100,000 ppm was well tolerated in 13-week dietary studies in rats and mice; that a 2-year gavage study in rats produced no toxicity at up to 2000 mg/ ascorbic acid/kg bw/day; that ascorbic acid at up to 1000 mg/kg bw produced no maternal toxicity, teratogenesis or fetal toxicity in mice or rats; that neither ascorbic acid or sodium ascorbate is genotoxic; that ascorbic acid was not carcinogenic in mice or rats at doses up to 50,000 ppm; and that sodium ascorbate may act as a promoter of urinary carcinoma. The Panel considered that data from one test article could be extrapolated to all of them, and that the apparent promotion of urinary carcinoma by sodium ascorbate was most likely attributable to effects on urinary sodium ion concentration and urinary pH (Elmore 2005).

Conclusion

L-Ascorbic acid, sodium ascorbate and calcium ascorbate are approved in the Code as additives permitted in processed foods (Section 16—2) and as forms of Vitamin C for infant formula products and food for infants (Section 29—7). Schedule 29 specifies that the minimum amount of vitamin C (ascorbic acid) in infant formula and follow-on formula must be 1.7 mg/100 kJ (Section 29—9) while the maximum amount of Vitamin C permitted in infant formula products is 5.4 mg/100 kJ (Section 29—10).

L-Ascorbic acid, sodium ascorbate and calcium ascorbate have been evaluated as food additives by JECFA. The Committee 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. No new evidence to contradict this conclusion has been located.

FSANZ considers that permitting L-ascorbic acid, sodium ascorbate and calcium ascorbate as food additives in follow-on formulas at GMP, and within the range of Vitamin C indicated by the maximum and minimum concentrations of Vitamin C in Schedule 29, does not pose toxicological concerns.

Acetylated distarch adipate (INS No.1422)

Codex permissions

Acetylated distarch adipate is permitted in the GSFA as an emulsifier, stabilizer, and thickener. For most food classes for which this additive is permitted, the maximum level is GMP. There are two numerical maximum levels; for soy-based follow-up formulae and for complementary foods for infants and young children.

The maximum level in soy-based follow-up formulae is 5,000 mg/kg on a ready-to-eat basis, singly or in combination with distarch phosphate (INS No.1412), phosphate distarch phosphate (INS No.1413), and/or acetylated distarch phosphate (INS No. 1414) in products conforming to the Standard for Follow-Up Formula (CODEX STAN 156-1987). An exception is made for use in hydrolysed protein and/or amino acid-based formula at 25,000 mg/kg.

The maximum level in complementary foods for infants and young children is 50,000 mg/kg, singly or in combination with other modified starches used as thickeners in products conforming to the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981). It is noted in the GSFA that it may be used at 60,000 mg/kg, singly or in combination with other starch thickeners in products conforming to the Standard for Canned Baby Foods (CODEX STAN 73-1981) (Codex Alimentarius GSFA Online, 2019).

JECFA evaluations

The most recent JECFA evaluation of acetylated distarch adipate as a stabilizer, thickening agent and binder was in 1982, when the Committee assigned an ADI of "not specified" to this and a number of other modified starches (JECFA 1982).

Additional studies

No new studies concerning the safety of acetylated distarch adipate were located by literature search.

Assessments by other regulatory agencies

In 2017, EFSA published a re-evaluation of twelve modified starches, including acetylated distarch adipate, as food additives. EFSA used a read-across approach to assess all twelve compounds, in the basis that modified starches are extensively hydrolysed by intestinal enzymes, and then fermented by intestinal microbes. Through the read-across approach,

sufficient data were available on short and long-term toxicity, carcinogenicity, and reproductive/developmental toxicity. They concluded that modified starches are not of genotoxic concern. No treatment-related effects relevant to humans were observed in rats fed up with 31 mg/kg bw/day of modified starch, and a modified starch (starch sodium octenyl succinate) was well tolerated in humans at up to a single dose of 25,000 mg (25 g). The Panel concluded that there are no safety concerns associated with the use of modified starches as food additives, and a numerical ADI is not required (EFSA 2017a).

Conclusion

Acetylated distarch adipate is approved in the Code as an additive permitted at GMP (Section 16—2).

Acetylated distarch adipate is one of a number of modified starches that have been evaluated as food additives by JECFA and assigned an ADI of “not specified”. No new evidence to contradict this conclusion has been located.

FSANZ considers that permitting acetylated distarch adipate as a food additive in follow-on formulas, in alignment with Codex permissions, does not pose toxicological concerns.

Gamma-tocopherol (INS 308) and delta-tocopherol (INS 309)

Assessments by other agencies

JECFA has not evaluated gamma-tocopherol or delta-tocopherol to date.

JECFA has established a group ADI of 0.15–2 mg/kg bw/day for dl-alpha-tocopherol and d-alpha-tocopherol concentrate, singly or in combination (WHO 1987). The ADI was based on clinical experience in humans and taking into account that α-tocopherol is an essential nutrient.

EFSA completed a re-evaluation of tocopherol-rich extract (E 306), alpha-tocopherol (E 307), gamma-tocopherol (E 308) and delta-tocopherol (E 309) as food additives in 2015 (EFSA 2015b). EFSA noted that tocopherols belong to the group of substances named vitamin E. Vitamin E is an essential vitamin and is naturally present in plant-derived foods, particularly fruit and vegetables.

EFSA considered that while data on gamma-tocopherol and delta-tocopherol are limited, the results from toxicity studies on alpha-tocopherol can be read across to the other tocopherols. This is based on similarities in the chemical structure and because alpha-tocopherol represents a worst case, as it is the form the body selectively retains.

EFSA concluded the available data were too limited to establish an ADI for the tocopherols. However, taking into account vitamin E is widely consumed via human food, is an essential nutrient and upper levels are not exceeded in any population group in the EU, except children in one survey from only one country, tocopherols are not of safety concern at the levels used in food. EFSA noted that the re-evaluation did not apply to infants under the age of 12 weeks, however.

Conclusion

Tocopherols concentrate, mixed is already permitted to be added to IFP at up to 10 mg/L. While gamma-tocopherol and delta-tocopherol are not currently permitted for addition to IFP, they are all forms of the essential nutrient vitamin E and results from toxicity studies on alpha-tocopherol also apply to gamma-tocopherol and delta-tocopherol.

On this basis, the addition of gamma-tocopherol or delta-tocopherol to IFP is not expected to be a safety concern, provided that the total amount of vitamin E present is within the minimum and maximum amounts set out in Section 29—9 of the Code.

Guar gum (INS 412)

Assessments by other agencies

Guar gum has been evaluated by JECFA, and an acceptable daily intake (ADI) 'not specified' was established based on a lack of adverse effects in the toxicity studies available at that time (WHO 1975). Use in infant formula was not specifically addressed in this evaluation. EFSA re-evaluated guar gum in 2016 and concluded there is no need for a numerical ADI for guar gum (EFSA 2017b). EFSA noted that guar gum is practically undigested and not absorbed intact, but significantly fermented by gastrointestinal bacteria in humans. No adverse effects were reported in subchronic and carcinogenicity studies at the highest dose tested, and there was no concern regarding genotoxicity. Oral intake of guar gum was well tolerated in adults.

EFSA's re-evaluation of guar gum did not consider infants under the age of 12 weeks, and EFSA has subsequently issued a call for information for data to support a risk assessment for the use of guar gum in food intended for infants below 16 weeks of age.

For infants over 12 weeks, EFSA noted there were no specific clinical data available addressing the safety of guar gum in 'dietary foods for infants for special medical purposes and special formulae for infants' and in 'dietary foods for baby and young children for special medical purposes' at the defined maximum use levels. EFSA noted that given their medical condition, infants and young children consuming foods in these categories may show a higher susceptibility to the gastrointestinal effects of guar gum than their healthy counterparts. Monitoring of any adverse effects including those in the gastrointestinal system in infants and young children consuming these foods under medical supervision could be helpful to reduce this uncertainty. Overall, EFSA concluded the available data do not allow an adequate assessment of the safety of guar gum in infants and young children consuming these foods for special medical purposes.

Conclusion

A contemporary safety assessment of the use of guar gum in infant formula and SMPPi including consideration of safety studies in an appropriate neonatal animal model is not currently available. However, there appears to be a history of use in such foods in the EU, with a MPL of 10,000 mg/L. Children consuming these foods would also be expected to be under medical supervision.

Sodium alginate (INS 401)

Assessments by other agencies

JECFA last assessed alginic acid and its ammonium, calcium, potassium and sodium salts at its 49th meeting. JECFA allocated a group ADI "not specified", but pointed out that laxative effects might occur at a high level of intake (WHO 1992). Use in infant formula was not specifically addressed in the evaluation.

EFSA re-evaluated alginic acid and its sodium, potassium, ammonium and calcium salts as food additives in 2017 (EFSA, 2017c). EFSA concluded there was no need for a numerical ADI for these substances. EFSA noted that for higher therapeutic daily doses corresponding to 417–834 mg sodium alginate/kg bw in the treatment of infants and young children for

gastric reflux, reported side-effects were gastrointestinal disorders including rare formation of intragastric ‘mass’. EFSA concluded that exposure of infants and young children to alginic acid and its salts from the use of these food additives should stay below therapeutic dosages at which side-effects could occur.

EFSA stated the available data did not allow an adequate assessment of the safety of alginic acid and its salts for infants consuming ‘dietary foods for special medical purposes and special formulae for infants’, based on a lack of adequate studies addressing the safety of use of alginic acid and its salts in this population under certain medical conditions.

Conclusion

A recent safety assessment of the use of sodium alginate in SMPPi is not currently available. However, there appears to be a history of use in such foods in the EU, with a MPL of 1000 mg/L. Children consuming these foods would also be expected to be under medical supervision.

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