## CODEX ALIMENTARIUS COMMISSION







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Agenda Item 5(a)

CX/FA 18/50/7 November 2017

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

**Fiftieth Session** 

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): PROVISIONS WITH COMMENT FROM CCPFV AND CCFO; PROVISIONS FOR LUTEIN ESTERS FROM TAGETES ERECTA AND OCTENYL SUCCINIC ACID (OSA)-MODIFIED GUM ARABIC; PROVISIONS ASSOCIATED WITH NOTE 22 IN FC 09.2.5; PROVISIONS WITH STABILIZER FUNCTION IN FC 01.1.1; PROVISIONS FOR TRISODIUM CITRATE IN FC 01.1.1; PROVISIONS IN TABLE 1 AND 2 OF THE GSFA IN FOOD CATEGORIES 09.0 THROUGH 16.0; PROPOSED DRAFT PROVISIONS IN FC 01.1.2 (REPORT OF THE EWG ON THE GSFA)

Prepared by the United States of America with the assistance of Argentina, Brazil, Canada, Chile, China, Columbia, European Union, India, Indonesia, Israel, Japan, Malaysia, New Zealand, Norway, Poland, Russian Federation, Singapore, Switzerland, European Food Emulsifier Manufacturers Association (EFEMA), European Chemical Industry Council – (CEFIC), EU Specialty Food Ingredients, FoodDrinkEurope, Global Organization for EPA and DHA Omega-3s (GOED), International Association of Color Manufacturers (IACM), International Alliance of Dietary/Food Supplement Associations (IADSA), International Council of Beverages Associations (ICBA), International Chewing Gum Association (ICGA), International Council of Grocery Manufacturer Associations (ICGMA), International Dairy Federation (IDF), International Food Additives Council (IFAC), International Fruit and Vegetable Juice Association (IFU), International Special Dietary Foods Industries (ISDI), and Natural Food Colours Association (NATCOL)

## Introduction

- 1. CCFA49 agreed to establish an EWG to provide recommendations to CCFA50 on the following topics:1
- (i) Replies of CCPFV and CCFO (REP 17/FA paras. 14(i) and 16);
- (ii) Proposed draft provisions for lutein esters from Tagetes erecta (INS 161b(iii)) and octenyl succinic acid (OSA)-modified gum arabic (INS 423) in Table 3 (REP 17/FA paras. 30 and 108(iii), Appendices II and VIII Part A);
- (iii) Provisions for food additives with Note 22 in FC 09.2.5 (comments for use in smoked fish paste) (REP 17/FA para. 74);
- (iv) Provision for trisodium citrate in FC 01.1.1 (comments on technological need for a numerical use level or GMP) (REP 17/FA para. 78);
- (v) Provisions related to FC 01.1.1 listed in CCFA49 CRD2 Annex 3 Part B (comments on technological need for the specific additive, the specific type of food products within the FC where the food additive is used and the ML necessary to reach the function of stabilizer) (REP 17/FA para. 81);
- (vi) Draft and proposed draft provisions in the GSFA in FC 09.0 to FC 16.0, with the exception of those additives with technological functions of colour or sweetener, adipates, nitrites and nitrates, and the provisions related to FC 14.2.3;
- (vii) Proposed draft provisions related to FC 01.1.2 with the exception of food additives provisions with the function of colour and sweetener.

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<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

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## **Working Documents**

2. The working documents for the report of the EWG on the General Standard for Food Additives are presented as appendices to this document. The appendices provide background on the topic under discussion, collate comments on the topic from the EWG, and provide recommendations for each topic.

- Separate appendices are presented for topic i (Appendix 1), topic ii (Appendix 2), topic iii (Appendix 3), topic vi (Appendix 5), and topic vii (Appendix 6).
- For reasons of efficiency,  $\underline{topics\ iv}$  and  $\underline{topic\ v}$  are combined into Appendix 4.

## Appendix 1: Replies of Codex Committee on Processed Fruits and Vegetables (CCPFV) and Codex Committee on Fats and Oils (CCFO)

- Among several topics, CCFA49 requested the EWG on the GSFA to CCFA50 to consider:
- Replies of Codex Committee on Processed Fruits and Vegetables (CCPFV) and Codex Committee on Fats and Oils (CCFO)

## Background:2

- 2. CCFA47 compiled proposals on existing draft and proposed draft provisions in Tables 1 and 2 of the GSFA for food additives with "Emulsifier, stabilizer, thickener" function for their use for technological function other than as emulsifier, stabilizer, or thickener.<sup>3</sup> The physical Working Group (PWG) on the GSFA to CCFA47 discussed the proposals of the EWG.<sup>4</sup> During discussion of provisions for food categories 02.1.2 (Vegetable oils and fats) and 02.1.3 (Lard, tallow, fish oils, and other animal fats), the WG noted uncertainty as to the technological justification for the use of antioxidants in food category 02.1.2 and sequestrants in food categories 02.1.2 and 02.1.3. It was noted that there is a full correspondence between food category 02.1.2, 02.1.3, and their corresponding commodity standards.
- 3. CCFA47 agreed to hold specific provisions at their current step and request clarity on the technological justification from the Codex Committee on Fats and Oils (CCFO) on:
- a. The use of antioxidants in general and lecithin (INS322(i)) in particular in food category 02.1.2;
- b. The use of tricalcium citrate (INS 333(ii)) and tripotasium citrate (INS 332(ii)) in products conforming to the Standards for Edible Fats and Oils not Covered by Individual Standards (CODEX STAN 19-1981), for Olive Oils and Olive Pomace Oils (CODEX STAN 33-1981) and for Named Vegetable Oils (CODEX STAN 210-1999);
- c. The use of lecithin (INS 332(i)) in products conforming to the Standards for Edible Fats and Oils not Covered by Individual Standards (CODEX STAN 19-1981) and for Named Animal Fats (CODEX STAN 211-1999);
- d. The use of mono- and diglycerides of fatty acids (INS 471) in products conforming to the *Standard for Edible Fats and Oils not Covered by Individual Standards* (CODEX STAN 19-1989) and in fish oils;
- e. The use of potassium dihydrogen citrate (INS 332(i)), sodium dihydrogen citrate (INS 331(i)), tricalcium citrate (INS 333(iii)), tripotassium citrate (INS 332(ii)), trisodium citrate (INS 331(iii)) and sodium alginate (INS 401) in fish oils.
- 4. The EWG on the GSFA to CCFA48 compiled proposals on existing draft, and proposed draft provisions in Tables 1 and 2 of the GSFA in food categories 01.2 through 08.4, with the exception of provisions for food additives with "colour" or "sweetener" function.<sup>5</sup> The PWG on the GSFA to CCFA48 discussed the proposals of the EWG.<sup>6</sup>
- a. During discussion of provisions for the use of specific emulsifiers and acidity regulators in food categories 02.1.2 (Vegetable oils and fats) and 02.1.3 (Lard, tallow, fish oil and other animal fats), it was noted that there is a full correspondence between these food categories and the corresponding commodity standards and that emulsifiers and acidity regulators were not allowed in the corresponding commodity standards. However, several members noted that emulsifiers and acidity regulators are used in products included in food categories 02.1.2 and 02.1.3.

<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

<sup>&</sup>lt;sup>2</sup> This document discusses provisions for which CCFA47 or CCFA48 requested guidance from CCPFV or CCFO. This document only includes provisions which are in the mandate of the eWG: it does not discuss provisions which are still under review by CCFO (see CX/FA 17/49/2 Add. 1), or for which CCFA49 requested further guidance from CCPFV (see REP 17/FA, para 14(ii), (iii)).

<sup>&</sup>lt;sup>3</sup> CX/FA 15/47/8

<sup>&</sup>lt;sup>4</sup> FA/47 CRD2

<sup>&</sup>lt;sup>5</sup> CX/FA 16/48/7

<sup>&</sup>lt;sup>6</sup> FA/48 CRD2

- b. During the discussion of proposed provision for Tocopherols (INS 307a, b, c) in food category 04.1.2.2 (Dried fruit), certain members noted that this food additive is used as an antioxidant in all subcategories of 04.1.2 (Processed fruit). However, other members noted that it was unclear how this technological justification corresponded to the use of Tocopherols in processed fruit in general, and in the commodity standards corresponding to the subcategories of food category 04.1.2.
- c. During the discussion of proposed provisions for Tartrates (INS 334, 335(ii), 337) in food categories 04.1.2.2 (Dried fruit), 04.1.2.3 (Fruit in vinegar, oil or brine), and 04.1.2.6 ((Fruit based spreads (e. g. chutney) excluding products of food category 04.1.2.5), it was noted that Tartrates are used as an acidity regulator in the standardized and non-standardized products in these food categories. However, the pWG also noted that the commodity standards corresponding to food category 04.1.2.2 do not allow acidity regulators and that Tartrates are not listed in commodity standards corresponding to food categories 04.1.2.3 and 04.1.2.6.
- d. During the discussion on the provisions for Propylene glycol alginate (INS 405) in food category 04.1.2.5 (Jams, jellies, marmalades), concerns were raised on its use as thickener in food products falling under this food category as the corresponding commodity standard (Codex Standard for Jams, Jellies and Marmalades (CODEX STAN 296-2009)) only allows Table 3 thickeners.
- 5. CCFA48 agreed to hold specific provisions at their current step and request clarity on the technological justification of the related additive from the corresponding commodity committee<sup>7</sup>:
- a. Codex Committee on Fats and Oils (CCFO) for guidance on the use in food categories:
  - i. 02.1.2 "Vegetable fats and oils", of: acidity regulators in general and tartrates (INS 334, 335 (ii), 337) specifically;
  - ii. 02.1.3 "Lard, tallow, fish oil, and other animal fats", of: emulsifiers in general and polyglycerol esters of fatty acids (INS 475), polyglycerol esters of interesterified ricinoleic acid (INS 476) and propylene glycol alginate (INS 405) specifically; and tartrates (INS 334, 335 (ii), 337) as acidity regulators
- b. Codex Committee on Processed Fruits and Vegetables (CCPFV) on the use in food categories:
  - i. 04.1.2 "Processed fruit", of: antioxidants in processed fruit in general and the use of Tocopherols (INS 307a, b, c), specifically in standardized and non-standardized foods for all subcategories;
  - ii. 04.1.2.3 "Fruit in vinegar, oil or brine", of: Tartrates (INS 334, 335(ii), 337) as acidity regulators in products conforming to the *Standard for Pickled Fruits and Vegetables (CODEX STAN 260-2011)*;
  - iii. 04.1.2.5 "Jams, jellies, marmalades", of: Propylene glycol alginate (INS 405) as a thickener in products conforming to the *Standard for Jams, Jellies and Marmalades (CODEX STAN 296-2009)*:
- 6. CCFO25 considered the matters referred from CCFA47 and CCFA488 and provided response to CCFA49.9 CCPFV28 considered the matters referred from CCFA4810 and provided response to CCFA49.11 CCFA49 agreed to request the EWG on the GSFA to CCFA50 to consider the replies of by CCFO and CCPFV and prepare proposals for the relevant provisions of the GSFA.12

<sup>&</sup>lt;sup>7</sup> REP 16/FA, para. 65.

<sup>&</sup>lt;sup>8</sup> REP17/FO, para 13 and Appendix II, part A.

<sup>&</sup>lt;sup>9</sup> CX/FA 17/49/2 Add. 1

<sup>&</sup>lt;sup>10</sup> REP17/PFV, paras 72-81.

<sup>&</sup>lt;sup>11</sup> CX/FA 17/49/2

<sup>&</sup>lt;sup>12</sup> REP17/FA paras 14(i) and 16.

#### **Working Document:**

7. The EWG issued two circulars for comment. The current document presents recommendations for each provision (adopt, adopt with revision, discontinue, discontinue and move to subcategories as appropriate, request information). These proposals are based upon a consensus approach taking into account alignment with corresponding Codex commodity standards, guidance from the related commodity committee, and comments on the first and second circulars by members of the EWG. These recommendations are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification.

## Conventions

- 8. This current document presents the draft and proposed draft provisions in food categories 02.1.2 and 02.1.3 related to guidance requested from CCFO, and food categories 04.1.2, 04.1.2.2, 04.1.2.3, 04.1.2.5 and 04.1.2.6 related to guidance requested from CCPFV. These provisions are presented in the format of the food categories listed in Table 2 of the GSFA. For each food category, information on corresponding Codex commodity standards and the use of food additives in those commodity standards is provided, as well as the decision of the PWG to CCFA45 or CCFA46 as to the horizontal justification of the use of emulsifiers, stabilizers, and thickeners, or of acidity regulators, for food categories which appear in the Annex to Table 3. For each provision, comments from the CCPFV and CCFO on the technological justification, a compilation of comments provided by EWG members to the first and second circulars, and relevant information from CCFA49, is provided.
- 9. The following conventions were used to prepare the working document:
- When the proposal is that a food additive provision be moved from a parent food category to a subcategory, the original provision in the parent food category will be indicated with strikethrough font and the new provision in the subcategory will be in **bolded** font with no Step indicated in the "Step/Adopted" column.

## Comments from the Codex Committee on Fats and Oils (CCFO) on the use of the food additives in food categories:

## Food Category No. 02.1.2 Vegetable oils and fats

Horizontal approach (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): acidity regulators/ES&T not horizontally justified

Corresponding commodity standards: 019-1981, 210-1999: Allows specific antioxidants, antioxidant synergists, and anti-foaming agent; 033-1981: Does not allow food additives (except tocopherols)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCFO	eWG comments	eWG Proposal
ADIPATES	355, 356, 357, 359	3000	1	7	Acidity regulator	The use of acidity regulators in FC 02.1.2 is not technologically justified	Chile, EU, RU, Malaysia, China: Supports discontinuation  USA: allowed in fats and oils in the USA at 3,000 mg/kg as an acidity regulator	Discontinue
LECITHIN	322 (i)	30000		7	Antioxidant, Emulsifier	Widely used as an antioxidant in vegetable oils and fats, and/or as an antioxidant synergist in combination with tocopherols and is technologically justified, except for virgin oils and olive oils; Lecithin could be used in CS 19-1981 and CS 211-1999 as an alternative to other antioxidants or for its synergic effect with other antioxidants at levels up to 30,000	USA, EU, Chile, India: Supports adoption with new note "excluding use in virgin oils and olive oils."  China, RU, Malaysia: Supports adoption with Note 27713  Indonesia: Supports_ML of 20000 mg/kg and supports the addition of new note "excluding use in virgin oils and	Adopt with new note "excluding use in virgin oils and olive oils."

<sup>13</sup> **Note 277:** Excluding virgin and cold pressed oils and products conforming to the standard for Olive Oils and Olive Pomace Oils (CODEX STAN 33-1981).

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCFO	eWG comments	eWG Proposal
						mg/kg	olive oils."  IFAC, FoodDrinkEurope: Supports adoption as listed  ICGMA: Supports proposal. Technological justification exists for the use of lecithin in oils beyond those listed in the note.	
TARTRATES	334, 335(i),(ii) ,336(i),(ii ), 337	5000	45	4	Acidity Regulator, Sequesterant, Stabilizer (Flavour enhancer - INS 334 only)	The use of acidity regulators in FC 02.1.2 is not technologically justified	Malaysia, EU, RU, China: Supports discontinuation  India: Does not support discontinuation as India allows the use of tartaric acid in this category	Discontinue
TRICALCIUM CITRATE	333(ii)	GMP		7	Acidity regulator, Emulsifying salt, Firming agent, Sequestrant, Stabilizer	Technologically justified as antioxidant synergists in products conforming to Standard for Edible Fats and Oils not Covered by Individual Standards (CODEX	EU, RU, Malaysia: Supports adoption as listed  ICGMA, FoodDrinkEurope: Supports adoption as listed	Adopt with Note XS33
TRIPOTASSIUM CITRATE	332(ii)	GMP		7	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	STAN19-1981) and Standard for Named Vegetable Oils (CODEX STAN 210- 1999); Is not technologically justified in this products confirming to Standard	China, EU, RU, Malaysia: Supports adoption as listed  ICGMA, FoodDrinkEurope: Supports adoption as listed	Adopt with Note XS33

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCFO	eWG comments	eWG Proposal
						for Olive Oils and Olive Pomace Oils CODEX STAN 33-1981		

## Food Category No. 02.1.3 Lard, tallow, fish oil, and other animal fats

Horizontal approach (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): acidity regulators/ES&T not horizontally justified

Corresponding commodity standards: 019-1981: Allows specific antioxidants, antioxidant synergists, and anti-foaming agent; 211-1999: Allows specific colours, antioxidants, and antioxidant synergists

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28th CCPO	eWG comments	eWGProposal
ADIPATES	355, 356, 357, 359	3000	1	7	Acidity regulator	The use of acidity regulators in food category 2.1.3 is not technologically justified.	Chile, EU, RU, China, Malaysia: Supports discontinuation  USA: allowed in fats and oils in the USA at 3,000 mg/kg as an acidity regulator	Discontinue
LECITHIN	322 (i)	30000		7	Antioxidant, Emulsifier	Many antioxidants are included in CS 19-1981 and 211-199. Lecithin could be used as an alternative to other antioxidants of for its synergic effect with other antioxidants. Lecithin may be used up to 30,000 mg/kg	EU, India, Malaysia: Support adoption  RU: Agrees with proposal (except vegetable virgin oils obtained pressing and olive oil)  Indonesia: Supports ML of 20000 mg/kg  IFAC, ICGMA, FoodDrinkEurope	Adopt

: Supports adop	nments eWGProposal
MONO-AND DIGLYCERIDES OF FATTY ACIDS  May be used as antifoaming agent in oils and fats conforming to Standard for Edible Fats and Oils not Covered by Individual Standards (CODEX Emulsifier, Stabilizer  Antifoaming agent, Stabilizer  Antifoaming agent, Stabilizer  Antifoaming agent, Standards for Edible Fats and Oils not Covered by Individual Standards (CODEX STAN 19-1981) for deep frying as an alternative to polydimethylsiloxane (INS 900a), and have been included in the draft standard for fish oil at GMP.  Antifoaming agent, Stabilizer  Antifoaming agent, Stabilizer  Antifoaming agent, Standards (CODEX STAN 19-1981) for deep frying as an alternative to polydimethylsiloxane (INS 900a), and have been included in the draft standard for fish oil at GMP.  (ADI being limited; & the ML proposed in the draft standard for fish oil); (2) Revise the proposed for 50 "Only for use as an emulsifier if ish oil at GMP, or an antifoaming and the proposed for 50 "Only for use as an an emulsifier if ish oil at GMP, or an antifoaming and the proposed for 50 "Only for use as an an emulsifier if ish oil at GMP, or an antifoaming and the proposed for 50 "Only for use as an an emulsifier if ish oil at GMP, or an antifoaming and the proposed for 50 "Only for use as an an emulsifier if ish oil at GMP, or an antifoaming and the proposed for 50 "Only for use and 50 the proposed for 50 the proposed for 50 the proposed for 50 the proposed for	EU, Sia: doption S211 or use in and e in oils deep orming dard for and overed all (CODEX 981)"  Adopt at GMP with note XS211 and new note "Only for use as an emulsifier in fish oil at GMP, or as an antifoaming agent in oils and fats for deep frying conforming to the Standard for Edible Fats and Oils Not Covered by Individual Standards (CODEX STAN 19-1981)";  the ed note y for an fier in at or as an

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPO	eWG comments	eWGProposal
							deep frying conforming to the Standard for Edible Fats and Oils Not Covered by Individual Standards (CODEX STAN 19- 1981)"; The above note would negate the need to add in note XS211  IFAC: Supports adoption as proposed  GOED: supports adoption	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	20000		7	Emulsifier	The use of emulsifiers in food category 2.1.3 (excluding fish oils) is not technologically justified.	Chile: Supports request for more information  EU: Supports discontinutation if no info is provided  RU: Does not permit use in FC 2.1.3. Proposal not technologically justified	Discontinue
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	10000		7	Emulsifier	The use of emulsifiers in food category 2.1.3 (excluding fish oils) is not technologically justified.	Chile: Supports request for more information  EU: Supports	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPO	eWG comments	eWGProposal
							discontinutation if no info is provided  RU: Does not permit use in FC 2.1.3. Proposal not technologically	
POTASSIUM DIHYDROGEN CITRATE	332(i)	GMP		7	Sequesterant	Not in the standard for fish oils as the use is not technologically justified in these products (EWG notes also not allowed in other standards)	justified  EU, RU, China: Supports discontinuation	Discontinue
PROPYLENE GLYCOL ALGINATE	405	11000		7	Bulking agent, Carrier, Emulsifier, Foaming Agent, Gelling Agent, Stabilizer, Thickener	The use of emulsifiers in food category 2.1.3 (excluding fish oils) is not technologically justified.	USA: allowed in fats and oils in the USA at 11,000 mg/kg as an ES&T  Chile: Supports request for more information  EU: Supports discontinutation if no info is provided  RU: Does not permit use in FC 2.1.3. Proposal not technologically justified  FoodDrinkEurope: Supports adoption as listed	Discontinue
SODIUM ALGINATE	401	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent,	The use of emulsifiers in food category 2.1.3 (excluding fish oils) is not technologically	EU, RU, China: Supports discontinuation	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPO	eWG comments	eWGProposal
					Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	justified. Sodium alginate is not in the standard for fish oils and is not technologically justified in this product	Chile: Proposes to request more information	
SODIUM DIHYDROGEN CITRATE	331(i)	GMP		7	Sequesterant	Not in the standard for fish oils as the use is not technologically justified in these products (EWG notes also not allowed in other standards)	Chile: Proposes to request more information to align with CXS 19, CXS 210 and CXS 211.  EU, RU, China: Supports discontinuation	Discontinue
TARTRATES	334, 335(i),(ii) , 336(i),(ii) , 337	5000	45	4	Acidity Regulator, Sequesterant, Stabilizer (Flavour enhancer - INS 334 only)	The use of acidity regulators in food category 02.1.3 is not technologically justified.	India: Does not support discontinuation as they allow the use of tartaric acid in this category  EU, RU, China: Supports	Discontinue
TRICALCIUM CITRATE	333(iii)	GMP		7	Sequesterant	Not in the standard for fish oils as the use is not technologically justified in these products (EWG notes also not allowed in other standards)	Chile: Proposes to request more information  EU, RU, China: Supports discontinuation	Discontinue
TRIPOTASSIUM CITRATE	332(ii)	GMP		7	Sequesterant	Not in the standard for fish oils as the use is not technologically justified in these products (EWG notes also not allowed in other standards)	Chile: Proposes to request more information  EU, RU, China: Supports discontinuation	Discontinue

## Comments from the Codex Committee on Processed Fruits and Vegetables (CCPFV) on the use in food categories:

## Food Category No. 04.1.2 Processed Fruit

Corresponding commodity standards: None; Multiple commodity standards correspond to subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, RU: Supports proposal  FoodDrinkEurope : Supports adoption as listed	Discuss in subcategories (current draft provision is in FC 04.1.2.2, there are adopted provisions in FCs 04.1.2.8 and 04.1.2.9)

## Food Category No. 04.1.2.1 (Frozen fruit)

Corresponding commodity standards: 52-1981, 69-1981, 75-1981, 76-1981, 103-1981: either no food additives permitted or allow ascorbic and citric acid

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, Chile: Proposes to request more information  RU: Does not permit use in FC 4.1.2. Proposal not technologically justified	Do not move from FC 04.1.2.2 – no information provided on use

#### Food Category No. 04.1.2.2 (Dried fruit)

Corresponding commodity standards: 67-1981, 130-1981: allows sorbic acid, sulphur dioxide, mineral oil (67-1981 only); 177-1991: allows antioxidants and preservatives in GSFA FC 04.1.2.2.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b,	200		7	Antioxidant	Used as antioxidants	Malaysia, RU,	Adopt with notes XS67, XS130

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
	С					in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	India: Supports adoption  China: Does not allow for use in this FC	
							<u>EU</u> : Questions if tech justification was provided for non-std products in subcategory	
							FoodDrinkEurope: Supports adoption as listed	

## Food Category No. 04.1.2.3 Fruit in vinegar, oil or brine

Corresponding commodity standards: 260-2007: Lists specific antioxidants, acidity regulators, antifoaming agents, colours, firming agents, flavour enhancers, preservatives, sequesterants, and sweeteners

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TARTRATES	334, 335(i),(ii) , 336(i),(ii) , 337	GMP	45	7	Acidity Regulator, Sequesterant, Stabilizer (Flavour enhancer - INS 334 only)	Acidity regulators are allowed in the Standard for Pickled Fruits and Vegetables (CODEX STAN 260-2007) and the use of tartrates in products conforming this Standard is technologically justified	Brazil: tartaric acid (INS 334) is allowed as acidulant and as acidity regulator in preserved fruits, with ML of 0.1g /100g (1000mg/kg) under legislation (RDC n. 08/2013)  RU: Supports use in this category  EU, India:	Adopt at ML of 1000 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
							Supports adoption  China: Does not allow for use in this FC	
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, Chile: Support request more information  RU: Does not allow in FC 4.1.2.3	Do not move from FC 04.1.2.2 – no information provided on use

## Food Category No. 04.1.2.4 (Canned or bottled (pasteurized) fruit)

**Corresponding commodity standards:** multiple commodity standards the majority of which allow only limited use of specific food additives. Those that list antioxidants list ascorbic acid for this function. None list tocopherols. Only 254-2007 lists a general reference to provisions in FC 04.1.2.4 of the GSFA.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWGr Proposal
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, Chile: Support request more information  RU: Does not permit use in FC 4.1.2.4. Proposal not technologically justified	Do not move from FC 04.1.2.2 – no information provided on use

## Food Category No. 04.1.2.5 Jams, Jellies and Marmalades

**Corresponding commodity standards: 296-2009:** Allows Table 3 acidity regulators, antifoaming agents, firming agents, preservatives, and thickeners. Also lists specific acidity regulators, antifoaming agents, colours, and preservatives

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Additive	INS	Max Level (mg/kg)	Note s	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
PROPYLENE GLYCOL ALGINATE	405	20000		7	Bulking agent, Carrier, Emulsifier, Foaming Agent, Gelling Agent, Stabilizer, Thickener	The Standard for Jams, Jellies and Marmalades (CODEX STAN 296-2009) made reference to thickeners used in accordance with Table 3 of the GSFA. One delegation reported INS 405 was used as a stabilizer in nonstandardized products. <sup>14</sup>	India: Supports adoption  RU, China: Supports adoption, allows for use of 5000 mg/kg  EU: Seeks clarity on what non-std products it is used in, questions if appropriate to refer to "special dietary uses" within this FC  IFAC, FoodDrinkEurop e: Supports adoption as listed  ICGMA: Support adoption, with revision to note to change the word "replace" to "replaced", notes material is allowed as a stabilizer in jams and jellies generally at a level not to exceed 0.4 percent by weight of the finished	Adopt with Notes XS296 and "for use only in products intended for further processing or special dietary uses, reduced or low sugar content, or where sweetening properties have been replaced wholly or partially by food additive sweeteners"

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<sup>&</sup>lt;sup>14</sup> CODEX STAN 296-2009 specifically states it does not apply to products intended for further processing or special dietary uses, reduced or low sugar content, or where sweetening properties have been replace wholly or partially by food additive sweeteners.

Additive	INS	Max Level (mg/kg)	Note s	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
							product per the U.S. CFR. Request consideration of adopting use in jams and jellies more broadly and w/ less restrictive note	
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, Chile: Supports request more information  RU: Does not permit use in FC 4.1.2.5. Proposal not technologically justified	Do not move from FC 04.1.2.2 – no information provided on use

## Food Category No. 04.1.2.6 (Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5)

**Corresponding commodity standards:** 160-1987: lists specific acidity regulators and preservatives.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b, c	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, Chile: Supports request for more information  RU: Does not permit use in FC 4.1.2.6. Proposal not technologically justified	Do not move from FC 04.1.2.2 – no information provided on use

## Food Category No. 04.1.2.7 (Candied fruit)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU, Chile: Support request for more information  RU: Does not permit use in FC 4.1.2.6. Proposal not technologically justified	Do not move from FC 04.1.2.2 – no information provided on use

## Food Category No. 04.1.2.8 (Fruit preparations, including pulp, purees, fruit toppings and coconut milk)

Corresponding commodity standards: 240-2003 (Aqueous Coconut Products): lists specific bleaching agents, ES&T, and preservatives; 314R-2013 (Date Paste): no additives allowed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	
			XS24 0,			Information on existing adopted provision for Tocopherols in FC 04.1.2.8 provided for information purposes only
	307a, b,		XS31			
TOCOPHEROLS	С	150	4R	2016	Antioxidant	

## Food Category No. 04.1.2.9 (Fruit-based desserts, incl. fruit-flavoured water-based desserts)

Corresponding commodity standards: None.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Information on existing adopted provision for Tocopherols in FC 04.1.2.9
	307a, b,					provided for information purposes only
TOCOPHEROLS	С	150	15	2016	Antioxidant	

## Food Category No. 04.1.2.10 (Fermented fruit products)

**Corresponding commodity standards:** 260-2007: lists specific acidity regulators, antifoaming agents, antioxidants, colours, firming agents, flavour enhancers, preservatives, sequesterants, and sweeteners

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity standards do not allow them	EU: Supports request for information  RU: Does not agree with proposal, technological justification is absent	Do not move from FC 04.1.2.2 – no information provided on use

## Food Category No. 04.1.2.11 (Fruit fillings for pastries)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Information on existing adopted provision for Tocopherols in FC
	307a, b,					04.1.2.11 provided for information purposes only
TOCOPHEROLS	С	150		2016	Antioxidant	

## Food Category No. 04.1.2.12 (Cooked fruit)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
TOCOPHEROLS	307a, b,	200			Antioxidant	Used as antioxidants in FC 04.1.2 in processed fruits, however most commodity	EU, Chile: Supports request for more information	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Technological justification provided by 28 <sup>th</sup> CCPFV	eWG comments	eWG Proposal
						standards do not allow them	RU: Does not agree with proposal, technological justification is absent	

## Appendix 2: Proposed draft provisions for lutein esters from Tagetes erecta (INS 161b(iii)) and octenyl succinic acid (OSA)-modified gum arabic (INS 423) in Table 3

- Among several topics, CCFA49 requested the EWG on the GSFA to CCFA50 to discuss:
- Proposed draft provisions for lutein esters from Tagetes erecta (INS 161b(iii)) and octenyl succinic acid (OSA)-modified gum arabic (INS 423) in Table 3

## **Background**

- 2. The 82<sup>nd</sup> Joint Expert Committee on Food Additives (JECFA) meeting evaluated the safety of lutein esters from Tagetes erecta (INS 161b(iii)) and octenyl succinic acid (OSA)-modified gum arabic (INS 423). This review resulted in an acceptable daily intake of "not specified" for both food additives. As a result, the 82<sup>nd</sup> JECFA recommended that CCFA50 include provisions for both food additives in Table 3 of the GSFA and circulate the provisions for comment at Step 3.<sup>2</sup> CCFA49 agreed to include provisions for lutein esters from Tagetes erecta (INS 161b(iii)) and octenyl succinic acid (OSA)-modified gum arabic (INS 423) in Table 3 of the GSFA and requested that the EWG on the GSFA to CCFA50 circulate these Table 3 provisions for comment at step 3.<sup>3</sup>
- 3. CCFA49 also agreed to request that proposals for new provisions for the use of lutein esters from Tagetes erecta (INS 161b(iii)) or octenyl succinic acid (OSA)-modified gum arabic (INS 423) in food categories listed in the Annex to Table 3 be provided in response to the circular letter requesting proposals for new and/or revision of adopted food additive provisions.<sup>4</sup>.

## **Working Document**

- 4. The EWG issued two circulars for comment. The current document is split into two Annexes:
  - a. Annex 1 presents recommendations on proposed draft provisions in Table 3 for lutein esters from Tagetes erecta (INS 161b(iii)) and octenyl succinic acid (OSA)-modified gum arabic (INS 423). The provisions under discussion are presented in the format of Table 3 of the GSFA.
  - b. Annex 2 provides recommendations from the EWG Chair on the procedure for consideration of draft and proposed draft Table 3 provisions. Annex 2 includes background discussion on the topic.
- 5. The current document presents recommendations. These recommendations are based upon a consensus approach taking into account alignment with corresponding Codex commodity standards and comments on the first and second circulars by members of the EWG. These recommendations are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification.

<sup>2</sup> CX/FA 17/49/3, para. 19 and Table 1.

<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

<sup>&</sup>lt;sup>3</sup> REP17/FA paras. 30 and 109, and Appendix II.

<sup>&</sup>lt;sup>4</sup> REP17/FA para. 30 and Appendix II.

#### Annex 1 - Part 1 - Table 3 provision for lutein esters from Tagetes erecta (INS 161b(iii))

The EWG issued two circulars for comment. The first circular requested comment on the proposed draft Table 3 provisions for INS 161b(iii). In response to the first circular, proposals were provided by EWG members to list INS 161b(iii) as acceptable in foods conforming to certain commodity standards. The second circular split these proposals into three categories and requested comment:

<u>Proposal 1- commodity standards with a general allowance for Table 3 additives of a specified functional class:</u> a proposal was submitted for the use of INS 161b(iii) in CODEX STAN 117-1981. CODEX STAN 117-1981 in general allows Table 3 additives with the functional class of "colour".

<u>Proposal 2 – commodity standards with allowances for specific Table 3 additives of a specified functional class</u>: a proposal was submitted for the use of INS 161b(iii) in CODEX STAN 87-1981. CODEX STAN 87-1981 allows specific Table 3 additives with the functional class of "colour" when used for surface decoration purposes only.

<u>Proposal 3 – commodity standards that currently do not allow Table 3 additives of a specified functional class</u>: a proposal was submitted for the use of INS 161b(iii) in CODEX STANs 105-1981 and 141-1983. These standards to not currently allow the use of colours.

The EWG members expressed general support for adoption of a provision for INS 161b(iii) in Table 3 in response to both circulars. However, the EWG members expressed different opinions on the proposals for the use of INS 161b(iii) in foods conforming to certain commodity standards. These proposals, a compilation of EWG member comments on those proposals, and a recommendation for each proposal are presented below:

INS	Additive	INS Functional Class	Step	Acceptable, including foods conforming to the following commodity standards	EWG comments*	EWG Recommendation
161b(iii)	Lutein esters from Tagetes erecta	Colour	3	Proposal 1: Add CODEX STAN 117-1981 "Bouillon and Consommés"	EU: Could accept (before alignment the standard referred to "Any colouring agents listed in Table III of the GSFA").  Japan, Brazil, Chile, India, USA, IACM: Supports adoption ICGA: Supports Proposal 1 and has no objection with combining it with e.g. Proposal 2  ICGMA, EU Specialty Food Ingredients: Supports adoption. We favor proposal 1.  NATCOL: Originated all three proposals. Supports Proposals 1, 2 & 3.	Adopt with CODEX STAN 117-1981*  *the need to add CODEX STAN 117-1981 to the provision may be negated by decision of WG on Alignment to not list standards with general allowances in specific Table 3 provisions (see Agenda Item 4(b))

		<b>EU:</b> Discuss further. Technological justification should be provided rather than asking for reasons why the use would not be appropriate.	Discuss further
	Proposal 2: Add CODEX STAN 87-	Note: Originally CS 87-1981 referred only to INS 175 Gold and INS 174 Silver. The alignment exercise recognized and accepted colour provisions adopted in category 5.1.4.	
	1981 "Chocolate and Chocolate Products"	NATCOL: Originated all three proposals. Supports Proposals 1, 2 & 3.	
		FoodDrinkEurope: Supports Proposal 2	
		<b>EWG Chair -</b> multiple provisions are adopted in FC 5.1.4 with note 183 (For use in surface decoration only) however, Table 3 lists multiple colors, without CS 87-1981 attached	
	Proposal 3: Add CODEX STAN 105-1981 "Cocoa powders" and 141-1983 "Cocoa mass"	EU: Strongly opposes to the use of colours in foods conforming to CS 105-1981 and CS 141-1983. The technological need for colours was (probably) considered and not recognised for those standards. Mixing of colours with cocoa powder, cocoa mass, cocoa cake etc. would mislead the consumer as regards the nature of the product.	Do not add CODEX STAN 105-1981 or 141-1983 to Table 3 provision for INS 161b(iii)
		<b>Brazil:</b> Does not agree with the use colors in these products (cocoa mass, cocoa powder, cocoa cake), because it can mislead the consumer regarding the intrinsic characteristics of chocolate products, contradicting item 3.2 from GSFA.	
		NATCOL: Originated all three proposals. Supports Proposals 1, 2 & 3.	

\*RU General comments on Appendix 2, Annex 1, Part 1: For INS 161b(iii) should be provided provisions only for Tables 1 and 2 of the GSFA with note (Maximum individually or for the combination of food colours with combined maximum limit). Next Ru proposals for use INS 161b(iii) according Tables 1 and 2 will be provided in response to the circular letter requesting proposals for new and/or revision of adopted food additive provisions:

Flavoured processed cheese – in ML=100 mg/kg Jams, jellies and marmalades– in ML=100 mg/kg Fish paste and crustacean paste and fermented fish products– in ML=100 mg/kg

#### Annex 1, Part 2 - Table 3 provision for Octenyl succinic acid (OSA)-modified gum arabic (INS 423)

The EWG issued two circulars for comment. The first and second circulars requested comment on the proposed draft Table 3 provisions for INS 423. The EWG members expressed general support for adoption of a provision for INS 161b(iii) in Table 3 in response to both circulars. In response to the second circular, a proposal was provided by an EWG members to list INS 423 as acceptable in foods conforming to commodity standards with general allowance for food additives with functional class of "emulsifier" or "firming agent". However, since this proposal to add CODEX STAN 117-1981 to the provision was submitted in response to the second circular the EWG did not have opportunity to comment on this proposal.

Proposal 1- provision as is: The EWG members expressed general support for adoption of a provision for INS 423 in Table 3.

<u>Proposal 2 – commodity standards with a general allowance for Table 3 additives of a specified functional class</u>: a proposal was submitted for the use of INS 423 in CODEX STANs 13-1981, 66-1981, 117-1981, 309R-2011, and 254-2007. These standards have all been aligned with the GSFA, appear in the "References to Commodity Standards for GSFA Table 3 Additives" section of Table 3, and in general allow Table 3 additives with the functional class of "emulsifier" or "firming agent".

A compilation of EWG member comments, and a recommendation on the provision, are presented below:

INS	Additive	INS Functional Class	Step	Acceptable, including foods conforming to the following commodity standards	EWG comments*	EWG Chair Recommendation
				Proposal 1: adopt as is	Japan, Brazil, Chile, India, Malaysia, USA, ICGMA, FoodDrinkEurope: Supports adoption	See Recommendation for Proposal 2.
423	Octenyl succinic acid (OSA)- modified gum arabic	Emulsifier, Firming agent	3	<b>Proposal 2:</b> Add CODEX STANs 13-1981, 66-1981, 117-1981, 309R-2011, and 254-2007	Japan: Proposes addition of listed commodity standards. They allow either emulsifier or firming agent listed in table 3 of the GSFA.	Adopt with CODEX STANs 13-1981, 66-1981, 117-1981, 309R-2011, and 254-2007* *need to add these CODEX STANs to the provision may be negated by decision of WG on Alignment to not list standards with general allowances in specific Table 3 provisions (see Agenda Item 4(b))

<sup>\*</sup>RU General comments on Appendix 2, Annex 1, Part 2: INS 423 should be provided provisions only for Tables 1 and 2 of the GSFA. Next Ru proposals for use INS 423 according Tables 1 and 2 will be provided in response to the circular letter requesting proposals for new and/or revision of adopted food additive provisions:

Canned fruits and vegetables glazed 10 g / kg;

Sauces 10 g / kg:

Drinks with reduced energy value and juice drinks 1 g / kg.

## Annex 2 - EWG Chair's proposal: Procedures for consideration of draft and proposed draft Table 3 provisions

#### A) Initial Procedure

The second circular presented a proposal from the EWG Chair to establish criteria and a procedure for inclusion of Table 3 provisions into the Step Process at step 2 and circulation of those provisions at Step 3. This proposal included Recommendations 1 and 2 below, and was put forth for consideration with the intent to conserve the resources of CCFA by ensuring the committee does not discuss provisions in the eWG and pWG of the GSFA for which there is already consensus.

In making this proposal the Chair notes that the main criteria for inclusion of a food additive in Table 3 of the GSFA are well established and concise. These main criteria are that the food additive has:

- a. a JECFA ADI of "not specified"; and
- b. an INS number and functional class

CCFA has been inconsistent in the process by which the Committee recommends provisions for adoption into Table 3 of the GSFA. At certain sessions CCFA has adopted a provision for an additive into Table 3 of the GSFA at the same session that the Committee received JECFA's evaluation of "not specified" for the additive as part of the standing Agenda Item 3(a) MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE ## MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA). At other sessions CCFA has instead circulated the Table 3 provision for comment by the eWG on the GSFA prior to adoption of the Table 3 provision at the next session.

Mindful of the resources of CCFA, and also the need to follow the Step Process, the Chair recommends that the eWG, and subsequently the 50<sup>th</sup> CCFA, consider criteria 1 and 2 discussed below as the criteria for automatic inclusion of a Table 3 provision for an additive into the step process at Step 2.

#### **Recommendation 1:**

The Chair recommends that the PWG recommend to the Plenary the following criteria for automatic inclusion of a Table 3 provision into the Step Process at step 2.

- 1) a JECFA ADI of "not specified"; and
- 2) an INS number and functional class

In such instance that an additive has an ADI of "not specified" and an INS number and functional class, the publication of a JECFA ADI of "not specified" in Agenda Item 3(a) prior to the Plenary Session can be considered a circulation of the provision for comment at Step 3. In this manner, the Committee could recommend endorsement of the provision at Step 5/8 at the same session that the Committee received JECFA's evaluation of "not specified" for the additive. If CCFA cannot reach consensus on adoption, the provision would be circulated for comment at a decision at the next session. Such a procedure would be in line with the Step Process and also conserve the resources of CCFA by ensuring the committee does not discuss provisions in the eWG and pWG of the GSFA for which there is already consensus.

#### **Recommendation 2:**

In the instance where an additive meets the main criteria discussed in Recommendation 1, the publication of a JECFA ADI of "not specified" in the standing CCFA Agenda Item 3(a) MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE ## MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) can be considered a circulation of the provision for comment at Step 3. In this manner, CCFA can recommend endorsement of the provision at Step 5/8 at the same session that the Committee considers JECFAS's evaluation of "not specified" for the additive.

#### EWG Comments on Recommendations 1 and 2:

**Japan**: Japan appreciates the efforts of the Unites States as the chair for leading the EWG on GSFA. We would like to provide our general comments to the chair's proposal for criteria for inclusion of Table 3 provisions into the Step Process at step 2 and circulation of those provisions at Step 3 as follows:

Japan supports the proposed two recommendations since such practices will conserve the resources of the CCFA and be in line with the Codex procedures. For more improvement and clarification, Japan would like to make an additional proposal on this issue.

In the current practice, Agenda Item 3(a) documents only include: 1) INS numbers; 2) Food additive names; 3) Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information; and 4) Recommended action by CCFA.

Japan suggests that draft Table 3 provisions in the GSFA should also be included in the Agenda Item 3(a) document. That is because Codex members need to check if the required information is included in Table 3 of the GSFA, i.e. INS number, Additive Name, Functional Class and Acceptable, including foods conforming to the following commodity standards. In particular, it is important for CCFA to consider if the proposed Table 3 additive is acceptable for the use in foods conforming to the certain standards for which alignment works have already been done. Some commodity standards allow Table 3 food additives with specific functional classes in general. Where food additives to be discussed in CCFA have such functional classes, reference numbers of such commodity standards should be specified in the column of "Acceptable, including foods conforming to the following commodity standards" as a starting point to discuss. For the reference, we would like to give an example of proposed draft food additive provisions for Lutein esters from *Tagetes erecta* (INS 161b(iii)) and Octenyl succinic acid (OSA) modifies gum arabic (INS 423) in Table 3 of the GSFA on below table.

Table. Proposed draft food additive provisions in Table 3 of the GSFA (STEP 3)

INS No	Additive	Functional Class	Acceptable, including foods conforming to the following commodity standards		
161b(iii)	Lutein esters from Tagetes erecta	Colour	CS 117-1981		
423	Octenyl succinic acid (OSA)- modifies gum arabic	Emulsifier, Firming agent	CS 254-2007, CS 66-1981, CS 57- 1981, CS 309R-2011, CS 117-1981		

**EU:** The EU appreciates the efforts of the chair to streamline the inclusion of additives with ADI not specified in Table 3. The EU does not have a clear position on the proposal at this stage.

Canada: Supports the Chair's proposed criteria for the entry of additives with non-numerical ADIs into Table 3 of the GSFA.

Notably, criterion 1) is the only criterion specifically prescribed in the section of the Procedural Manual: Procedures for consideration of the entry and review of food additive provisions in the General Standard for Food Additives necessary for the entry of an additive with a non-numerical ADI to Table 3. Criterion 2) is, of course, a necessary criterion for the entry of any additive into the GSFA. Given this, Canada would suggest that it would be inappropriate to require any additional criteria other than those proposed in Recommendation 1 for the inclusion of provisions for additives with non-numerical ADIs into Table 3.

Despite the above, Canada would not object to the possibility that a Member could raise an objection to the entry of an additive into Table 3, for a valid reason that would need to be supported by the Committee.

#### Recommendation 1:

Brazil, Malaysia, Japan: Supports Recommendation 1

**ICGA, ICGMA, ICBA:** Supports recommendation 1. We believe it will increase efficiency and reduce unnecessary delays when agreement exists and there is no safety concern.

**RU:** as specified in Section 3.2 of the Preamble to the GSFA, the criteria for automatic inclusion FA in Table 3 provision into the Step Process at step 2 should be next Recommendations:

- 1) a JECFA ADI of "not specified", and
- 2) an INS number and functional class, and
- 3) serves one or more of the technological functions and does not mislead the consumer

#### Recommendation 2:

Canada, Japan, Brazil, Malaysia, ICGA, ICGMA, ICBA: Support Recommendation 2.

**RU:** In case the food additive <u>and the area of its application</u> correspond to the indicated 3 criteria, can be considered a circulation of the provision for comment at Step 3. In this manner, CCFA can recommend endorsement of the provision at Step 5/8 at the same session that the Committee receives JECFAS's evaluation of "not specified" for the additive

## B) Additional Recommendations Past the Initial Procedure

In compiling the report of the EWG, it was noted that proposals for provisions for Table 3 can be classified into three categories based upon the listing of the additive as acceptable in foods conforming to certain commodity standards. Those categories are discussed below. While compiling the report of the EWG it was also noted that the Initial Procedure for Table 3 additives captured in Recommendations 1 and 2 would not be sufficient to provide adequate discussion within CCFA for some of these categories. In this Section of Annex 2 of Appendix 2 the Chair of the EWG proposes further recommendations in addition to those presented in the "Initial Procedure" to address those categories that cannot be addressed by Recommendations 1 and 2. In such instance, Recommendations 1 and 2 would still be applied to allow efficient adoption of the Table 3 provision for general use. However, further action (as discussed below) would be necessary to allow the use of the Table 3 additive in foods conforming to commodity standards with listings restricted to specific Table 3 additives of a given functional class.

<u>Category 1 - commodity standards with a general allowance for Table 3 additives of a specified functional class:</u> The WG on Alignment is currently working on a proposal to no longer list commodity standards with general allowances for Table 3 additives, or general allowances for Table 3 additives of a specific functional class, in specific provisions in Table 3 (see Agenda Item 4(b)). If the proposal by the WG on Alignment is enacted, Recommendations 1 and 2 above would be sufficient to allow provisions in this category to be adopted.

Category 2 - commodity standards with allowances for specific Table 3 additives of a specified functional class where the corresponding food category is **not** listed in the Annex to Table 3: In the GSFA, the use of a Table 3 additive as acceptable in foods conforming to these commodity standards would be listed in specific provisions in Table 3. The addition of new Table 3 additives to the commodity standard would require an appropriate discussion by CCFA which cannot be accomplished by Recommendations 1 and 2. In such instance, Recommendations 1 and 2 would still be applied to allow efficient adoption of the Table 3 provision for general use. However, proposals to amend the Table 3 provision to list specific commodity standards in the Table 3 provision would be submitted to the Circular Letter (CL) for proposals for new and/or revision of food additive provisions of the GSFA.<sup>5</sup> To enable this, revisions to the form distributed in Annex 1 of the CL could be enacted to clarify that the CL is the appropriate mechanism to request:

#### Recommendation 3:

The EWG Chair recommends that the PWG discuss a proposal to revise Annex 1 of the Circular Letter for *proposals* for new and/or revision of food additive provisions of the GSFA. This would facilitate the initial proposal for the addition of a new Table 3 additive to these commodity standards to provide information on all criteria outlined in Section 3.2 of the Preamble to the GSFA.

Revisions (additions) to the form in Annex 1 of the Circular Letter are indicated in **bold** text.

Proposed Use(s) Of the Food Additive:

П	revising ar	n existina	provision	in	Tables	<b>1</b> o	r 2	of	the	<b>GSF</b>	Α.	٥r

☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"); or

<u>Category 3 - commodity standards where the corresponding food category is listed in the Annex to Table 3:</u>
In the GSFA, the use of a Table 3 additive as acceptable in foods conforming to these commodity standards would be listed in the corresponding food category in Tables 1 and 2 of the GSFA <u>not</u> Table 3. In such instance, Recommendations 1 and 2 would still be applied to allow efficient adoption of the Table 3 provision for general use. However, a provision for the Table 3 additive in the corresponding food category in Tables 1 and 2 of the GSFA would be submitted to the CL for *proposals for new and/or revision of food additive provisions of the GSFA*.

Table 3 of the GSFA contains the section "References to Commodity Standards for GSFA Table 3 Additives". It may be helpful if this section was given a footnote to clarify that the use of Table 3 additives in commodity standards where the corresponding food category is listed in the Annex to Table 3 are listed in Tables 1 and 2, not Table 3.

#### **Recommendation 4:**

The EWG Chair recommends that the PWG discuss forwarding a request to the WG on Alignment to consider revising the "References to Commodity Standards for GSFA Table 3 Additives" section of Table 3. The intent of the revision is to clarify that the use of Table 3 additives in commodity standards where the corresponding food category is listed in the Annex to Table 3 are listed in Tables 1 and 2, not Table 3.

The proposal is to add a footnote to the "References to Commodity Standards for GSFA Table 3 Additives" section of Table. The suggested text for the footnote is:

This Section only lists Commodity Standards where the corresponding GSFA Food Category is <u>not</u> listed in the Annex to Table 3. Provisions for the use of specific Table 3 additives in Commodity Standards where the corresponding GSFA Food Category <u>is</u> listed in the Annex to Table 3 can be found in those corresponding Food Categories in Tables 1 and 2.

Since the issues pertaining to Category 2 and Category 3 were not recognized until compilation of the EWG report, Recommendations 3 and 4 were not distributed to the EWG for comment.

<sup>&</sup>lt;sup>5</sup> The corresponding CL for CCFA50 is CL 2017/47-FA.

#### Appendix 3: Provisions for food additives with Note 22 in FC 09.2.5

- 1. Among several topics, CCFA49 requested the EWG on the GSFA to CCFA50 to discuss:1
  - Provisions for food additives with Note 22 in FC 09.2.5 (comments for use in smoked fish paste)

## **Background**

- 2. CCFA48 considered proposals to align the provisions in food category 09.2.5 (*Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms*) with CODEX STAN 311-2013 (*Smoked Fish, Smoke-flavoured Fish, and Smoke-dried Fish*).<sup>2</sup> Prior to alignment, Note 22 ("For use in smoked fish only") was attached to multiple provisions in food category 09.2.5. The e-WG noted that those food additives with provisions in FC 09.2.5 with Note 22 were not listed in CODEX STAN 311-2013 and therefore were not technologically justified in foods covered by that standard. CCFA48 noted that multiple adopted provisions associated with Note 22 pertained to food additives that were not allowed in CODEX STAN 311-2013. CCFA48 also noted that Section 1 of CODEX STAN 311-2013 defines smoked fish products that are not within the scope of the standard. As such CCFA48 revised Note 22 to read as "For use in non-standardized smoked fish products only, as defined in Section 1 of the Standard for Smoked Fish, Smoke-flavoured Fish and Smoke-dried Fish (CODEX STAN 311-2013)", and tasked the eWG on the GSFA to request information on the use of food additives with Note 22 in non-standardized products as defined in CODEX STAN 311-2013.<sup>3</sup>
- 3. The EWG on the GSFA to CCFA49 considered the scope of non-standardized products as defined in Section 1 of CODEX STAN 311-2015 and provided recommendations for each provision in the GSFA with note 22.4 The physical working group (PWG) on the GSFA to CCFA49 concluded that smoked fish pastes are the only non-standardized product defined in Section 1 of CODEX STAN 311-2015 that are also included within the descriptor of food category 09.2.5. The PWG recommended that Note 22 be revised to read as "For use in smoked fish pastes only". The pWG also recommended that provisions with Note 22 for which information on the use in fish pastes in general had been provided be circulated requesting information on the use of these additives in smoked fish pastes in particular.<sup>5</sup>
- 4. CCFA49 endorsed the recommendations of the PWG to revise Note 22 to read "For use in smoked fish pastes only" and to circulate specific provisions in food category 09.2.5 for comment on the use of those food additives in smoked fish pastes.<sup>6</sup>

#### **Working Document**

5. The EWG issued two circulars for comment. The current document presents recommendations to discontinue all provisions under discussion, except the provision for Beet Red (INS 162). The basis of the proposal is that no information was provided by EWG members in response to the first and second circulars that these food additives are used in smoked fish pastes. Information was provided by EWG members in response to the first and second circulars that Beet Red (INS 162) is used in smoked fish pastes.

#### Conventions

6. The current document presents the provisions under discussion in the format of food category 09.2.5 in Table 2 of the GSFA. Information on corresponding Codex commodity standards and the use of food additives in those commodity standards is provided. The document also presents a compilation of comments provided by EWG members to the first and second circulars as well as relevant information from CCFA49.

<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

<sup>&</sup>lt;sup>2</sup> CX/FA 16/48/6, Appen. 5 and 6.

<sup>&</sup>lt;sup>3</sup> REP16/FA paras 44-46.

<sup>&</sup>lt;sup>4</sup> CX/FA 17-49-7, Appendix 4.

<sup>&</sup>lt;sup>5</sup> FA/49 CRD2

<sup>&</sup>lt;sup>6</sup> REP17/FA para 74.

<u>Food Category No.</u> 09.2.5 (Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms) Corresponding commodity standards: 167-1989, 189-1993, 222-2001, 236-2003, 244-2004, 311-2013

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted/ Year Revised	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
AMARANTH	123	300	22 & XS311	7	Colour	Z <sup>nd</sup> Circular proposal: Discontinue;     No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular      Malaysia: Supports discontinuation      RU: amaranth (INS123) not allowed for to use in food industry in Russian Federation	Discontinue; No maximum use level and technological justification provided
BEET RED	162	GMP	22 & XS311	7	Colour	2 <sup>nd</sup> Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular IACM, NATCOL: Necessary to provide color to smoked salmon paste to restore the salmon colour lost in processing, to make the products more appealing; Natural alternative to other red colours already listed in GSFA for this application. Already allowed for use in fish paste in EU at quantum satis and already being used by some producers in EU. RU: Agrees with 2 <sup>nd</sup> circular proposal	Retain provision at current step
BRILLIANT BLACK (BLACK PN)	151	500	22 & XS311	7	Colour	2 <sup>nd</sup> Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular  RU: Agrees with 2 <sup>nd</sup> circular proposal in ML=100 mg/kg* because ADI is low (0-1 mg/kg bw)	Discontinue; No maximum use level and technological justification provided
BROWN HT	155	500	22 & XS311	7	Colour	2nd Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1st Circular RU: Agrees with proposal in ML=100 mg/kg* because ADI is	Discontinue; No maximum use level and technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted/ Year Revised	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						low (0-1.5 mg/kg bw)	
CHLOROPHYLLS	140	GMP	22 & XS311	7	Colour	2 <sup>nd</sup> Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular <u>RU</u> : Agrees with proposal	Discontinue; No maximum use level and technological justification provided
CURCUMIN	100(i)	500	22, XS311 & NN8	7	Colour	2 <sup>nd</sup> Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular RU: Agrees with proposal in ML=100 mg/kg* because ADI is low (0-3 mg/kg bw)	Discontinue; No maximum use level and technological justification provided
LUTEIN FROM TAGETES ERECTA	161b(i)	100	22 & XS311	4	Colour	2 <sup>nd</sup> Circular proposal: Discontinue;  No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular  RU: Agrees with proposal *	Discontinue; No maximum use level and technological justification provided
QUINOLINE YELLOW	104	500	22 & XS311	7	Colour	2 <sup>nd</sup> Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1 <sup>st</sup> Circular RU: Agrees with proposal in ML=100 mg/kg* because ADI is low (0-3 mg/kg bw)	Discontinue; No maximum use level and technological justification provided
TITANIUM DIOXIDE	171	GMP	22 & XS311	7	Colour	<ul> <li>2<sup>nd</sup> Circular proposal: Discontinue; No maximum use level and technological justification provided in reply to 1<sup>st</sup> Circular</li> <li>Malaysia: Supports discontinuation</li> <li>RU: Does not agree with proposal. INS 171 should be excluded from INS list because toxicity of i nanocompounds</li> </ul>	Discontinue; No maximum use level and technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted/ Year Revised	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						which are in titanium dioxide	

- Note 22: For use in smoked fish paste only.
- Note XS311: Excluding products conforming to the Standard for Smoked Fish, Smoked-flavoured Fish and Smoke-dried Fish (CODEX STAN 311-2013).
- Note NN8: For use in dried and/or salted fish only
- Russian Federation: \*Note: individually or for the combination with maximum individually or for the combination of food colours with combined maximum limit

## e-WG Comments

#### **EU General Comments:**

The EU comments applicable to all provisions in Appendix 3: In the absence of the technological justification the EU supports discontinuation of the provisions listed in Appendix 3.

#### Appendix 4: Provisions related to FC 01.1.1

- 1. Among several topics, CCFA49 requested the EWG on the GSFA to CCFA50 to discuss:1
- Provisions related to FC 01.1.1 (comments on technological need for the specific additive, the specific type of food products within the FC where the food additive is used and the ML necessary to reach the function of stabilizer)
- Provision for Trisodium citrate in FC 01.1.1 (comments on technological need for a numerical use level or GMP)

## **Background**

- 2. CCFA48 revised the structure, title and descriptor of food category 01.1 (Fluid milk and milk products) and its subcategories. CCFA48 also considered that the scope of the revised food category 01.1 and its subcategories 01.1.1 (Fluid milk (plain)), 01.1.3 (Fluid buttermilk (plain)), and 01.1.4 (Flavoured fluid milk drinks) had not substantially changed from the scope of the corresponding historical food categories, and therefore determined that it was not necessary to revoke and/or discontinue the provisions in the historical food categories, but rather to place those provisions in the corresponding revised food categories.<sup>2</sup> CCFA48 also requested that the EWG on the GSFA consider these food additives to verify their appropriateness in the revised food categories.<sup>3</sup>
- 3. The EWG on the GSFA to CCFA49 compiled comments on the appropriateness of food additive provisions, both adopted and in the step process, in the revised food category 01.1 and its subcategories 01.1.1, 01.1.3 and 01.1.4.4 The physical working group (PWG) on the GSFA to CCFA49 discussed the proposals and information compiled by the EWG.<sup>5</sup>
- 4. The PWG on the GSFA to CCFA49 discussed the following topics pertaining to the provisions in food category 01.1.1:
- a. On the use of stabilizers in food category 01.1.1 (*Fluid milk (plain)*): several members raised concerns that many stabilizers also function as thickeners and their use may change the character of the products conforming to this food category. It was also noted that phosphates and citrates could be used as stabilizers in the products conforming to 01.1.1; therefore, other stabilizers are not needed. However, other members noted that certain types of products in this food category require the use of stabilizers other than phosphates and citrates. Therefore, the PWG compiled the provisions for additives with "stabilizer" function in food category 01.1.1 for which member support had been provided<sup>6</sup> and recommended that those provisions be held at their current step and circulated for comment.
- b. On the general use of Trisodium citrate (INS 331(iii)) in UHT and sterilized products conforming to food category 01.1.1: one member organization indicated that the use of Trisodium citrate (INS 331(iii)) should have a numeric use level. However, it was also discussed that Trisodium citrate (INS 331(iii)) has a JECFA ADI of "not specified" and that the normal practice of this Committee is to assign a maximum use level of GMP for such additives. In instances where numeric use levels were utilized for food additives with a JECFA ADI of "not specified", the technological justification for a numeric use level should be provided. In order to allow time for information to be provided on the technological need for a numerical use level, the pWG recommended that this issue be discussed further at Plenary.

<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

<sup>&</sup>lt;sup>2</sup> REP 16/FA, paras 78-86.

<sup>&</sup>lt;sup>3</sup> REP 16/FA, para. 101.

<sup>&</sup>lt;sup>4</sup> CX/FA 17/49/7, Appendix 5.

<sup>&</sup>lt;sup>5</sup> FA/49 CRD2.

<sup>&</sup>lt;sup>6</sup> These provisions were compiled in in FA/49 CRD 2 Annex 3, Part B.

## 5. CCFA49 agreed to:

- a. Hold the draft and proposed draft provisions for food additives in FC 01.1.1 with stabilizer function, as listed in CCFA49 CRD2 Annex 3 Part B, as well as the provision for microcrystalline cellulose (cellulose gum) (INS 460(ii)), at their current step. CCFA49 also requested that the EWG on the GSFA to CCFA50 circulate these provisions and request information on: (i) technological justification for the specific additive; and (ii) specific types of food products the additive is used in; and (iii) the use levels necessary to achieve the technological function as stabilizer.<sup>7</sup>
- b. Direct the EWG on the GSFA to CCFA50 to request comment on the technological need for a numeric or GMP use level for Trisodium citrate (INS 331(iii)) in food category 01.1.1.8

#### **Working Document**

- 6. The EWG issued two circulars for comment. This current document presents proposals for this Appendix split into two Annexes:
- a. <u>Annex 1</u> presents proposals for specific provisions in food category 01.1.1 with stabilizer function. Comments from EWG members on specific provisions have been collated and summarized and are presented with the provision. General comments from EWG members that are not specific to any one provision are presented at the end of Annex 1.
- b. Annex 2 presents a recommendation on the proposal to adopt a provision for Trisodium citrate (INS 331(iii)) at GMP in food category 01.1.1. Comments from EWG members on the first and second circulars comments are presented at the end of Annex 2.
- 7. The current document presents recommendations for each provision (adopt, adopt with revision, discontinue, request information). These proposals are based upon a consensus approach taking into account comments on the first and second circulars by members of the EWG. These recommendations are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification.

#### Conventions

8. These provisions are presented in the format of the food categories listed in Table 2 of the GSFA. The document also presents a compilation of comments provided by EWG members to the first and second circulars as well as relevant information from CCFA49.

<sup>&</sup>lt;sup>7</sup> REP17/FA paras. 81 and 109.

<sup>&</sup>lt;sup>8</sup> REP17/FA paras 77, 78, and 109.

## Food Category No. 01.1.1 (Fluid milk (plain))

Corresponding commodity standards: none

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
CARRAGEENAN	407	10,000		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	2nd Circular proposal: Adopt at ML 400; add new Note "for use in UHT treated milks only";  Request information on use in contrast to phosphates and citrates.  Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives.  Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new additives with other technological functions.  EU: Strongly opposes. High heat treatment (higher than standard UHT treatment) is not needed and is not desirable from quality/ nutritional point of view. The EU has doubts on the need for a long shelf life for UHT milks stored at or above 30°C.  In contrast to phosphates and citrates carrangeenan has very strong gelling and thickening properties. Such properties change the nature of fluid milk.  FoodDrinkEurope: Supports proposal  ICGMA: Supports adoption based on the technological justification noted in comments to the first circular. We can support the second circular proposal, including the numerical usage level on this Table 3 additive given the concerns noted by	Adopt at ML 400; add new Note "for use in UHT treated milks only"; new Note "only for uses as emulsifier/stabilizer"

Additive	INS	Max Level	Notes	Step	INS Functional	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
		(mg/kg)		-	Class		·
						other Codex members and the sensitivity of this category. The	
						functional differences between carrageenan and	
						phosphates/citrates as reported to ICGMA relates to protein	
						stabilization performance at higher heat treatments where the	
						heat treatment is held for a period longer than traditional UHT	
						treatment. Carrageenan offers unique protein interaction in the	
						milk necessary for these harsher treatments that is not	
						sufficiently provided by phosphates and citrates.	
						Although the number of products in international commerce in	
						which such a high and sustained heat treatment is necessary	
						may be limited, we understand such products do exist. The	
						primary application/market for such products is in hot climates	
						where storage conditions are sub-optimal for traditional UHT	
						milks and access to fresh fluid milks that are not heat treated	
						and/or refrigeration may be limited. We note that the comments	
						opposing the use of this material in UHT milks are almost	
						exclusively from countries/regions where climatic/environmental	
						conditions that would warrant the use of these materials do not	
						exist. It may be helpful to consider whether different additives	
						may be technologically justified in products as a result of	
						environmental conditions that may differ around the world.	
						We also note the general comments from some members that	
						indicate concern about the thickening properties of many of	
						these substances. A possible compromise might be the addition	
						of another note further limiting the use of the additive such as	
						"for use as a stabilizer only." Although this does not restrict the	
						inherent functionality of certain carrageenans, it would clearly	
						communicate the intent of the listing in the GSFA	
						<u>IDF</u> : Supports proposal with the proposed note, and only for	
						uses as emulsifier/stabilizer.	
						IFAC: Supports adoption of this provision at ML 400 and with	
						the new Note "for use in UHT treated milks only." In addition, we	

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						object to the word "only" as these gums serve the technical function of preventing separation without altering the milk product.  Malaysia: Do not support the adoption.  RU: Does not agree with proposal  2nd Circular proposal: Adopt at ML 400; add new Note "for use	
GELLAN GUM	418	GMP		7	Stabilizer, Thickener	in UHT treated milks only";  Request information on use in contrast to phosphates and citrates.  Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives.  Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new additives with other technological functions.  EU: Strongly opposes. High heat treatment (higher than standard UHT treatment) is not needed and is not desirable from quality/ nutritional point of view.  In contrast to phosphates and citrates gellan gum has very strong gelling and thickening properties. Such properties change the nature of fluid milk.  EU Specialty Food Ingredients: Supports the adoption of "for use in UHT treated milks only." We would however have an	Adopt at ML 400; add new Note "for use in UHT treated milks only"; new Note "only for uses as emulsifier/stabilizer"

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						objection to "only" because gellan gum serves the technical	
						function of preventing separation without altering the milk	
						product.	
						FoodDrinkEurope: Supports proposal	
						ICGMA: Supports adoption. Gellan gum has similar functionality	
						in UHT products to carrageenan. Gellan gum hydrates at	
						temperatures commonly reached during UHT processing and	
						has comparable protein interactions in milk to carrageenan.	
						Gellan is also able to provide stability by formation of structures	
						which reduce problems with age gelation. Although the literature	
						is less developed for gellan than for carrageenan, it is likely the	
						similar functionality that makes gellan more desirable in higher	
						heat treated products than phosphates and citrates. Typical	
						usage level would be no more than 400 mg/kg.	
						<u>IDF</u> : Supports proposal with the proposed note, and only for uses as stabilizer.	
						IFAC: IFAC supports adoptionbased on the technological	
						justification noted in comments to the first circular. We can	
						support the second circular proposal, including the numerical	
						usage level on this Table 3 additive given the concerns noted by	
						other Codex members and the sensitivity of this category. The	
						functional differences between gellan gum (like carrageenan)	
						and phosphates/citrates as reported to ICGMA relates to protein	
						stabilization performance at higher heat treatments where the	
						heat treatment is held for a period longer than traditional UHT	
						treatment.	
						Although the number of products in international commerce in	
						which such a high and sustained heat treatment is necessary	
						may be limited, we understand such products do exist. The	
						primary application/market for such products is in hot climates	
						where storage conditions are sub-optimal for traditional UHT	
						milks and access to fresh fluid milks that are not heat treated	

Additive	Additive INS Level Notes Step Functional Class		2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal		
					and/or refrigeration may be limited. We note that the comments opposing the use of this material in UHT milks are almost exclusively from countries/regions where climatic/environmental conditions that would warrant the use of these materials do not exist. It may be helpful to consider whether different additives may be technologically justified in products as a result of environmental conditions that may differ around the world.  We also note the general comments from some members that indicate concern about the thickening properties of many of these substances. A possible compromise might be the addition of another note further limiting the use of the additive such as "for use as a stabilizer only." Although this does not restrict inherent functionality, it would clearly communicate the intent of the listing in the GSFA.  Malaysia: Do not support the adoption.  RU: Does not agree with proposal	
GUAR GUM	412	6000	7	Emulsifier, Stabilizer, Thickener	<ul> <li>2nd Circular proposal: Request information on actual use level in UHT treated milks</li> <li>Request information on use in contrast to phosphates and citrates.</li> <li>Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives.</li> <li>Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new</li> </ul>	Adopt at ML 500; add new Note "for use in UHT treated milks only"; new Note "only for uses as emulsifier/stabilizer"

Additive IN:	Additive INS Level Notes Step Functional (mg/kg) Class		Functional	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal	
					additives with other technological functions.  EU: Strongly opposes and wonders what would be the product containing carrageenan, mono and di-glycerides of fatty acids and guar gum? Would it still be milk?  UHT fluid milk is on the EU market and the EU is not aware of any issue with "age gelation and fouling".  FoodDrinkEurope: Supports proposal  ICGMA: Despite further review, ICGMA has been unable to identify specific information on numerical usage level for this material in stabilization systems in UHT milks. Literature indicates the most common usage would be as part of a system of stabilizers with the total usage of the system ranging from 50 to 500 mg/kg. The difficulty in providing a specific usage level relates to the relative percentages of the other stabilizers used in the system, protein levels and protein damage as a result of heat treatment. Given use as a component of a system, it is therefore reasonable to assume that the individual usage level of this material is not likely to exceed 500 mg/kg, although the actual usage level may be much lower.  We also note the general comments from some members that indicate concern about the thickening properties of many of these substances. A possible compromise might be the addition of another note further limiting the use of the additive such as "for use as a stabilizer only." Although this does not restrict inherent functionality, it would clearly communicate the intent of the listing in the GSFA.  IDF: Supports this provision with the note limiting to UHT treated milks, and only for uses as emulsifier/stabilizer.  Malaysia: Do not support the adoption.	

Additive	(mg/kg) Class		Functional	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal		
MICROCRYSTALLI NE CELLULOSE (CELLULOSE GEL)	460(i)	Level	Notes	Step 7	Functional	RU: Does not agree with proposal  2nd Circular proposal: Adopt; add new Note "for use in UHT treated milks only";  Request information on use in contrast to phosphates and citrates.  Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives.  Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new additives with other technological functions.  EU: Strongly opposes. High heat treatment (higher than standard UHT treatment) is not needed and is not desirable from quality/ nutritional point of view.  In contrast to phosphates and citrates microcrystalline cellulose has strong gelling and thickening properties. Such properties change the nature of fluid milk.  FoodDrinkEurope: Supports proposal	Request information on actual use level in UHT treated milks as an emulsifier/stabilizer
						FoodDrinkEurope: Supports proposal  IDF: Supports proposal with the proposed note, and only for uses as emulsifier/stabilizer.  IFAC: IFAC supports adoption. Like other gums, cellulose gum	
						can be used in in UHT plain milks due to its heat stability by formation of structures which reduce problems with age gelation.	

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						This renders the UHT product stable despite high heat treatment, which might not be achievable with alternatives such as phosphates and citrates.  In addition, we object to the word "only" as these gums serve the technical function of preventing separation without altering the milk product.  Malaysia: Do not support the adoption.  RU: Does not agree with proposal	
MONO- AND DI- GLYCERIDES OF FATTY ACIDS	471	10,000		7	Antifoaming agent, Emulsifier, Stabilizer	2nd Circular proposal: Request information on actual use level in UHT treated milks Request information on use in contrast to phosphates and citrates. Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives. Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new additives with other technological functions. EFEMA: INS 471 is already used in certain regions of the world to stabilise UHT milk. 0.1 – 0.3 % of INS 471 are typically used in UHT milk (usually around 0.1 %). With regards to use in contrast to phosphates and citrates specifically, please note that mono- and diglycerides improve the	Adopt at ML 1000; add new Note "for use in UHT treated milks only"; new Note "only for uses as emulsifier/stabilizer"

Additive IN		Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
	(mg/kg)			Class	emulsion stability of the milk which especially is important in UHT milk where a long shelf life (6-12 month) at ambient temperature is requested. Its use thus extends the shelf life and preserves the taste and sets off seasonal variations in the milk. Mono- and diglycerides act in the interphase between the water phase and the fat globules, preventing coalescence of the fat globules over time. This means that the mono- and diglycerides control fat crystallization, retard creaming and separation in the milk. Creaming and separation is seen as a defect by the consumers and may lead to disposal of products. Phosphates and citrates does not have the same effect on the stability of the emulsion, they work more on the stability of the proteins. Thus the use of mono-and diglycerides is a supplement to use of Phosphates and citrates.  EU: Strongly opposes. The information provided indicates the change of the character of fluid milk. Appropriate shelf life is achievable with the standard UHT treatment and good hygiene (sanitation) and processing conditions.  FoodDrinkEurope: Supports proposal  ICGMA: Despite further review, ICGMA has been unable to identify specific information on numerical usage level for this material in stabilization systems in UHT milks. Literature indicates the most common usage would be as part of a system of stabilizers with the total usage of the system ranging from 50 to 1000 mg/kg. The difficulty in providing a specific usage level relates to the relative percentages of the other stabilizers used in the system, protein levels and protein damage as a result of heat treatment. Given use as a component of a system, it is therefore reasonable to assume that the individual usage level of this material is not likely to exceed 1000 mg/kg, although the actual usage level may be much lower.  We also note the general comments from some members that	

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						indicate concern about the thickening properties of many of these substances. A possible compromise might be the addition of another note further limiting the use of the additive such as "for use as a stabilizer only." Although this does not restrict inherent functionality, it would clearly communicate the intent of the listing in the GSFA.  IDF: Supports this provision with the note limiting to UHT treated milks, and only for uses as emulsifier/stabilizer.  IFAC: Mono- and di- glycerides of fatty acids can be used to reduce surface tension of the milk, which prevents fouling layer build-up and then allows for longer run-times of equipment, which might not be achieved with alternatives such as phosphates and citrates. The ML necessary to achieve this function is 10,000 mg/kg. IFAC considers that Note 227 should be added.  Regarding the request for information on actual use levels in UHT treated milks, the recommended use level in UHT treated milk is 1,000 ppm = 0.1%  Regarding the request for information on use in contrast to phosphates and citrates, phosphates and citrates exert protein stability by ion binding and pH adjustment. Mono- and diglycerides control fat crystallization and prevent creaming during storage. Use of mono- and di-glycerides is a supplement to use of phosphates and citrates. Further, mono- and di-glycerides extends shelf life, preserves the taste, and sets off-seasonal variations in the milk.  RU: Does not agree with proposal	
POLYDEXTROSES	1200	GMP		7	Bulking agent, Glazing agent,	2 <sup>nd</sup> Circular proposal: Adopt; add new Note "for use in UHT treated milks only";  Request information on use in contrast to phosphates and	Request information on actual use level in UHT treated milks as an emulsifier/stabilizer

Additive	INS	Max Level	Notes	Step	INS Functional	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
Additive	INS	(mg/kg)	Notes	- Step	Class  Humectant, Stabilizer, Thickener	citrates.  Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives.  Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new additives with other technological functions.  EU: Strongly opposes. The information provided clearly indicates the intention to change the character of fluid milk.  FoodDrinkEurope: Supports proposal  IFAC: IFAC supports adoption. Polydextrose adds body to low/reduced fat milks, contributing to mouthfeel and the perception of creaminess, thereby increasing organoleptic acceptability to consumers. As consumers continue to look for ways to reduce caloric intake, tools like polydextroses allow manufacturers to provide acceptable products with fewer calories, including low and no fat milks.  Malaysia: Do not support the adoption.  RU: Does not agree with proposal	ewe rinai Proposai
SODIUM ALGINATE	401	GMP		4	Bulking agent, Carrier, Emulsifier, Foaming agent,	2 <sup>nd</sup> Circular proposal: Discontinue; No information on use provided  EU: Supports discontinuation	Discontinue; No information on use provided

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
					Gelling agent, Glazing agent, Humectant, Sequestran t, Stabilizer, Thickener	Malaysia: Do not support the adoption.  RU: Does not agree with proposal	
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	GMP		4	Bulking agent, Emulsifier, Firming agent, Gelling agent, Humectant, Stabilizer, Thickener	Note "for use in UHT treated milks only";  Request information on use in contrast to phosphates and citrates.  Request further discussion on the limitation of emulsifiers/stabilizers to phosphates and citrates in context that additives under discussion are Table 3 additives.  Chile: Does not agree with the proposal on 2nd circular, since the additives being studied fulfill the technological function of thickener, which is not necessary in this category of food, as it would alter their sensorial characteristics. Currently, Codex allows the use of phosphates and nitrates as stabilizers in this category, since it is justified in the case of some natural liquid milk heat treated, so that, it is not necessary to incorporate new additives with other technological functions.  EU: Strongly opposes. High heat treatment (higher than standard UHT treatment) is not needed and is not desirable from quality/ nutritional point of view.	Adopt at ML 1000; add new Note "for use in UHT treated milks only"; new Note "only for uses as emulsifier/stabilizer"

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
						In contrast to phosphates and citrates	
						sodium carboxymethyl cellulose has strong	
						gelling and thickening properties. Such	
						properties change the nature of fluid milk.	
						FoodDrinkEurope: Supports proposal	
						IDF: Supports this provision with the note	
						limiting to UHT treated milks, and only for	
						uses as emulsifier/stabilizer.	
						IFAC: IFAC supports adoption. Like other	
						gums, cellulose gum can be used in in UHT	
						plain milks due to its heat stability by	
						formation of structures which reduce	
						problems with age gelation. This renders the	
						UHT product stable despite high heat	
						treatment, which might not be achievable	
						with alternatives such as phosphates and	
						citrates. The ML needed to achieve this	
						function is 1000 mg/kg.	
						In addition, we object to the word "only" as	
						these gums serve the technical function of	
						preventing separation without altering the	
						milk product.	
						Malaysia: Do not support the adoption.	
						RU: Does not agree with proposal	

#### EWG General Comments - Annex 1- Stabilizers in FC 01.1.1

#### **USA** general comments:

The USA supports the use of stabilizers in ultra-high temperature (UHT) treated products of FC 01.1.1. Generally, the use of food additives in food products of FC 01.1.1 is essential for preserving the nutritional quality, enhancing the keeping quality or stability and aiding in the manufacturing, processing, or storage of these products. Specifically, stabilizers used in food products in FC 01.1.1 are intended to maintain or improve the consistency, water-binding capacity, and texture in fluid milk products.

The USA believes that the use of phosphates and citrates as stabilizers does not preclude the use of other food additives for that technological function. The USA encourages the eWG to focus on the technological need for specific food additives, as needed, rather than on limiting the total number of additives that are approved for use. Due to differences in the effectiveness of additives in certain products of FC 01.1.1, manufacturing process, proprietary additive use, and environmental conditions in the country of sale, it is not appropriate to compare an additive under consideration with the technological use of phosphates and citrates. Additionally, limiting the number of permitted stabilizers in FC 01.1.1 could result in increased concentrations of food additives in product formulations if manufacturers are forced to switch to food additives that are less effective for particular products.

The USA considers that since many of the proposed food additives in FC 01.1.1 are Table 3 additives, it is appropriate to limit their use to GMP in order to achieve the desired technological function of stabilizer. The USA also considers that these food additives are self-limiting once the technological function is achieved. Any use levels of these food additives outside of that necessary for stabilizer function would negatively affect the organoleptic properties of the product.

#### **Brazil general comments:**

Brazil agrees with RU general comments and with the following position of the EU: "The EU believes that in this food category, which is in Annex to Table 3, the use of food additives has to be kept to the necessary minimum and not influencing the characteristics of milk. Milk is a complete food which is stable on its own".

As reported by RU, fluid milk is the basis for the production of various infant foods. According to Section 4.3 of the GSFA Preamble, carry-over principle is unacceptable for foods belonging to a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants, b) 13.2 - Complementary foods for infants and young children.

Brazil suggests that the entity that stated about the technological superiority of these additives in relation to citrates and phosphates presents the technical fundament, proving, even, that these additives are able to inhibit the gelation defect. Brazil understands that this defect results mainly from the proteolysis practiced by thermoresistant enzymes produced by microorganisms present in raw milk. It means that the defect is related to the use of low quality raw material; therefore, the use of the additive is not justified when good manufacturing practices (GMP) are not complied.

In Brazil, a tropical country, the use of citrates and phosphates is fully adequate to ensure the stability of UHT milk under storage conditions at room temperature (which is often higher than 30 °C).

Finally, Brazil emphasizes that does not oppose the approval of new additives for UHT milk, provided they comply with the principles established by the GSFA. The problem is that these additives, in addition to the stabilizing function, invariably promote changes in the viscosity of the product, which can mislead the consumer (this problem does not happen with phosphates and citrates).

#### **RU general comments:**

- 1. RU does not agree with use of this FA in subcategory «01.1.1 Milk (plain)» ultra-high temperature (UHT) treatment or sterilization milk are not connected with modification of its physical or chemickal characteristics and would not lead to any changes of milk (plain) aggregative state.
- 2. Fluid milk (plain) composition:
  Milk protein (a) (% m/m) min. 3.0%
  Milk fat (% m/m) less than 10%
  Titrable acidity (0T) 20-21
  Density, kg/m3 1024-1030.

Nutrition bioavailability of milk (plain) will be decreased in case of using Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener as a milk (plain) compounds, because the most important function of these food additives – adhesion. All of these food additives absorbing a great amount of water. Proteins and vitamins contained in milk (plain) could be absorbed too. There are a lot of scientific evident of these facts. As a result the nutrition value will be descended in case of these food additives using in milk (plain) composition.

- 3. Using of these food additives as compound of milk (plain) could mislead consumers. There is a broad field for adulteration because in case of using of these food additives organoleptic properties of of milk (plain) will be changed. So on skimmed milk could be sold as not skimmed milk.
- 4. Milk (plain) is broadly used as a compound of food for infant, baby food and young children. The most of these food additives not allowed for infant and baby consumptions (see Carry-over principles of food additives into foods).
- 5. There are not technological justifications for to use these FA in this FC.

#### Canada general comments:

Canada does not currently permit any additives for use in plain fluid milk products that are subject to this food category (01.1.1). This suggests that, in the Canadian market at least, there is not a need for additives in these products.

With respect to the ESTs set out in Annex 1, Canada notes that the justifications provided by some Members and Observers are for the use of stabilizers and emulsifiers in very specific milk products such as ultra high temperature (UHT)-treated milks. These comments suggest that there is an identified need for their use in certain products and markets. Therefore, Canada has no objection, in principle, to the use of emulsifiers and stabilizers in UHT-treated milks and their adoption in the GSFA as along as appropriate notes are used in the GSFA to restrict their use to these milk products (see rationale below).

Given that several foods subject to FC 01.1.1 constitute staple foods, Canada recommends that there be some protection against over-population of needless additives in this FC. Therefore, Canada suggests that (1) food additives be limited to certain foods for which their need has been identified; and (2) that horizontal justifications for additives not be applied to additives for the same technological function (i.e., that additives be considered on a case-by-case basis).

Consideration (1) has been put forward because the rationales provided for ESTs, for example, suggest a need for ESTs in UHT milks only. Canada suggests, then, that Note 227 "for use in sterilized and UHT treated milks only" should be added to those proposed provisions.

Consideration (2) has been put forward because it is apparent from the ICGMA's response, for instance, that different ESTs have differing technological effects.

Canada's overall position is the same for sodium citrate (Annex 2).

#### **EU general comments:**

The arguments provided in reply to the 1<sup>st</sup> circular did not convince the EU on the technological need of additional additives in FC 01.1.1. On the contrary the intended use indicates the intentions to change consistency (texture) and therefore changing the nature of fluid milk which in EU's view misleads the consumer. The EU would like to point out that "stabilizer" is defined as "A food additive, which makes it possible to maintain a uniform dispersion of two or more components" (CAC/GL 36-1989) whilst practically all additives under discussion can act as a thickener ("A food additive, which increases the viscosity of a food") which is indicated in the eWG comments as well. The EU does not question that the additives under discussion would be able to change consistency, texture and water binding capacity, however, the EU considers that such changes in fluid milk are not in line with section 3.2 of the GSFA Preamble.

# International Dairy Federation (IDF) General comment on the technological need for the additives under discussion in contrast to phosphates and citrates:

#### BACKGROUND:

- Phosphates stabilize milk proteins against coagulation from extreme heat, pH or sheer; buffer products within the desired pH range; support emulsification by interacting with proteins; and bind calcium in milk gels. Nutritionally, phosphates can help fortify with calcium, magnesium or potassium. Phosphates sequester metal ions and also have bacteriostatic effects. Many of the applications in processing of dairy products involve interactions between phosphates and casein, or the calcium in the casein micelles.
- Citrate and phosphate ions decrease tendency for fat coalescence (Sodium citrate, Disodium Phosphate). These salts decrease the degree of protein aggregation. Calcium and magnesium ions have the opposite effect, promote partial coalescence. Calcium sulfate, for example, results in a drier ice cream. Calcium and Magnesium increase the degree of protein aggregation. Salts may also influence electrostatic interactions. Fat globules carry a small net negative charge, these ions could increase or decrease that charge as they were attracted to or repelled from surface.

Therefore, the use of phosphates and citrates is effective for minimizing the "settling" out of milk proteins for milk receiving higher heat treatment processes. Other food additives do provide this same benefit as well as other benefits to dairy beverages based on:

- changes in the pH of the milk (unflavored cultured milk products)

- the source of the milk (goat's milk and to a slightly lesser extent, sheep's milk)

- and processing (Ultra High Temperature treatment for instance).

Other additives may minimize precipitation of components such as the milk protein and lactose which the consumer does not understand is harmless, but which they do know is that "normal" milk does not have.

Recommendations on the expression of the ML for Trisodium citrate (INS 331(iii)) in food category 01.1.1:

# Food Category No. 01.1.1 (Fluid milk (plain))

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted/ Year Revised	INS Functional Class	2 <sup>nd</sup> Circular proposal/ eWG comments	eWG Final Proposal
TRISODIUM CITRATE	331(iii)	GMP		7	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular proposal: Adopt as GMP; add new Note "for use in UHT treated milks only" Comments to 1st circular provided supporting information for use at GMP and no information was provided on why GMP is not sufficient.  Chile, FoodDrinkEurope, ICGMA, IDF: Supports proposal  Malaysia: Generally can support the GMP level and limitation for use in UHT milk. More information is required to support either to limit certain species, e.g. goat's milk.	Adopt as GMP; add Note 227 "For use in sterilized and UHT treated milks only"; new Note "only for uses as emulsifier/stabilizer"  Chair's Note: Phosphates are adopted in this food category with Note 227 "For use in sterilized and UHT treated milks only."

#### EWG General Comments - Annex 2 - Trisodium citrate (INS 331(iii) in food category 01.1.1

#### **USA** general comments:

The USA is in support of a maximum use level of good manufacturing practice (GMP) for Trisodium citrate (INS 331(iii)) in FC 01.1.1.

The addition of Trisodium citrate to fluid milk is to help prevent curdling thus improving the rheological and physical properties of the fluid milk product. Trisodium citrate also reduces sediment of solid particles to acceptable levels and to reduce heat induced thickening and coagulation in concentrated milk upon UHT treatment. For example, goat's and cow's milk produced without added stabilizer produces heavy sediment upon UHT treatment. In the context of Section 3.2 of the preamble to the GSFA, the use of Trisodium citrate as a stabilizer helps aid in the processing and preparation of fluid milk that allows the milk to be palatable. Trisodium citrate in food products of FC 01.1.1 does not reduce the nutritional quality of fluid milk or mislead the consumer since the product is labelled informing the consumer of the food additives in the product, stabilizers are used in these products globally and the use of stabilizers in these products should be expected.

Section 1.4 of the preamble to the GSFA states that, "the primary objective of establishing maximum use levels for food additives in various food groups is to ensure that the intake of an additive from all its uses does not exceed its ADI. Upon JECFA review, Trisodium citrate was assigned n ADI of "not specified". In the GSFA, Trisodium citrate is a Table 3 food additive and has an allowable use level of GMP. Section 2 of the preamble to the GSFA notes that "under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers."

The USA considers the use of Trisodium citrate in food products of FC 01.1.1 should be expected at levels necessary to achieve the desired technological function as stabilizer. Any increased use levels of the food additive would likely spoil or make the food product rancid affecting the organoleptic properties, thus rendering that food product unfit for international trade.

#### Colombia general comments:

It allows the use of crusher alone or combined with phosphates fulfills the technological function of stabilizer in ultrapasteurisadas milks. It is important to clarify that this additive must be on the list of ingredients.

#### **RU** general comments:

There is technological justification for to use of Trisodium citrate INS 331(iii) in case with only UHT goat milk.

#### International Dairy Federation (IDF) general comments:

IDF wishes to retain provision for INS 331(iii) with note limiting to " UHT heat-treated milks from certain species only, e.g. goat's milk.

Trisodium citrate (INS 331 (iii)) is necessary in food category 1.1.1 for UHT heat-treated milks from certain species, e.g. goat's milk, for the following reasons:

- Production of UHT treated goat milk may require some technological adjustments using phosphates and citrates.
- Without stabilizers, some goat milk coagulates before reaching the temperatures required for UHT treatments.

"Trisodium citrate is used in a number of dairy products to stabilize the proteins, such as long shelf like milks. It is also used in some natural and processed cheeses not only as an acidifying agent but for its stabilizing properties in keeping the cheese, processed cheese and cheese products from becoming greasy if melted. Based on this technological justification for its use, the fact that JECFA established an ADI "not specified", there appears to be no toxicological concerns from other sources than JECFA and its current use in some dairy products, Trisodium Citrate should remain in Table 3 of the GSFA at a level of "GMP."

1. Trisodium Citrate is already found in Table 2 of the GSFA (2017) for dairy products at GMP levels.

TRISODII	UM CITRATE Trisodium citrate Functional Class: Acidity re Sequestr	gulator, Emulsifier, E ant, Stabilizer	Emulsifying s	alt,
FoodCatNo	FoodCategory	MaxLevel	Notes	Year Adopted
01.1.3	Fluid buttermilk (plain)	GMP	261	2013
01.2.2	Renneted milk (plain)	GMP		2013
01.4.1	Pasteurized cream (plain)	GMP	236	2013
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	GMP		2013
01.8.2	Dried whey and whey products, excluding whey cheeses	GMP		2006
02.1.1	Butter oil, anhydrous milkfat, ghee	GMP	171	2006

- 2. Trisodium Citrate is listed in Table 3 of the GSFA for use in all food categories and has been evaluated by JECFA with an ADI "not specified" supporting a level of GMP.
- 3. The Handbook of Toxicology (2002) identified no significant issues even when feed to laboratory animals at fairly high levels.

#### **EU general comments:**

There is a technological need for Trisodium citrate in UHT goat milk. Goat milk produces heavy sediment on UHT treatment. There is an experimental evidence that Trisodium citrate is able to act as an efficient stabilizer reducing ionic calcium (citrates react with calcium limiting the pH decrease and increasing the buffering capacity) which prevents formation of the sediment. Hence the amount of citrate is also an important parameter that governs the ionic calcium level.

To the EU's knowledge the maximum level up to 4000 ppm is appropriate to adjust the milk pH to an optimum range as regards the heat stability without having any possible adverse effect as for the nature and quality of milk. For that reason the EU is advocating the ML of 4000 mg/L in UHT goat milk.

# Appendix 5: Provisions in Table 1 and 2 of the GSFA in food categories 09.0 through 016.0, with the exception of those additives with technological functions of colour or sweetener, adipates, nitrites and nitrates and the provisions related to FC 14.2.3

- 1. Among several topics, CCFA49 requested the EWG on the GSFA to CCFA50 to:1
- Request information and justification on the proposed food additive provisions held at the current step in Table 1 and 2 of the GSFA in food categories 09.0 through 016.0, with the exception of those additives with technological functions of colour or sweetener, adipates, nitrites and nitrates, and the provisions related to FC 14.2.3

#### **Background**

2. CCFA49 agreed that the EWG on the GSFA to CCFA50 should prepare proposals for the remaining draft and proposed draft provisions for food additives in food categories 09.0 through 16.0, with the exception of provisions for food additives with "colour" or "sweetener" function, adipates, nitrites and nitrates and the provisions related to FC 14.2.3.

#### **Working Document:**

- 3. The EWG issued two circulars for comment. This current document presents proposals on the remaining draft and proposed draft provisions in Tables 1 and 2 of the GSFA in food categories (FCs) 09.0 through 16.0. However, within FCs 09.0 through 16.0 this document does not include draft and proposed draft provisions for:
- food additives with "colour" or "sweetener" function;
- adipates (INS 355, 359), nitrates (INS 251, 252), and nitrites (INS 249, 250), each of which are the subject of on-going work as a result of decisions made by CCFA49 and therefore are not appropriate subjects for the EWG on the GSFA.<sup>2</sup>;
- provision related to FC 14.2.3.
- 4. The current document presents recommendations for each provision (adopt, adopt with revision, discontinue, discontinue and move to subcategories as appropriate, request information). These proposals are based upon a consensus approach taking into account alignment with corresponding Codex commodity standards and comments on the first and second circulars by members of the EWG. These recommendations are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification.

#### Conventions

- 5. The current document presents the provisions under discussion in the format of the food categories listed in Table 2 of the GSFA. Information on corresponding Codex commodity standards and the use of food additives in those commodity standards is provided for each food category. Information on the decision of the physical working group (PWG) on the GSFA to CCFA45 or CCFA46 (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II) pertaining to the horizontal justification of food additives with "acidity regulator" or "emulsifier, stabilizer, and thickener" function in food categories listed in the Annex to Table 3 is provided. The document also presents a compilation of comments provided by EWG members to the first and second circulars as well as relevant information from CCFA49.
- 6. The following conventions were used to prepare the working document:
- When the proposal is that a food additive provision be moved from a parent food category to a subcategory, or vice-versa, the original provision in the original food category is indicated with strikethrough font and the new provision to be added to a different food category as a result is indicated in **bolded** font with no Step indicated in the "Step/Adopted" column.

<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

<sup>&</sup>lt;sup>2</sup> REP 17/FA paras 86 and 87, 106.

# <u>Draft and proposed draft provisions in the GSFA in FC 09.0 to FC 16.0, with the exception of those additives with technological and functions of colour or sweetener, adipates, nitrites and nitrates and the provisions related to FC 14.2.3</u>

#### Food Category No. 09.0 Fish and fish products, including mollusks, crustaceans, and echinoderms

Corresponding commodity standards: None; Multiple standards apply to subcategories, some of which do not allow food additives

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	4 <del>75</del>	10,000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Discontinue in parent category; Discuss in subcategories  Chile, RU: Agrees with proposal	Discontinue in parent category; Discuss in subcategories
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	<del>476</del>	5,000		7	Emulsifier	2nd Circular Proposal: Discontinue in parent category; Discuss in subcategories  Chile, RU: Agrees with proposal	Discontinue in parent category; Discuss in subcategories

#### Food Category No. 09.1 Fresh fish and fish products, including mollusks, crustaceans, and echinoderms

Corresponding commodity standards: None; Corresponding commodity standard to subcategory 09.1.2

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this food category; provisions are discussed in subcategory
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#### Food Category No. 09.1.1 Fresh fish

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators and ES&T are not justified in this food category on a general basis.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.1.1  Brazil, Chile, EU, Malaysia, Norway, Singapore, RU: supports do not adoption in	Do not adopt in in FC 09.1.1

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						FC 09.1.2.	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.1.1  Brazil, Chile, EU, Norway, Singapore, RU: supports do not adoption in FC 09.1.2.	Do not adopt in in FC 09.1.1

#### Food Category No. 09.1.2 Fresh mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators and ES&T are not justified in this food category on a general basis.

Corresponding commodity standards: 292-2008: No additives permitted in Live Bivalve Molluscs, Raw Bivalve Molluscs allows antioxidants from FC 09.1.2 and 09.2.1; 312-2013: No additives permitted; 315-2014: No additives permitted except Phosphates in Quick Frozen Scallop Meat and Quick Frozen Roe-on Scallop Meat Processed With Phosphates

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.1.2  Brazil, Chile, EU, Malaysia, Norway, Singapore, RU: supports do not adoption in FC 09.1.2.	Do not adopt in in FC 09.1.2
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.1.2  Brazil, Chile, EU, Norway, Singapore, RU: supports do not adoption in FC 09.1.2.	Do not adopt in in FC 09.1.2

Corresponding commodity standards: None; Multiple standards apply to subcategories, some of which do not allow food additives

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
GLYCEROL	4 <del>22</del>	GMP		4	Humectant, Thickener	<ul> <li>2nd Circular Proposal: Move to FC 09.2.1 only.</li> <li>Chile, RU: Agrees with proposal</li> <li>Norway: discontinue as acidity regulators and ES&amp;T are not justified in this food category on a general basis.</li> </ul>	Move to FC 09.2.1 only

Food Category No. 09.2.1 Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators justified on a case-by-case basis, ES&T are justified with Note 29 "For non-standardized food only"

Corresponding commodity standards: 36-1981: Lists specific antioxidants; 92-1981, 95-1981: Lists specific humectants, preservatives and antioxidants; 165-1989: Lists specific humectants, antioxidants, acidity regulators and thickeners; 190-1995: Lists specific humectants and antioxidants; 191-1995: No additives permitted; 292-2008: No additives permitted in Live Bivalve Molluscs, Raw Bivalve Molluscs allows antioxidants from FC 09.1.2 and 09.2.1; 312-2013: No additives permitted; 315-2014: No additives permitted except Phosphates in Quick Frozen Scallop Meat and Quick Frozen Roe-on Scallop Meat Processed With Phosphates

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
GLYCEROL	422	GMP			Humectant, Thickener	2nd Circular Proposal: Adopt as listed with new Note: 29 Request information on use in nonstandardized food. China, FoodDrinkEurope, RU: Agrees with proposal with Note 29 EU: supports requesting info on use in nonstandardised. Norway: Discontinue ES&T are not justified in this food category on a general basis. Humectants are only	Request information on use in non-standardized food.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						justified in frozen fish and frozen Frozen Scallop Meat. It is unclear what kind of products note 29 "For non-standardized food only" will be	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.1; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.1.  Japan: Proposes adoption at 5000 mg/kg with Note 241 "For use in surimi products only". Polyglycerol esters of fatty acids are used in frozen surimi for further processing to prevent protein denaturation by freezing process. The maximum use level is 5000 mg/kg in the frozen surimi.	Adopt at 5000 mg/kg with Note 241 "For use in surimi products only"
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.2.1; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.1.	Do not adopt in in FC 09.2.1; No comments provided on use
SUCROSE ESTERS OF FATTY ACIDS	473	10000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC      Chile, EU: supports to request information on technological justification; types of products used in, and use level in this FC.      Malaysia: Support for adoption with Note 29 and with Note 348	Discontinue; no information on technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						Norway: Discontinue ES&T are not justified in this food category on a general basis. CCFFP code of practice define glazing as a thin layer of is without any food additives. It is unclear what kind of products note 29 "For non-standardized food only" will be  RU: There is not technological justification. This proposal should be discontinued.	

Food Category No. 09.2.2 Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified; ES&T are justified with Note 29 "For non-standardized food only"

Corresponding commodity standards: 166-1989: Lists specific humectants, antioxidants, acidity regulators, thickeners, raising agents, flavour enhancers, colours and emulsifiers

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.2; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.2.	Do not adopt in in FC 09.2.2; No comments provided on use
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.2.2; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.2.	Do not adopt in in FC 09.2.2; No comments provided on use
TOCOPHEROLS	307a, b,	GMP	15	7	Antioxidant	2nd Circular Proposal: Adopt at 200 with Note XS166	Adopt at 200 mg/kg with Note XS166

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						Brazil: Supports the adoption of a numerical use level, considering that it is an additive with numerical ADI (2mg/kg bw/d).  Chile, FoodDrinkEurope, Malaysia, RU: Supports proposal  Norway: Discontinue; FA with specified ADI should have numerical ML. It is unclear what kind of products note 29 "For nonstandardized food only" will be	

<u>Food Category No.</u> 09.2.3 Frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified; ES&T are justified Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.3; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.3  Japan: proposes adoption at 5000 mg/kg. Polyglycerol esters of fatty acids are used in frozen minced fish products to prevent protein denaturation in freezing process. The maximum use level is 5000 mg/kg.	Adopt at 5000 mg/kg
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.2.3; No comments provided on use	Do not adopt in in FC 09.2.3; No comments provided on use

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						Chile, EU, Norway, RU: supports do not adoption in FC 09.2.3	

<u>Food Category No.</u> 09.2.4 Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified, ES&T are not justified

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
LAURIC ARGINATE ETHYL ESTER	243	200		4	Preservative	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC  Chile, EU, Norway, RU: supports to request information on technological justification; types of products used in, and use level in this FC.	Discontinue; no information on technological justification provided
SUCROSE ESTERS OF FATTY ACIDS	<del>473</del>	10000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Discontinue in parent category; Discuss in subcategories  Chile, EU, RU: Agrees with proposal	Discontinue in parent category; Discuss in subcategories

## Food Category No. 09.2.4.1 Cooked fish and fish products

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified; ES&T are justified with the Note 241 "For use in surimi products only".

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
SODIUM DIACETATE	262(ii)	3000		7	Acidity regulator, Preservative,	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in	Discontinue; no information on technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
					Sequestrant	this FC  Chile, EU, RU: supports to request information on technological justification; types of products used in, and use level in this FC.	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.4.1; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.4.1.  Japan: proposes adoption at 1000 mg/kg with new note "For use in fish sausage only."  Polyglycerol esters of fatty acids are used in fish sausage to prevent its contents from adhering to casing film (outer package) by reducing interfacial tension.	Adopt at 1000 mg/kg with new note "For use in fish sausage only."
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.2.4.1; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.4.1.	Do not adopt in in FC 09.2.4.1; No comments provided on use
SUCROSE ESTERS OF FATTY ACIDS	473	10000			Emulsifier, Foaming agent, Glazing agent, Stabilizer	Znd Circular Proposal: Adopt as listed with Note 348; Add Provisions for INS 473a and 474      Chile, FoodDrinkEurope: Supports proposal      Eu: note 241 "For use in surimi products only" should be used      Norway: Discontinue     ES&T are not justified in this food category	Adopt as listed with Notes 348; Add Provisions for INS 473a and 474

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						on a general basis.  Japan: Sucrose esters of fatty acids are used at up to 10000 mg/kg in cooked surimi product (kamaboko) and tube-shaped surimi product (chikuwa) as stabilizer to prevent retrogradation of the products and to maintain their elasticity.  Japan supports adding Note 348 and the provisions for INS 473a and 474 since these additives share the group ADI.  RU: Does not agree with proposal. ML is so higher. Technological justification has been given only for surimi product.	

## Food Category No. 09.2.4.2 Cooked mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified, ES&T are not justified

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.4.2  Brazil, Chile, EU, Norway, RU: supports do not adoption in FC 09.2.4.2.	Do not adopt in in FC 09.2.4.2
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	Proposal: Do not adopt in in FC 09.2.4.2  Brazil, Chile, EU, RU: supports do not adoption in FC 09.2.4.2.	Do not adopt in in FC 09.2.4.2

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
SUCROSE ESTERS OF FATTY ACIDS	473	10000			Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.4.2; No comments provided on use  EU, RU: supports do not adoption in FC 09.2.4.2.  Norway: Discontinue ES&T are not justified in this food category on a general basis.	Do not adopt in in FC 09.2.4.2; No comments provided on use

# Food Category No. 09.2.4.3 Fried fish and fish products, including mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified; ES&T are justified with the Note 41 "For use in breading or batter coatings only".

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Adopt with Note 41  "For use in breading or batter coatings only."  EU: INS 475 was not listed in the similar standardized food (CS 166-1989) where only two emulsifiers with the ADI not specified were listed (INS 471 and INS 322). Could it be clarified why INS 475 needed if in similar products the use of INS 471 and INS 322 was sufficient?)  FoodDrinkEurope: Supports proposal  Japan: supports 2nd circular proposal. Polyglycerol esters of fatty acids are used in batter coatings to disperse oil uniformly. The	Adopt at 5000 mg/kg with Note 41 "For use in breading or batter coatings only."

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						Morway: Discontinue When CCFFP reviewed chapter 4 in CS 166-1989 neither POLYGLYCEROL ESTERS OF FATTY ACIDS nor POLYGLYCEROL ESTERS OF FATTY ACIDS were found technological justified  RU: Does not agree with proposal. There not technological justification and justification of ML level (now it is so higher).  2nd Circular Proposal: Do not adopt in in	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	FC 09.2.4.3; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.4.3.	Do not adopt in in FC 09.2.4.3; No comments provided on use
SORBITAN ESTERS OF FATTY ACIDS	491-495	1000		4	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Discontinue  Chile, EU, Norway, RU: supports discontinuation	Discontinue; no information on technological justification provided
SUCROSE ESTERS OF FATTY ACIDS	473	10000			Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.4.3  EU, Norway, RU: supports do not adoption in FC 09.2.4.3.	Do not adopt in in FC 09.2.4.3

Food Category No. 09.2.5 Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms

Horizontal Approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): Acidity regulators are justified, with note 267 "Excluding products conforming to the Standard for Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes (CODEX STAN 167-1989), the Standard for Dried Shark Fins (CODEX STAN 189-1993), the Standard for Crackers from marine and Freshwater Fish, Crustaceans and Molluscan Shellfish (CODEX STAN 222-2001) and the Standard for Boiled Dried Salted Anchovies (CODEX STAN 236-2003)"; ES&T justified with the note 300 "For use in salted squid only".

Corresponding commodity standards: 167-1989: Lists Sorbates with the function of preservatives; 189-1993: No additives permitted; 222-2001: Lists specific sequestrants and flavour enhancers; 236-2003: No additives permitted; 244-2004: Lists specific acidity regulators and preservatives; 311-2013: Lists specific acidity regulators, antioxidants, colours, packaging gases and preservatives in Smoked fish and Smoke-flavoured fish, No additives permitted in Smoked-Dried Fish

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
LAURIC ARGINATE ETHYL ESTER	243	200		4	Preservative	<ul> <li>2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC</li> <li>Chile, EU, Norway: supports to request information on technological justification; types of products used in, and use level in this FC.</li> <li>RU: The proposal should be discontinued. There is not technological justification.</li> </ul>	Discontinue; no information on technological justification provided
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.2.5; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.5.	Do not adopt in in FC 09.2.5; No comments provided on use
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.2.5; No comments provided on use  Chile, EU, Norway, RU: supports do not adoption in FC 09.2.5.	Do not adopt in in FC 09.2.5; No comments provided on use
PHOSPHATES	338; 339(i)- (iii); 340(i)- (iii); 341(i)- (iii); 342(i)-	2200	29, 33 & 334	2	Acidity regulator, Emulsifier, Humectant, Preservative, Sequestrant, Stabilizer, Thickener	2nd Circular Proposal: Adopt as listed with Notes 33, 334, XS167, XS 189, XS 236, XS244, XS311, 334, and "INS 452(i-v) only in products conforming to the Standard for Crackers From Marine and Freshwater Fish, crustacean and Molluscan Shellfish (CODEX STAN 222-2001)"	Adopt as listed with Notes 33, 334, XS167, XS 189, XS 236, XS244, XS311, 334, and "INS 452(i-v) only in products conforming to the Standard for Crackers From Marine and Freshwater Fish, crustacean and Molluscan Shellfish

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
	(ii); 343(i)- (iii); 450(i)- (iii),(v)- (vii), (ix); 451(i),(ii) ; 452(i)- (v); 542					CEFIC, IFAC, and ICGMA: IFAC supports the adoption of these provisions with the addition of Notes 33, 334, XS167, XS189, XS236, XS244, XS311, 334 and the proposed note related to CODEX STAN 222-2001. Phosphates can provide acidity regulation and humectant functions in these products.	(CODEX STAN 222-2001)"
						<u>EU</u> : the use of phosphates has to be carefully considered to avoid their possible misuse (binding additional water). The EU assumes that this consideration was taken into account by the CCFFP, therefore, all commodity standards falling in this category do not allow phosphates (except one – related to highly processed products such as crackers). From this point of view the EU does not consider the use of phosphates as justified and does not support the adoption.	
						Norway: Discontinue ES&T are not justified in this food category on a general basis. Sequestrants are technological justified in crackers made from Marine and Freshwater Fish, crustacean, Molluscan and Shellfish,	
						Japan: proposes following new note: 29 "For use in smoked molluscs and salted molluscs non-standardized food only."" be added to this provision.	
						Phosphates are used as sequestrant to prevent discoloration in smoked molluscs. They are also used as sequestrant to prevent fat oxidation in salted molluscs.squid. Smoked molluscs and	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						salted molluscs aresquid is fallen within food category 09.2.5 but not covered by any commodity standards including CODEX STAN 222-2001  Maximum use level is 700 mg/kg as phosphorus.  RU: The proposal should be discontinued. There is not technological justification.	
SORBITAN ESTERS OF FATTY ACIDS	491-495	100		4	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Discontinue; no information on technological justification provided  Chile, EU, Norway, RU: supports discontinuation	Discontinue; no information on technological justification provided
SUCROSE ESTERS OF FATTY ACIDS	473	10,000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Discontinue; no information on technological justification provided  Chile, EU, Norway, RU: supports discontinuation	Discontinue; no information on technological justification provided

## Food Category No. 09.3 Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms

Corresponding commodity standards: None; Corresponding commodity standard to subcategory 09.3.3

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	There are no provisions under discussion in this food category; included for information purposes only
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# <u>Food Category No.</u> 09.3.1 Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
LAURIC ARGINATE	243	200		4	Preservative	2nd Circular Proposal: Request	Discontinue; no information on

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
ETHYL ESTER						information on technological justification, types of products used in, and use level in this FC	technological justification provided
						<u>Chile, EU, Norway</u> : supports to request information on technological justification; types of products used in, and use level in this FC.	
						RU: Agrees with discontinuation of proposal	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.3.1; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.1.  Japan: proposes adoption at 1000 mg/kg with new note "For use in marinated products only." Polyglycerol esters of fatty acids are used in marinated fish products to disperse oil uniformly in marinade and to prevent generating foams. The maximum use level is 1000 mg/kg.	Adopt at 1000 mg/kg with new note "For use in marinated products only."
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.3.1; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.1.	Do not adopt in in FC 09.3.1; No comments provided on use

<u>Food Category No.</u> 09.3.2 Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine Corresponding commodity standards: None

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
LAURIC ARGINATE ETHYL ESTER	243	200		4	Preservative	2nd Circular Proposal: Discontinue, no information on technological justification provided  Chile, EU, RU: supports discontinuation	Discontinue, no information on technological justification provided
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.3.2; No comments provided on use Chile, EU, RU: supports do not adoption in FC 09.3.2.  Japan: proposes adoption at 1000 mg/kg with new note "For use in pickled products only." Polyglycerol esters of fatty acids are used in pickled fish products to prevent generating foams. The maximum use level is 1000 mg/kg.	Adopt at 1000 mg/kg with new note "For use in pickled products only."
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.3.2; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.2.	Do not adopt in in FC 09.3.2; No comments provided on use

# Food Category No. 09.3.3 Salmon substitutes, caviar, and other fish roe products

Corresponding commodity standards: 291-2010: Additives permitted except colours and texturizing agents, permit acidity regulators, antioxidants and preservatives listed in Table 3

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
LAURIC ARGINATE ETHYL ESTER	243	200		4	Preservative	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC	Discontinue; no information on technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						Chile, EU, Norway: supports to request information on technological justification; types of products used in, and use level in this FC.  RU: The proposal should be discontinued. There is not technological justification.	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.3.3; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.3.	Do not adopt in in FC 09.3.3; No comments provided on use
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.3.3; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.3.	Do not adopt in in FC 09.3.3; No comments provided on use

<u>Food Category No.</u> 09.3.4 Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g. fish paste), excluding products of food categories 09.3.1 - 09.3.3

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
LAURIC ARGINATE ETHYL ESTER	243	200		4	Preservative	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC  Chile, EU, Norway: supports to request information on technological justification;	Discontinue; no information on technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						types of products used in, and use level in this FC.  RU: Does not agree with proposal. INS 243 not allowed in RU.	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.3.4; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.4.	Do not adopt in in FC 09.3.4; No comments provided on use
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.3.4; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.3.4.	Do not adopt in in FC 09.3.4; No comments provided on use

# Food Category No. 09.4 Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms

Corresponding commodity standards: 3-1981: No additives permitted; 37-1981: Lists specific colours, sequestrants and acidity regulators; 70-1981, 94-1981 and 119-1981: Lists specific thickeners and gelling agents, modified starches and acidity regulators; 90-1981: Lists specific acidity regulators, sequestrants and flavour enhancers

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10,000			Emulsifier, Stabilizer	2nd Circular Proposal: Do not adopt in in FC 09.4; No comments provided on use  Chile, EU, RU: supports do not adoption in FC 09.4	Do not adopt in in FC 09.4; No comments provided on use
POLYGLYCEROL ESTERS OF INTERESTERIFIED	476	5,000			Emulsifier	2nd Circular Proposal: Do not adopt in in FC 09.4; No comments provided on use	Do not adopt in in FC 09.4; No comments provided on use

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
RICINOLEIC ACID						Chile, EU, RU: supports do not adoption in FC 09.4	
SUCROSE ESTERS OF FATTY ACIDS	473	10000		4	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Discontinue; no information on technological justification provided  Chile, EU, RU: supports discontinuation	Discontinue; no information on technological justification provided
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	10000		7	Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC  Chile, EU, Norway: supports to request information on technological justification; types of products used in, and use level in this FC.  RU: The proposal should be discontinued. There is not technological justification.	Discontinue; no information on technological justification provided
SUCROGLYCERIDE S	474	10000		7	Emulsifier	2nd Circular Proposal: Discontinue; no information on technological justification provided Chile, EU, RU: supports discontinuation	Discontinue; no information on technological justification provided
TARTRATES	334, 335(ii), 337	500	45	4	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Request information on technological justification, types of products used in, and use level in this FC  Chile, EU, Norway: supports to request information on technological justification; types of products used in, and use level in this FC.  RU: The proposal should be discontinued. There is not technological justification.	Discontinue; no information on technological justification provided

Food Category No. 10.0 Eggs and egg products

Horizontal approach:

Corresponding commodity standards: None

Additive	INS Lev (mg/	el Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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## Food Category No. 10.1 Fresh eggs

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is not justified in this food category on a general basis.

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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### Food Category No. 10.2 Egg products

Horizontal approach: only subcategories 10.2.1 and 10.2.2 are in Annex to Table 3, acidity regulators and ES&T justified on a general basis Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Request information on actual use level      EU: supports the 2 <sup>nd</sup> circular proposal. The EU could accept 1000 ppm.      Malaysia: concerns with aluminium-containing food additives in order to limit exposure in light of revised PTWI by JECFA.	Adopt at 1000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						RU: Supports adoption at ML 1000 mg/kg singly or in combination with INS 476	
						<u>Chile</u> : supports 2 <sup>nd</sup> circular proposal	
						2nd Circular Proposal: Request information on actual use levels	
POLYGLYCEROL ESTERS OF	476	5000		7	Emulsifier	EU: info on technological need should be requested. INS 476 does not share the ADI with INS 475	Adopt at 1000
INTERESTERIFIED RICINOLEIC ACID	470					RU: Supports adoption at ML 1000 mg/kg singly or in combination with INS 475	
						Chile: supports 2 <sup>nd</sup> circular proposal	
SODIUM DIACETATE	262(ii)	1000		7	Acidity regulator, Preservative, Sequestrant	2nd Circular Proposal: Request information on technological justification  Chile, EU: supports 2 <sup>nd</sup> circular proposal	Request information on technological justification
						RU: Supports adoption	

## Food Category No. 10.2.1 Liquid egg products

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is justified in this food category on a general basis.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
ALUMINIUM SULFATE	520	100	6	7	Firming agent	2nd Circular Proposal: Request information on actual use level	Adopt at 30 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						Brazil, EU, Malaysia Singapore: Does not support adoption. JECFA has recommended the reduction of aluminium exposure to the extent possible. According to paragraph 21, REP14/FA, "the Committee recalled that JECFA had established a new PTWI of 2 mg/kg body weight for aluminium from all sources and that CCFA had revised the provisions for aluminium-containing food additives in several commodity standards, as well as in the GSFA, in response to the JECFA recommendation to decrease the use of aluminium-containing food additives to the extent possible."  EU: revised the use of Al-containing additives (including Al lakes of colours and food additive specifications) in 2012 and only two very specific entries for INS 520 were left. One of them was for "liquid egg white for egg foams only" at 25 ppm  RU: Supports adoption at ML 30 mg/kg  Chile: supports 2 <sup>nd</sup> circular proposal	
NISIN	234	6.25	233	3	Preservative	2nd Circular Proposal: Adopt as listed  Chile: Does not support adoption due to restrictions on the use of this additive in Chile.  EU: has technological justification been provided? Needed in pasteurized products?  ICGMA, IFAC: Support adoption.  Studies on liquid egg products show that some heat resistant Gram-positive	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						bacteria can survive the pasteurization process and are capable of growth under refrigerated temperatures. These and other studies show that nisin is effective in controlling <i>Bacillus cereus</i> , <i>Listeria innocua and Listeria monocytogenes</i> , common contaminants associated with liquid egg processing and liquid egg products. Use of nisin can help enhance the safety of these product. See also 2 <sup>nd</sup> Circular General Comment <u>RU</u> : Strongly opposes proposal because nisin – antibiotic. The problem of antibiotic resistance recognized by WHO.	
						Japan supports the 2 <sup>nd</sup> circular proposal. Nisin is used in liquid egg products to prevent microbiological deterioration and prolong its shelf-life.	
						South Africa: Supports adoption. Studies on liquid egg products show that some heat resistant Gram-positive bacteria can survive the pasteurization process and are capable of growth under refrigerated temperatures. These and other studies show that nisin is effective in controlling Bacillus cereus, Listeria innocua and Listeria monocytogenes, common contaminants associated with liquid egg processing and liquid egg products. Use of nisin can help enhance the safety of these products.	
PROPYLENE GLYCOL ALGINATE	405	10000		4	Bulking agent, Carrier,	2 <sup>nd</sup> Circular Proposal: Request info on actual use levels	Adopt at 10,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	IFAC: Support adoption. Stabilizers and thickeners are generally needed in liquid egg products to maintain desired consistency and avoid separation.  RU: The proposal should be discontinued. There is no technological justification.  Chile: supports 2 <sup>nd</sup> circular proposal  EU: questions the technological need - no specific justification why INS 405 is needed was provided  ICGMA: Based on information provided to ICGMA, the maximum usage level of 10,000 mg/kg should be maintained	
STEAROYL LACTYLATES	481(i), 482(i)	500		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt as listed  EU: questions the technological need - no specific justification why INS 481- 482 is needed was provided. It is not necessary to increase the exposure to INS 481-482 in this food category.  ICGMA, IFAC: supports second circular proposals, including adopting at a usage level of 500 mg/kg. Stabilizers are generally needed in liquid egg products to maintain desired consistency and avoid separation  RU: The proposal should be discontinued. There is no technological justification.	Adopt as listed

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is justified in this food category on a general basis.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
ALUMINIUM SULFATE	520	100	6	2	Firming agent	2nd Circular Proposal: Request information on actual use levels  Brazil, Chile, EU, Malaysia, Singapore: Does not support adoption. JECFA has recommended the reduction of aluminium exposure to the extent possible. According to paragraph 21, REP14/FA, "the Committee recalled that JECFA had established a new PTWI of 2 mg/kg body weight for aluminium from all sources and that CCFA had revised the provisions for aluminium-containing food additives in several commodity standards, as well as in the GSFA, in response to the JECFA recommendation to decrease the use of aluminium-containing food additives to the  RU: The proposal should be discontinued, because JECFA recommendation to decrease the use of aluminium-containing food additives	Discontinue
DEXTRINS, ROASTED STARCH	1400	GMP		2	Carrier, Emulsifier, Stabilizer, Thickener	2nd Circular Proposal: Adopt as listed  EU: supports the 2nd circular proposal  ICGMA: supports the second circular proposal. Stabilizers and thickeners are generally needed in frozen egg products to maintain desired consistency and avoid separation.  Japan supports 2nd circular proposal. This additive is used to restore egg's	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						viscosity, foaming, emulsifying, sponge forming properties lost during pasteurization and freeze storage.  RU: The proposal should be discontinued. There is not technological	
						justification.  2nd Circular proposal: Adopt as listed	
PROPYLENE GLYCOL ALGINATE	405	10000		4	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	EU questions the technological need - no specific justification why INS 405 is needed was provided  ICGMA, IFAC: supports the second circular proposal. 10,000 mg/kg should be retained as ML. Stabilizers and thickeners are generally needed in frozen egg products to maintain desired consistency and avoid separation.  RU: Does not support adoption; not allowed in RF in this FC. No technological justification	Adopt as listed
STEAROYL LACTYLATES	481(i), 482(i)	500		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt as listed  EU questions the technological need - no specific justification why INS 481- 482 is needed was provided. It is not necessary to increase the exposure to INS 481-482 in this food category.  ICGMA, IFAC: supports 2nd circular proposal. 500 mg/kg is necessary to provide technological function described in first circular comments.  RU: The proposal should be discontinued. There is no technological justification.	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal

Food Category No. 10.2.3 Dried and/or heat coagulated egg products

Horizontal approach: FC 10.2.3 is not in the Annex to Table 3

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
STEAROYL LACTYLATES	481(i), 482(i)	5000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	EU: questions the technological need - no specific justification why INS 481-482 is needed was provided. It is not necessary to increase the exposure to INS 481-482 in this food category  RU: The proposal should be discontinued. There is not technological justification.  ICGMA, IFAC: supports 2 <sup>nd</sup> circular proposal. 5000 mg/kg is necessary to provide consistency and avoid separation throughout the heating and drying process.	Adopt as listed

## Food Category No. 10.3 Preserved eggs, including alkaline, salted, and canned eggs

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
SODIUM DIACETATE	262(ii)	1000		7	Acidity regulator,	2 <sup>nd</sup> Circular proposal: Request information on technological justification	Request information on

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Preservative, Sequestrant	and actual use level  RU: Supports adoption  Chile: supports 2 <sup>nd</sup> circular proposal  EU supports the 2 <sup>nd</sup> circular proposal.	technological justification and actual use level

# Food Category No. 10.4 Egg-based desserts (e.g. custard)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	9000		7	Emulsifier, Stabilizer	Z <sup>nd</sup> Circular proposal: Request information on technological justification and actual use level      RU: Supports adoption at ML = 1000 mg/kg      Chile: supports 2 <sup>nd</sup> circular proposal      EU supports the 2 <sup>nd</sup> circular proposal.      Japan: Polyglycerol esters of fatty acids are used in custard filling for cake to maintain stable emulsification during its shelf life. They are also used in flan to prevent heat coagulation.  Maximum use level is 6,000 mg/kg.	Adopt at 6,000
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	<ul> <li>2nd Circular proposal: Request information on technological justification and actual use level</li> <li>RU: Supports adoption at ML = 1000 mg/kg singly or in combination with INS 475</li> <li>Chile: supports 2nd circular proposal</li> </ul>	Adopt at 1,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL ALGINATE	405	10000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	EU supports the 2 <sup>nd</sup> circular proposal.  2 <sup>nd</sup> Circular proposal: Request information on technological justification and use level  IFAC: Supports adoption  Chile, EU: supports 2 <sup>nd</sup> circular proposal  Japan: Propylene glycol alginate is used in egg custard to increase viscosity of the product. The maximum use level is 10,000 mg/kg	Adopt at 10,000
SODIUM DIACETATE	262(ii)	2000		7	Acidity regulator, Preservative, Sequestrant	2nd Circular proposal: Adopt as listed  RU: Supports adoption	Adopt as listed
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		7	491: Emulsifier 492-494: Emulsifier, Stabilizer 495: Emulsifier	2nd Circular proposal: Adopt  RU: The proposal should not be adopted. There is no technological justification.  Chile: Request tech justification  EU: supports 2nd circular proposal  Japan: Japan supports the 2nd circular proposal. Please see Japan's comments in Revision to Appendix 5. Sorbitan esters of fatty acids are also used in flan and custard filling for fine bakery wares to maintain stable emulsification during its shelf life. Maximum use level is 1,000 mg/kg.	Adopt as listed
STEAROYL	481(i),	5000		7	Emulsifier,	2 <sup>nd</sup> Circular proposal: Request technological justification	Request technological

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
LACTYLATES	482(i)				Flour treatment agent, Foaming agent, Stabilizer	IFAC: Supports adoption  RU: The proposal should not be adopted. There is no technological justification.  Chile, EU: supports the 2 <sup>nd</sup> circular proposal.	justification
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular proposal Request information on technological justification and use level.  RU: Does not support adoption; no tech. justification.  Chile, EU: supports the 2nd circular proposal.  Japan: supports adoption.  Sucrose esters of fatty acids are used in custard filling for cake to maintain stable emulsification during its shelf life.  Maximum use level is 5,000 mg/kg.	Adopt at 5,000
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	<ul> <li>2nd Circular proposal: Request information on technological justification and use level</li> <li>RU: Does not support adoption; no tech. justification.</li> <li>Chile, EU: supports the 2nd circular proposal.</li> </ul>	Discontinue
SUCROGLYCERIDE S	474	5000			Emulsifier	2 <sup>nd</sup> Circular proposal: Request information on technological justification and use level  RU: Does not support adoption; no tech. justification	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						Chile, EU: supports the 2 <sup>nd</sup> circular proposal.	
TARTRATES	334, 335(ii), 337	2000	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	<ul> <li>2<sup>nd</sup> Circular proposal: Request information on technological justification and use level</li> <li>RU: Does not support adoption; no tech. justification</li> <li>EU: supports the 2<sup>nd</sup> circular proposal.</li> </ul>	Discontinue

## Food Category No. 11.0 Sweeteners, including honey

Corresponding commodity standards: None

	Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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### Food Category No. 11.1 White sugar, dextrose anhydrous, dextrose monohydrate, fructose

Horizontal approach: (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is **not** justified in this food category on a general basis.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category or its subcategories; included for information purposes only
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Horizontal approach: (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is not justified in this food category on a general basis.

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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<u>Food Category No.</u> 11.3 Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is not justified in this food category on a general basis.

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
INVERTASES	1103	GMP		4	Stabilizer	2nd Circular proposal: Discontinue	Discontinue
						Chile, EU, RU: supports discontinue	

<u>Food Category No.</u> 11.4 Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings)

Horizontal approach: (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is justified in this food category on a general basis, with note 258 "Excludingmaple syrup".

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
INVERTASES	1103	GMP		4	Stabilizer	2nd Circular proposal: Discontinue EU: Currently there is no provision for INS 1103 in the GSFA. It was assessed by the 57th JECFA (2001) as acceptable as enzyme preparation used in confectionary and pastry applications and if limited by GMP.  EU, RU: supports the 2nd circular proposal.	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL ALGINATE	405	5000	258	7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	Z <sup>nd</sup> Circular proposal: Request information on technological justification and actual use levels      EU: Supports the 2 <sup>nd</sup> circular proposal. The horizontal approach was developed for Table 3 additives not for additives with numerical ADIs for which the exposure needs to be controlled.      Chile, RU: supports the 2 <sup>nd</sup> circular proposal.      Japan: Propylene glycol alginate is used in syrups for fine bakery wares and ices (e.g. caramel syrup, flavoured syrups) to achieve consistent viscosity between batches. The maximum use level is 10,000 mg/kg.	Adopt at 10,000

## Food Category No. 11.5 Honey

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is **not** justified in this food category on a general basis.

Corresponding commodity standards: 12-1981 No additives permitted

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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Food Category No. 11.6 Table-top sweeteners, including those containing high-intensity sweeteners

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
ETHYL MALTOL	637	GMP		7	Flavour enhancer	Z <sup>nd</sup> Circular proposal: Request information on actual use level      EU: supports the 2 <sup>nd</sup> circular proposal. Used as a flavor enhancer or a flavouring? ML needed      Chile,: supports the 2 <sup>nd</sup> circular proposal.  RU: In RU use only lake flavour	Discontinue
PROPYLENE GLYCOL	1520	5000		7	Emulsifier, Glazing Agent, Humectant	2 <sup>nd</sup> Circular proposal: Adopt at 3,000  EU: INS 1520 is authorized in the EU only as a secondary FA (the ML 500 – 1000 ppm; the level in the final food shall not exceed 3000 ppm in general and 1000 ppm for beverages). EU is asking for the technological justification in table top sweeteners.  RU: Does not support adoption. There is not technological justification. ML too high	Adopt at 1,000
TARTRATES	334, 335(ii), 337	GMP	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant,	2nd Circular proposal: Adopt at GMP  Brazil: supports adoption of a numerical use level, considering that it is an additive with numerical ADI (30mg/kg bw/d). In Brazilian legislation, tartaric acid (INS 334) is allowed as acidulant in liquid table top sweetener, with ML of 0.20 g/100 mL (2000mg/kg).  EU: supported the 1st circular proposal, i.e. "Not a Table 3 additive, request information on numerical use level". The EU could accept the ML	Adopt at 2,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Stabilizer	proposed by Brazil, i.e. 2000 ppm.	

### Food Category No. 12.0 Salts, spices, soups, sauces, salads, protein products

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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#### Food Category No. 12.1 Salt and salt substitutes

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is not justified in this food category on a general basis.

## Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category or its subcategories; included for information purposes only
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# <u>Food Category No.</u> 12.2 Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
TOCOPHEROLS	307a, b,	1000		7	Antioxidant	2nd Circularl proposal: Adopt as listed	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						based products such as a spice paste can contain substantial amounts of valuable (nutrition and taste) secondary plant metabolites many of which are sensitive to oxidation.  Oxidation in turn results in deterioration of products quality (nutritional value, taste (off flavour formation)). This shortens shelf life and also increases the risk that consumers buy a product that is not satisfactory in terms of taste and quality. Tocopherols are a group of lipophilic antioxidants which, also in combination with hydrophilic antioxidants such as ascorbic acid, can protect a product from getting rancid and developing off-flavours. The combined use with ascorbic acid(sodium ascorbate is likely most effective as by the combination both, the more lipophilic and the more hydrophilic constituents of a product can be protected from oxidation  ICGMA: Supports adoption	
						Tocopherols are particularly useful across this category as they can be used in both liquid or powdered applications, which are consistent with the multiple types of products that fall within this parent category. Tocopherols are generally resistant to high temperature processing steps, and have low volatility and good solubility in fats and oils, which make the uniquely functional shelf stable condiments. They are also particularly important in safeguarding flavor profiles sensitive to oxidation when	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						used in spice and seasoning mixes, such as those found in instant noodle dishes or in premixed spiced blends for marinades. While the proposed usage level, 1,000 mg/kg, should be suitable for most uses in this food category, concentrations of up to 2,000 ppm may be necessary for oils containing highly polyunsaturated fatty acids. The EWG could consider a note allowing the higher level use only in condiment products containing plant derived oils.	
						EU: opposes adoption. The EU notes the difference in the technological need between (1) herbs and spices (practically no additives are needed) and (2) seasonings and condiments. The EU recommends, in line with the procedures, to consult the active commodity committee (Codex Committee on Spices and Culinary Herbs)	
						India: supports adoption. While the proposed usage level, 1,000 mg/kg, should be suitable for most uses in this food category, concentrations of up to 2,000 ppm may be necessary for oils containing highly polyunsaturated fatty acids. The EWG could consider a note allowing the higher level of use only in condiment products containing plant derived oils	
						ICGMA: supports adoption in this parent category as proposed by the second circular. Tocopherols are	

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						particularly useful across this category as they can be used in both liquid or powdered applications, which are consistent with the multiple types of products that fall within this parent category. Tocopherols are generally resistant to high temperature processing steps, and have low volatility and good solubility in fats and oils, which make the uniquely functional shelf stable condiments. They are also particularly important in safeguarding flavor profiles sensitive to oxidation when used in spice and seasoning mixes, such as those found in instant noodle dishes or in premixed spiced blends for marinades. While the proposed usage level, 1,000 mg/kg, should be suitable for most uses in this food category, concentrations of up to 2,000 ppm may be necessary for oils containing highly polyunsaturated fatty acids. The EWG could consider a note allowing the higher level use only in condiment products containing plant derived oils.	
						Malaysia: Support adoption	
						RU: Does not support proposal because it is food supplement with established adequate level of consumption. Recommended level of daily intake tocopherols (vit E) – 10 vu/ per person per day. In case of vit E (tocopherols) consumption in quantity more than 360 TE/per day per person (from all sources) could be negative reactions of human	

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						organism	

## Food Category No. 12.2.1 Herbs and spices

Horizontal approach: (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is not justified in herbs on a general basis.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
ASCORBIC ACID, L-	300	GMP	51	4	Acidity regulator, Antioxidant, Sequestrant	Znd Circular proposal: Adopt at GMP      EU Specialty Food Ingredients: see technical justification above for tocopherol (for food category 12.2) as a whole      India: Additive not allowed in herbs      EU: opposes adoption. The EU notes the difference in the technological need between (1) herbs and spices (practically no additives are needed) and (2) seasonings and condiments. The EU recommends, in line with the procedures, to consult the active commodity committee (Codex Committee on Spices and Culinary Herbs)      FoodDrinkEurope: Support adoption      Japan: supports 2nd circular proposal. Ascorbic acid is used in spice as acidity regulator in pepper containing powdered lemon as an ingredient to adjust sour taste.	Adopt at GMP

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						RU: Does not support adoption. Request information on technological function, use in spices and/or herbs	
MAGNESIUM STEARATE	470(iii)	10000		2	Anticaking agent, Emulsifier, Thickener	Prazil: Salts of fatty acids with Mg (INS 470) allowed as anticaking in herbs and spices at GMP.  India: Additive not allowed in this category  EU: could see the need for certain anticaking agents. However, the EU recommends, in line with the procedures, to consult the active commodity committee (Codex Committee on Spices and Culinary Herbs)  FoodDrinkEurope: Support proposal  RU: Does not support adoption. Request information on technological function, use in spices and/or herbs	Adopt at GMP
SILICON DIOXIDE, AMORPHOUS	551	GMP	51	4	Anticaking agent, Antifoaming agent, Carrier	Brazil: Silicon dioxide (INS 551) is allowed as anticaking in herbs and spices at GMP.  India: Additive not allowed in herbs  EU: could see the need for certain anticaking agents. However, the EU recommends, in line with the procedures, to consult the active commodity committee (Codex Committee on Spices and Culinary	Adopt at GMP

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						Herbs)  FoodDrinkEurope: Support proposal  Japan: supports 2 <sup>nd</sup> circular proposal. This additive is used in spice and spice mix as anticaking agent to prevent sticking to one another.  RU: Does not support adoption. Request information on technological function, use in spices and/or herbs	
SODIUM ASCORBATE	301	GMP	51	4	Antioxidant	Indonesia: Adopt at 5000 ppm  2nd Circular proposal: Request further information on technological justification  India: Additive not allowed in herbs  EU: supports the 2nd circular proposal.  Japan: supports adoption of this food additive provision with new note "For use in spice only".  Sodium ascorbate is used in spice as antioxidant to prevent oxidation during shelf life.  RU: Does not support adoption	Adopt at GMP with new Note "For use in spice only" (see Japan comment).
SODIUM CARBONATE	500(i)	GMP	51	4	Acidity regulator, Anticaking agent, Raising agent, Stabilizer,	EU Specialty Food Ingredients: see technical justification above for tocopherol (for food category 12.2) as a whole. The use of sodium ascorbate may be indicated in those cases where the use of ascorbic acid	Adopt at GMP

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Thickener	as an antioxidant imparts to much acidity to the product. It might also be indicated for keeping an optimal pH value to use ascorbic acid and sodium ascorbate in combination.	
						India: Additive not allowed: Foods in General at GMP	
						<u>EU:</u> recommends, in line with the procedures, to consult the active commodity committee (Codex Committee on Spices and Culinary Herbs)	
						FoodDrinkEurope: Support proposal	
						RU: Does not support adoption. Request information on technological function, use in spices and/or herbs	
						<ul><li>2<sup>nd</sup> Circular proposal: Adopt at 2000 mg/kg with Note 348.</li><li>Chile: Request tech justification</li></ul>	
						<u>EU</u> : discontinue	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	20000		4	Emulsifier, Glazing agent, Stabilizer	Japan: supports the 2 <sup>nd</sup> circular proposal. This food additive is used in curry roux to prevent separation of fat and water, and it does not affect the nature of the products. The maximum use level is 2000 mg/kg, singly or in combination with INS 473 and INS474.  Japan supports adding Note 348 since INS 473, 473a and 474 share the group ADI.	Adopt at 2,000 with Note 348

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						RU: Does not support adoption. Request information on technological justification	
SUCROGLYCERIDE S	474	20000			Emulsifier	2nd Circular proposal: Request information on technological justification  India: Additive not allowed in this category  Chile, RU: Request tech justification  EU: discontinue	Discontinue

# Food Category No. 12.2.2 Seasonings and condiments

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL	1520	970000		7	Emulsifier, Glazing Agent, Humectant	2nd Circular proposal: Adopt at 20,000  Brazil: wonders if there is an error on ML, considering that it is too high for these functions. Typical use levels are in the range of 1500mg/kg – 20000mg/kg. Considering an ADI of 70mg/kg bw/d, and the proposed level of 970.000 mg/kg, an adult of 60 kg could consume only 4.32g of seasonings and condiments not to extrapolate ADI. So, the ML should be reduced.  India: Believes additive is technologically justified for use as emulsifier in seasonings and	Adopt at 20,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						condiments. Propylene Glycol is commonly used for emulsification in fat and oil based seasonings and condiments. Propylene glycol reacts well with fatty acids while being water soluble at the same time.	
						<u>EU</u> : not convinced on the technological need. What are the products for which INS 1520 is needed and why this food additive is necessary? Note: according to the descriptor FC 12.2.2 does not include condiment sauces (emulsified sauces and dips fall under FC 12.6.1).	
						FoodDrinkEurope, India: Support proposal	
						ICGMA: supports the 2 <sup>nd</sup> circular proposal, and appreciates Brazil's comments regarding the initially proposed ML. We agree with the 2 <sup>nd</sup> circular proposal of 20,000 mg/kg which would be sufficient. Propylene glycol reacts well with fatty acids while also being water soluble. It is commonly used to provide emulsification in seasoning or condiment mixtures that may include multiple components, such as oil and water, that do not traditionally mix	
						Malaysia: Support 2 <sup>nd</sup> circular proposal	
						RU: Does not support adoption. Request information on technological justification. ML is too high.	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL ALGINATE	405	6000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	India: Believes additive is technologically justified for use as emulsifier in seasonings and condiments. Propylene Glycol is commonly used for emulsification in fat and oil based seasonings and condiments. Propylene glycol reacts well with fatty acids while being water soluble at the same time. Recommended use level: 6000 mg/Kg  EU: not convinced of the technological need. What are the products for which INS 1520 is needed and why this food additive is necessary? Note: according to the descriptor FC 12.2.2 does not include condiment sauces (emulsified sauces and dips fall under FC 12.6.1).  FoodDrinkEurope: Support proposal RU: Does not support adoption. Request information on technological justification. ML is too high.	Adopt at 6,000
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	2000		4	Emulsifier, Glazing agent, Stabilizer	2nd Circular proposal: Adopt at 20,000  ICGMA, India: Supports adoption. Sucrose oligoesters provide stable emulsions for use in water-in-oil emulsified foods, particularly certain condiments and liquid spice blends that contain oils. We do not object to the proposed note. Proposed usage level is suitable to achieve desired technological function.	Adopt at 20,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						<u>EU</u> : not convinced of the technological need. What are the products for which INS 1520 is needed and why this food additive is necessary? Note: according to the descriptor FC 12.2.2 does not include condiment sauces (emulsified sauces and dips fall under FC 12.6.1).	
						FoodDrinkEurope: Support proposal  ICGMA: supports second circular proposal, including proposed 2,000 mg/kg ML. We note comments in response to the first circular that provide details of technological justification	
						Japan: Supports proposal. Used in "oriental seasoning mix (dashi)" and "topping to sprinkle on rice (furikake)" as glazing agent. This food additive provides protective coatings, and prevents moisture absorption and adhering to each other. The maximum use level is 20000 mg/kg, as proposed in the FA/49 INF/01	
						RU: Does not support adoption. Request information on technological justification. ML is too high	
SUCROGLYCERIDE S	474	2000			Emulsifier	2nd Circular proposal: Adopt at 2000 India: provide stable emulsions for use in water-in-oil emulsified foods, particularly certain condiments and liquid spice blends that contain oils.  EU: not convinced of technological	Adopt at 2,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						need. What are the products for which INS 1520 is needed and why this food additive is necessary? Note: according to the descriptor FC 12.2.2 does not include condiment sauces (emulsified sauces and dips fall under FC 12.6.1).	
						FoodDrinkEurope: Support proposal  RU: Does not support adoption.  Request information on technological justification. ML is too high	
TARTRATES	334, 335(ii), 337	7500	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	Supports 2nd circular proposal circular proposal circular proposal in the adoption?   FoodDrinkEurope, India: Support proposal circular proposal. Tartrates are added to certain condiments for their dual properties as acidity regulators and flavor enhancers   RU: Request information on technological justification for certain condiments (which???)	Adopt as listed

Food Category No. 12.3 Vinegars

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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# Food Category No. 12.4 Mustards

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL	1520	15000		7	Emulsifier, Glazing Agent, Humectant	2nd Circular proposal: Request information on technological justification and use levels  EU: apart from use level, info on technological justification is needed. INS 1520 is authorized in the EU as a secondary food additive (ML 500 – 1000 ppm; level in the final food shall not exceed 3000 ppm in general and 1000 ppm for beverages)  Chile, RU: supports request tech justification	Discontinue
STEAROYL LACTYLATES	481(i), 482(i)	2500		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular proposal: Adopt as listed   EU, RU - no technological justification provided – discontinue   FoodDrinkEurope: Support adoption   IFAC: Supports adoption	Adopt as listed
TARTRATES	334, 335(ii), 337	5000	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337:	2 <sup>nd</sup> Circular proposal: Request information on technological justification  Chile, EU, RU: supports request tech justification	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	Indonesia: supports adoption.  Maximum use level in Indonesia 5000 mg/kg	
TOCOPHEROLS	307a, b,	200		7	Antioxidant	Isted  EU Specialty Food Ingredients: This F.C. includes by definition mustard seeds which are rich in essential oils, and also may include added edible oils which in turn may contain substantial amounts of PUFA. Those ingredients contain constituents known to be sensitive to oxidation and thus are prone to developing an inferior taste profile. The use of tocopherols as an antioxidant may help preserve a favourable taste profile of the product.  EU: supports adoption.  FoodDrinkEurope: Support adoption  ICGMA supports adoption. Our members have reported similar technological justification as reported by the EU Specialty Food Ingredients organization in their response to the first circular. 200 mg/kg should be sufficient to achieve desired technological function  RU: Does not support proposal because it is food supplement with established adequate level of consumption. Recommended level of	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						daily intake tocopherols (vit E) – 10 vu/ per person per day. In case of vit E (tocopherols) consumption in quantity more than 360 TE/per day per person (from all sources) could be negative reactions of human organism	

## Food Category No. 12.5 Soups and broths

Corresponding commodity standards: 117-1981 Acidity regulators, anticaking agents (in dehydrated product only), antifoaming agents, antioxidants, colours, emulsifiers, flavour enhancers, humectants, packaging gases, preservatives, stabilizers, sweeteners and thickeners used in accordance with Tables 1, 2 and 3 of the GSFA in FC 12.5 and parent and sub-categories. Flavourings should comply with CAC/GL 66-2008.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	2nd Circular proposal: Request information on technological justification for standardized and nonstandardised foods  Chile: Supports 2nd circular proposal  Malaysia: Support adoption  RU: supports discontinuation	Request information on technological justification for standardized and non-standardised foods
PROPYLENE GLYCOL ALGINATE	405	10000		4	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	2nd Circular proposal: Request information on technological justification for standardized and nonstandardised foods  EU: discontinue or provide justification for non-standardised foods. This category was fully aligned with CS 117-1981. This additive was not listed in CS 117-1981 before the alignment.	Move to subcategory FC 12.5.1. (Propylene glycol alginate is used in ready-to-eat soups to thicken the product. The maximum use level is 10,000 mg/kg.)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						IFAC: Supports adoption  Chile, EU, RU: supports the 2 <sup>nd</sup> circular proposal.  Japan: proposes this draft provision be moved to its subcategory FC 12.5.1. Propylene glycol alginate is used in ready-to-eat soups to thicken the product. The maximum use level is 10,000 mg/kg.  Malaysia: Support adoption	
SODIUM DIACETATE	262(ii)	500		7	Acidity regulator, Preservative, Sequestrant	2nd Circular proposal: Request information on technological justification for standardized and nonstandardised foods  Chile, EU: supports the 2nd circular proposal.  ICGMA, IFAC: supports adoption of this provision. Following consultation with our members, we note that Sodium diacetate dissociates into acetic acid and sodium acetate. This enables it to function both as a buffer/an acidity regulator in the soup as well as an effective antimicrobial agent for inhibiting the growth of yeast & mold and spoilage bacteria.  We note the comments from the EU regarding CS 117-1981 not originally listing Sodium Diacetate prior to being aligned with the GSFA. However, CS 117-1981 did allow certain preservatives. As technological justification has been provided	Adopt at 500

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						supporting the use of this additive in both standardized and unstandardized foods and the original commodity standard permitted substances with a preservative function, we request that CCFA consider updating the commodity standard and GSFA.  Malaysia: Support adoption	
TARTRATES	334, 335(ii), 337	5000	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2 <sup>nd</sup> Circular proposal: Request information on technological justification for standardized and nonstandardised foods  Chile, EU: supports the 2 <sup>nd</sup> circular proposal.  India: allows use of Tartaric acid in this category  Malaysia: Support adoption	Request information on technological justification for standardized and non-standardised foods

### Food Category No. 12.5.1 Ready-to-eat soups and broths, including canned, bottled, and frozen

Corresponding commodity standards: 117-1981 Acidity regulators, anticaking agents (in dehydrated product only), antifoaming agents, antioxidants, colours, emulsifiers, flavour enhancers, humectants, packaging gases, preservatives, stabilizers, sweeteners and thickeners used in accordance with Tables 1, 2 and 3 of the GSFA in FC 12.5 and parent and sub-categories. Flavourings should comply with CAC/GL 66-2008.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
NISIN	234	5	233	6	Preservative	<u>2<sup>nd</sup> Circular proposal</u> : Adopt as listed	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						Chile, EU: does not support. INS 234 was not listed in CS 117-1981. The EU is not convinced on the technological need. Canned products are usually sterilized. The EU is concerned if the intention is to reduce time/temperature requirements.  As for chilled products – they have usually short shelf life and are intended to be heat treated before consumption – no need for this additive	
						India, FoodDrinkEurope: Support proposal  ICGMA, IFAC: supports 2nd circular proposal Microbial challenge study	
						proposal. Microbial challenge study data shows that nisin helps retard outgrowth of Bacillus cereus in soups (chicken soup with dumplings and beef noodle soup were used as model systems). In ready-to-eat pasteurized, refrigerated soups, microbial challenge study data shows that nisin (1) delays outgrowth of Lactic acid spoilage bacteria; when held at 8 degrees C, nisin treated soups maintained keeping quality 11-35 days longer than untreated soups (2) reduced	
						initial Listeria monocytogenes counts by 1 log and treated soups maintained keeping quality 2 additional days compared to untreated controls when held under refrigeration at 8 degrees C.  We note the comments of the EU	

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
		(mg/kg)		Adopted	Ciass	with regard to the alignment work on CS 117-1981. It seems that we are again in a similar situation where a commodity standard allows a functional class of food additives (preservatives), but during the alignment process there was no consideration given to the use of other additives with a preservative function that may have been developed and reviewed by JECFA since the original commodity standard was last updated. We not precedent exists for CCFA to add the use of nisin to commoditized foods when the original commodity standard allowed the use of preservatives and technological justification for the use of nisin is provided. It appears that this precedent would apply in this case and so ICGMA suggests that immediate adoption of this provision. With CCFA's clear mandate to update food additive provisions in commodity standards in the absence of an active commodity committee and the precedent referenced, there is no reason to use CCFA's limited resources to further review this provision. Technological justification exists and the relevant commodity standard provides for the use of preservatives. Nisin is a relatively new preservative, was not considered when the original	
						commodity standard was developed in 1981 (more than 30 years ago), and has clear technological justification and food safety benefits.	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						India, Malaysia: Support adoption  RU: Opposes adoption because nisin – antibiotic. The problem of antibiotic resistance recognized by WHO.  South Africa: Supports adoption. Use of nisin helps to reduce time/temperature requirements of the heat processing thus helping to maintain the textural and color quality of the canned products. In pasteurized chilled soups, nisin prevents/delays outgrowth of heat resistant spores and pathogenic bacteria such as Listeria; nisin helps reduce loss due spoilage and enhance the safety of these products.	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	2nd Circular proposal: Request information on technological justification for standardized and non-standardised foods  Chile, EU supports the 2nd circular proposal.  Japan: Polyglycerol esters of fatty acids are used to prevent oil separation in ready-to-eat corn soup and chowder. These are not covered by CODEX STAN 117-1981. The maximum use level is 400 mg/kg.	Adopt at 400 with Note XS 117
PROPYLENE GLYCOL ALGINATE	405	10000		4	Bulking agent, Carrier,	2 <sup>nd</sup> Circular proposal: Request information on technological justification for standardized and	Move from parent category FC 12.5 (Propylene glycol

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	non-standardised foods  Chile, EU, RU: supports the 2 <sup>nd</sup> circular proposal.  Japan: proposes this draft provision be moved from FC 12.5. Propylene glycol alginate is used in ready-to-eat soups to thicken the product. The maximum use level is 10,000 mg/kg.  Malaysia: Support adoption	alginate is used in ready-to-eat soups to thicken the product. The maximum use level is 10,000 mg/kg.)

## Food Category No. 12.5.2 Mixes for soups and broths

Corresponding commodity standards: 117-1981 Acidity regulators, anticaking agents (in dehydrated product only), antifoaming agents, antioxidants, colours, emulsifiers, flavour enhancers, humectants, packaging gases, preservatives, stabilizers, sweeteners and thickeners used in accordance with Tables 1, 2 and 3 of the GSFA in FC 12.5 and parent and sub-categories. Flavourings should comply with CAC/GL 66-2008

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000	127	7	Emulsifier, Stabilizer	2nd Circular proposal: Request information on technological justification for standardised and non-standardised foods  Chile, EU supports the 2nd circular proposal.  Japan: Polyglycerol esters of fatty acids are used to prevent oil separation in concentrated corn soup which is not covered by CODEX STAN 117-1981. The maximum use level is 3000 mg/kg	Adopt at 3,000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL	1520	500	127	7	Emulsifier, Glazing Agent, Humectant	RU: supports discontinuation  2nd Circular proposal: Request information on technological justification for standardised and non-standardised foods  Chile, EU supports the 2 <sup>nd</sup> circular proposal.  RU: supports discontinuation	Discontinue
SORBITAN ESTERS OF FATTY ACIDS	491-495	250	127	7	491: Emulsifier 492-494: Emulsifier, Stabilizer 495: Emulsifier	<ul> <li>2nd Circular proposal: Request information on technological justification for standardised and non-standardised foods</li> <li>Chile, EU, RU: supports the 2nd circular proposal.</li> </ul>	Discontinue

# Food Category No. 12.6 Sauces and like products

Corresponding commodity standards: None, 306R-2011 and 302-2011 correspond to subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	4 <del>75</del>	10000		4	Emulsifier, Stabilizer	I2nd Circular proposal: Discuss in subcategories  EU, RU: supports proposal	Discuss in subcategories
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	4 <del>76</del>	5000		7	Emulsifier	2 <sup>nd</sup> Circular proposal: Discuss in subcategories  EU, RU: supports proposal	Discuss in subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
SODIUM DIACETATE	<del>262(ii)</del>	<del>2500</del>		7	Acidity regulator, Preservative, Sequestrant	Initial proposal: Discuss in subcategories  EU, RU: supports proposal	Discuss in subcategories
SUCROSE ESTERS OF FATTY ACIDS	473	10000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular proposal: Request information on technological justification  EU: has technological need been provided? If yes, EU can accept.  Malaysia: Supports adoption w note 348  EWG Chair: Already existing adopted provision for INS 474. Group ADI for INS 474, 473, 474(a) of 0-30 mg/kg  Chile, supports the 2nd circular proposal.  Japan proposes adoption at 10,000 mg/kg with Note 348. Sucrose esters of fatty acids are used to prevent separation of oil and fat and to provide stable emulsification. The maximum use level is 10,000 mg/kg.  RU: supports discontinuation; no technological justification provided	Adopt at 10,000 with Note 348
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	10000			Emulsifier, Glazing agent, Stabilizer	2nd Circular proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU: could we add the provisions which are not in the step process?	Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
		(119719)				EWG Chair: Consequential change. Normal process is to consider justification in each subcategory. Already existing adopted provision for INS 474. Group ADI for INS 474, 473, 474(a) of 0-30 mg/kg  FoodDrinkEurope: Support 2 <sup>nd</sup> Circular proposal  Japan supports the 2nd proposal. Sucrose oligoesters, type I and type II are used to prevent separation of oil and fat and provide stable emulsification. Japan supports adding Note 348 since INS 473, 473a and 474 share the group ADI.	473a) and sucroglycerides (INS 474))
						RU: supports discontinuation; technological justification not provided; and ML=10000 mg/kg too hgih	

# Food Category No. 12.6.1 Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	5000	20	7	Emulsifier, Humectant	2nd Circular proposal: Discontinue  EU, RU: supports discontinuation	Discontinue
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	GMP		7	Emulsifier, Stabilizer	2 <sup>nd</sup> Circular proposal: Request information on technological justification and actual use levels	Adopt at 5,000
ACIDS						Brazil: Considering ADI of 0.1 mg/kg bw/d, and proposed level of 5000 mg/kg,	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						an adult of 60 kg could consume only 1.2 g of emulsified sauce not to exceed ADI. ML should be reduced if provision is adopted.  Malaysia: Supports adoption	
						Chile, EU: supports the 2 <sup>nd</sup> circular proposal.	
						<u>Japan:</u> supports the 2 <sup>nd</sup> circular proposal. Polyglycerol esters of fatty acids are used in dressing to prevent oil separation. The maximum use level is 5000 mg/kg.	
						RU: supports discontinuation; no technological justification provided	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	2nd Circular proposal: Adopt at 5,000  Japan: Polyglycerol esters of interestified ricinoleic acid are used to prevent oil separation. The maximum use level is 5000 mg/kg.  EU, FoodDrinkEurope, India, Malaysia: Support adoption	Adopt at 5000
PROPYLENE GLYCOL	1520	800		7	Emulsifier, Glazing Agent, Humectant	2nd Circular proposal: Adopt as listed  ICGMA: Supports adoption. Propylene glycol reacts well with fatty acids while also being water soluble. It is commonly used to provide emulsification in sauces that may include multiple components, such as oil and water, that do not traditionally mix. We can also confirm that the usage would not be as a secondary additive  EU: what is emulsified? (the ML is quite low comparing the one proposed in FC 12.2.2 – SFA use?)	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
PROPYLENE GLYCOL ALGINATE	405	10000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	FoodDrinkEurope, Malaysia: Support adoption  RU: INS1520 could be used only as carrier for FA. There is no technological justification  2nd Circular proposal: Adopt at 8000  ICGMA, IFAC: Supports adoption. Propylene glycol alginate is commonly used to provide emulsification in sauces that may include multiple components, such as oil and water, that do not traditionally mix. It is also important in salad dressings for its ability to help herbs remain suspended in the mixture  EU: supports the 2nd circular proposal  FoodDrinkEurope, India, Malaysia: Support adoption  ICGMA, IFAC: can support the 2nd circular proposal. We agree with the EU that 8000 mg/kg should provide sufficient technological effect to provide the technological function described in our first circular comments.  India: supports adoption as proposal. Propylene glycol alginate is used in salad	Adopt at 8000
SODIUM DIACETATE	262(ii)	2500			Acidity regulator, Preservative, Sequestrant	dressing to prevent oil separation and thicken the product.  2nd Circular proposal: Request information on technological justification Chile, EU: supports the 2nd circular proposal	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						ICGMA, IFAC: supports adoption. As noted in response to provisions for this material in FC 12.5, sodium diacetate dissociates into acetic acid and sodium acetate. This enables it to function both as a buffer/an acidity regulator in the emulsified sauce/dressing as well as an effective antimicrobial agent for inhibiting the growth of yeast & mold and spoilage bacteria. This technological function, which we have been advised is essential to some of our members' formulations enhances food safety and, because the products in which it is used are traded internationally, would hamper trade if this provision was discontinued.  RU: supports discontinuation; technological justification not provided	
SORBITAN ESTERS OF FATTY ACIDS	491-495	10000		7	491: Emulsifier 492-494: Emulsifier, Stabilizer 495: Emulsifier	2 <sup>nd</sup> Circular proposal: Adopt at 5000  EU, FoodDrinkEurope, IFAC, India, Malaysia: Support adoption at 5,000  Japan: supports the 2 <sup>nd</sup> circular proposal. Sorbitan esters of fatty acids are used in dressing to prevent oil separation. The maximum use level is 5000 mg/kg.	Adopt at 5000
STEAROYL LACTYLATES	481(i), 482(i)	10000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2 <sup>nd</sup> Circular proposal: Adopt as listed  ICGMA, IFAC: Supports adoption.  Stearoyl lactylates are used to provide emulsification in sauces and dressings to help maintain oil and water mixtures  EU: questions the technological need - no specific justification why INS 481-482 is needed was provided. It is not	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						necessary to increase the exposure to INS 481-482 in this food category  FoodDrinkEurope: Support adoption  ICGMA: supports adoption. Information provided by ICGMA members continues to indicate this product is being used in emulsification of sauces and dressings that are traded internationally  IFAC, Malaysia: supports adoption	
						RU: supports only as emulsifier for sauces and dressings	
TARTRATES	334, 335(ii), 337	2860	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular proposal: Adopt as listed  Brazil: ML is unusual, so Brazil is wondering if this number was obtained from conversion. In category 12.6.2 the value is 5000 mg/kg.  Columbia: used by food industry as acidifier, acidity regulator and acidulant, with DMU of 3g / kg  EU: has the technological justification been provided?  EWG Chair: ML is reflected correctly  FoodDrinkEurope: Support adoption  Indonesia: proposes ML of 2000 mg/kg	Adopt at 2,000
TOCOPHEROLS	307a, b,	600		7	Antioxidant	2nd Circular proposal: Adopt as listed  Columbia: used by the food industry as antioxidant at GMP EU: has the technological justification	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
		(ing/kg)				been provided?  EU Specialty Food Ingredients: By definition, this F.C. contains fatty components, on top often in an emulsified form. Edible oils regularly contain unsaturated fatty acids which are prone to oxidation, and this all the more the larger the surface area and thus exposure to air (oxygen). Emulsification considerably enlarges exposed surface and thus renders a product more susceptible to rancidity. Tocopherols, as fat soluble antioxidants, are an effective means to retard oxidation and rancidity development.  ICGMA: Supports adoption. Tocopherols prevent oxidation which can impact the taste and texture of certain sauces, particularly those high in oil or fat content. Notes earlier comments provided by EU Specialty Food Ingredients in response to the first circular that provide technological justification.  FoodDrinkEurope, Malaysia: Support adoption	
						RU: Does not support proposal because it is food supplement with established adequate level of consumption.  Recommended level of daily intake tocopherols (vit E) – 10 vu/ per person per day. In case of vit E (tocopherols) consumption in quantity more than 360 TE/per day per person (from all sources) could be negative reactions of human organism	

Food Category No. 12.6.2 Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy)

Horizontal approach:

**Corresponding commodity standards: 306R-2011** specific acidity regulators, antioxidants, colours, preservatives, emulsifiers, sweeteners, stabilizers, and thickeners.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000		7	Emulsifier, Stabilizer	2nd Circular proposal: Request information on technological justification for standardized and non-standardised foods  Malaysia: Supports in view of alignment with corresponding standard  Chile, EU supports the 2nd circular proposal  Japan: Polyglycerol esters of fatty acids are used in white sauce, not covered by CODEX STAN 306R-2011 but fallen into this category, to prevent separation of oil and fat. The maximum use level is 5000 mg/kg.	Adopt at 5000
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000			Emulsifier	Circular proposal Request information on technological justification      Chile, EU supports the 2 <sup>nd</sup> circular proposal      RU: supports discontinuation because no technological justification provided	Do not adopt
PROPYLENE GLYCOL	1520	500		7	Emulsifier, Glazing Agent, Humectant	2nd Circular proposal Request information on technological justification Chile, EU supports the 2nd circular proposal  RU: supports discontinuation because technological justification not provided/	Do not adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						Could be used only as carrier.	
PROPYLENE GLYCOL ALGINATE	405	8000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	2nd Circular proposal: Request information on technological justification for standardized and non-standardised  Chile, EU supports the 2nd circular proposal  Japan: Propylene glycol alginate is used in cheese sauce, not covered by CODEX STAN 306R-2011 but fallen into this category, to increase viscosity of the product  RU: supports discontinuation because	Adopt as listed
						no technological justification provided  2nd Circular proposal: Request	
						information on technological justification for standardized and non-standardised foods	
						Chile, EU: supports the 2 <sup>nd</sup> circular proposal	
SODIUM DIACETATE	262(ii)	2500			Acidity regulator, Preservative, Sequestrant	ICGMA, IFAC: support adoption. As noted above, sodium diacetate dissociates into acetic acid and sodium acetate in sauces. This enables it to function both as a buffer/an acidity regulator in the sauce as well as an effective antimicrobial agent for inhibiting the growth of yeast & mold and spoilage bacteria. This technological function, which we have been advised is essential to some of our members' formulations enhances food safety and, because the products in which it is used are traded internationally, would hamper trade if this provision was discontinued.	Adopt at 2500

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						RU: supports discontinuation because no technological justification provided	
SORBITAN ESTERS OF FATTY ACIDS	491-495	4000		7	491: Emulsifier 492-494: Emulsifier, Stabilizer 495: Emulsifier	Z <sup>nd</sup> Circular proposal: Request information on technological justification for standardized and non-standardised foods      Chile, EU: supports the 2 <sup>nd</sup> circular proposal      RU: supports discontinuation because no technological justification provided	Do not adopt
STEAROYL LACTYLATES	481(i), 482(i)	2500		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular proposal: Request information on technological justification for standardized and non-standardised foods  IFAC: Supports adoption with Note XS306R  Chile, EU supports the 2nd circular proposal  RU: supports discontinuation because no technological justification provided	Adopt with Note XS 306R
TARTRATES	334, 335(ii), 337	5000	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant,	2nd Circular proposal: Request information on technological justification for standardized and non-standardised foods  Chile, EU: supports the 2nd circular proposal  RU: supports discontinuation because not technological justification provided	Do not adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Stabilizer		
TOCOPHEROLS	307a, b,	600		7	Antioxidant	EU: has the technological justification been provided for non-standardised products?  ICGMA: Supports adoption. Tocopherols prevent oxidation which can impact the taste and texture of certain sauces, particularly those high in oil or fat content.  FoodDrinkEurope: Support proposal  RU: Does not support proposal because there have not technological justification and it is food supplement with established adequate level of consumption. Recommended level of daily intake tocopherols (vit E) – 10 vu/per person per day. In case of vit E (tocopherols) consumption in quantity more than 360 TE/per day per person (from all sources) could be negative reactions of human organism	Adopt as listed

# Food Category No. 12.6.3 Mixes for sauces and gravies

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000		7	Emulsifier, Stabilizer	<ul><li>2<sup>nd</sup> Circular proposal: Adopt at 5000</li><li>EU: has the technological justification been provided? The EU is not aware of</li></ul>	Adopt at 5000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						the need for this additive in this category.  Chile: Request tech justification  ICGMA supports 2 <sup>nd</sup> circular proposal and notes comments submitted to the first circular that provide technological justification for use in this food category.  Japan: supports adoption. Used to uniformly disperse oil in finished sauce. Maximum use level is 5,000 mg/kg.  RU: supports discontinuation because no technological justification provided	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000			Emulsifier	2nd Circular proposal: Adopt at 5000  Japan: Supports adoption; Polyglycerol esters of interestified ricinoleic acid are used to prevent oil separation. The maximum use level is 5000 mg/kg.  EU, FoodDrinkEurope, Malaysia: supports adoption	Adopt at 5000
PROPYLENE GLYCOL ALGINATE	405	8000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	2nd Circular proposal: Request information on technological justification  IFAC: Supports adoption  Chile, EU supports the 2nd circular proposal  RU: supports discontinuation because no technological justification provided	Do not adopt
SODIUM DIACETATE	262(ii)	2500			Acidity regulator,	2 <sup>nd</sup> Circular proposal: Request information on technological justification	Adopt at 2500

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
		(iiig/kg)			Preservative, Sequestrant	Chile, EU supports the 2 <sup>nd</sup> circular proposal  ICGMA, IFAC: supports adoption. Similar to the manner in which this material functions in mixed sauces, in dry mixes. it dissociates into acetic acid and sodium acetate when the dry mixes are reconstituted. This enables it to function both as a buffer/an acidity regulator in the sauce as well as an effective antimicrobial agent for inhibiting the growth of yeast & mold and spoilage bacteria. This technological function, which we have been advised is essential to some of our members' formulations enhances food safety and, because the products in which it is used are traded internationally, would hamper trade if this provision was discontinued.  RU: supports discontinuation because no technological justification provided	
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		7	491: Emulsifier 492-494: Emulsifier, Stabilizer 495: Emulsifier	Znd Circular proposal: Request information on technological justification      Chile, EU supports the 2nd circular proposal      Japan: Sorbitan esters of fatty acids are used to prevent oil separation in dehydrated curry sauce.      Maximum use level is 50 mg/kg      RU: supports discontinuation because no technological justification provided	Adopt at 50
STEAROYL LACTYLATES	481(i), 482(i)	2500		7	Emulsifier, Flour treatment	2 <sup>nd</sup> Circular proposal: Request information on technological justification	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					agent, Foaming agent, Stabilizer	IFAC: Supports adoption  Chile, EU supports the 2 <sup>nd</sup> circular proposal  RU: supports discontinuation because no technological justification provided	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000		7	Emulsifier, Glazing agent, Stabilizer	2 <sup>nd</sup> Circular proposal: Discontinue  EU, Malaysia, RU: supports discontinue	Discontinue
TARTRATES	334, 335(ii), 337	GMP	45	7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular proposal Adopt at 5000  Brazil: INS 334 and 335ii allowed as acidulant in dehydrated sauce, at 0.5g/100g (5000mg/kg).  EU, FoodDrinkEurope, India, Japan, Malaysia: support adoption  Japan: supports 2nd circular proposal. TartratesPolyglycerol esters of fatty acids are used as stabilizer in concentrated sauce to uniformly disperse oil in finished sauce. Maximum use level is 100 mg/kg.  RU: supports discontinuation because no technological justification provided	Adopt at 5000
TOCOPHEROLS	307a, b,	300		7	Antioxidant	2nd Circular proposal: Adopt as listed  EU, FoodDrinkEurope, Malaysia: support adoption ICGMA supports 2nd circular proposal. Tocopherols prevent oxidation which can impact the taste and properties of sauces when they are rehydrated	Adopt as listed

**Corresponding commodity standards: 302-2011** specific acidity regulators, flavour enhancers, colours, preservatives, emulsifiers, sweeteners, stabilizers, and thickeners.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000			Emulsifier, Stabilizer	Z <sup>nd</sup> Circular proposal: Request information on technological justification for standardised and non-standardised foods      Chile, EU supports the 2 <sup>nd</sup> circular proposal      RU: supports discontinuation because no technological justification provided	Discontinue
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000			Emulsifier	Znd Circular proposal: Request information on technological justification for standardised and non-standardised foods      Chile, EU supports the 2nd circular proposal      RU: supports discontinuation because no technological justification provided	Discontinue
PROPYLENE GLYCOL ALGINATE	405	8000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	Z <sup>nd</sup> Circular proposal: Request information on technological justification for standardised and non-standardised foods      IFAC: Supports adoption with Note XS302      Chile, EU supports the 2 <sup>nd</sup> circular proposal      RU: supports discontinuation because no technological justification provided	Adopt with Note XS302
SODIUM DIACETATE	262(ii)	2500			Acidity regulator, Preservative,	2 <sup>nd</sup> Circular proposal: Adopt with Note XS302  IFAC: Supports adoption with Note XS302	Adopt with note XS302

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
					Sequestrant	Chile, EU supports the 2 <sup>nd</sup> circular proposal  RU: supports discontinuation because no technological justification provided	
STEAROYL LACTYLATES	481(i), 482(i)	2500		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular proposal: Request information on technological justification for standardised and non-standardised foods      IFAC: Supports adoption with Note XS302      Chile, EU supports the 2 <sup>nd</sup> circular proposal      RU: supports discontinuation because no technological justification provided	Discontinue
TARTRATES	334, 335(ii), 337	200		7	334: Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant 335(ii), 337: Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular proposal: Request information on technological justification for standardised and non-standardised foods  EU: has the technological justification been provided for non-standardised products? If yes, the EU could accept  RU: supports discontinuation because no technological justification provided	Discontinue
TOCOPHEROLS	307a, b,	300		7	Antioxidant	Initial proposal: Request information on technological justification for standardised and non-standardised foods	Discontinue

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						<u>EU</u> : has the technological justification been provided for non-standardised products? If yes, the EU could accept <u>Chile, EU</u> supports the 2 <sup>nd</sup> circular proposal	
						RU: supports discontinuation because no technological justification provided	

<u>Food Category No.</u> 12.7 Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	4000		7	Emulsifier	Initial proposal: Discontinue if no tech justification provided.  EU supports the 2 <sup>nd</sup> circular proposal  RU: supports discontinuation	Discontinue
SODIUM DIACETATE	262(ii)	3000		7	Acidity regulator, Preservative, Sequestrant	2nd Circular proposal: Request information on technological justification  Chile, EU supports the 2nd circular proposal  ICGMA, IFAC: supports adoption. Similar to the manner in which this material functions in sauces the sodium diacetate added to dressing dissociates into acetic acid and sodium acetate. This enables it to function both as a buffer/an acidity regulator in the sauce as well as an	Adopt at 3000

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						effective antimicrobial agent for inhibiting the growth of yeast & mold and spoilage bacteria. This technological function, which we have been advised is essential to some of our members' formulations enhances food safety and, because the products in which it is used are traded internationally, would hamper trade if this provision was discontinued. <u>RU</u> : supports discontinuation because no technological justification provided	
TOCOPHEROLS	307 a, b,	200		7	Antioxidant	2nd Circular proposal: Request information on technological justification  Chile, EU supports the 2nd circular proposal  RU: supports discontinuation because no technological justification provided	Discontinue

# Food Category No. 12.8 Yeast and like products

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	15000	104	7	491: Emulsifier 492-494: Emulsifier, Stabilizer 495: Emulsifier	Initial proposal: Adopt as listed  ICGMA, IFAC: Support adoption.  Sorbitan esters of fatty acids are used in dry yeast to improve the drying and rehydration properties of yeasts that are dried to very low water content. The material stabilizes the yeast cells during drying and increases the rehydration of the yeast in the dough, resulting in	Adopt as listed

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						quicker fermentation and better batter properties (emulsification)	
						EFEMA: Recommended dosage level is up to 15.000 mg/kg in dry yeast. Regarding Note 104, we consider that it would not be applicable since the sorbitanester is used in yeast, not in bread. The yeast could be used in bread and then a max. limit of 15.000 mg/kg is needed. We would thus suggest removing the Note 104.	
						FoodDrinkEurope, IFAC: Supports adoption	
						ICGMA supports 2 <sup>nd</sup> circular proposal and notes earlier comments submitted by EFEMA, ICGMA and IFAC in response to the first circular that provide technological justification	
						Japan supports 2 <sup>nd</sup> circular proposal. This additive is used in dry yeast to preserve the leaving activity of the yeast by preventing leakage of yeast solids from the cells during rehydration. Max use level is 3,000 mg/kg.	
						RU: supports discontinuation because no technological justification provided	
TOCOPHEROLS	307a, b,	200		7	Antioxidant	2 <sup>nd</sup> Circular proposal: Request information on technological justification and actual use levels	Discontinue
	С					<u>EU</u> : Has the technological justification and justification of the need for the ML been provided? If yes, the EU could	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						accept.  Chile, EU supports the 2 <sup>nd</sup> circular proposal	
						RU: supports discontinuation because no technological justification provided	

## Food Category No. 12.9 Soybean-based seasonings and condiments

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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## Food Category No. 12.9.1 Fermented soybean paste (e.g., miso)

**Corresponding commodity standards: 298R-2009** allows Table 3 and specifically listed acidity regulators, antioxidants, colours, flavour enhancers, preservatives, stabilizers and sweeteners.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Initial proposal: Adopt with note excluding INS 213 and for use in foods corresponding to CS 298R-2009 only  Columbia: used by the food industry as preservative at 1000 ppm  EU_accepts proposal  FoodDrinkEurope: Supports proposal  RU: Proposal should be clarified in the	Adopt with note excluding INS 213 and for use in foods corresponding to CS 298R-2009 only

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
						scope of benzoates consumption from all	
						sources	

## Food Category No. 12.9.2 Soybean sauce

Corresponding commodity standards: None

Additive	INS L	Max Level Notes ng/kg)	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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## Food Category No. 12.9.2.1 Fermented soybean sauce

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Z <sup>nd</sup> Circular proposal: Request further information on exposure in context of JECFA evaluation      Columbia: used as preservative at 1000 ppm      Chile, EU supports the 2 <sup>nd</sup> circular proposal.      RU: Proposal should be clarified in the scope of benzoates consumption from all sources	Request further information on exposure in context of JECFA evaluation

Food Category No. 12.9.2.2 Non-fermented soybean sauce

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Z <sup>nd</sup> Circular proposal: Request further information on exposure in context of JECFA evaluation      Columbia: used as preservative at 1000 ppm      Chile, EU supports the 2 <sup>nd</sup> circular proposal.      RU: Proposal should be clarified in the scope of benzoates consumption from all sources	Request further information on exposure in context of JECFA evaluation

# Food Category No. 12.9.2.3 Other soybean sauces

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Initial proposal: Request information on actual use levels  Brazil: In Brazilian legislation, benzoates (INS 210, 211, 212 and 213) are allowed as preservative in non-emulsified sauces, with ML of 0.1g/100g (1000mg/kg).  Chile: Supports 2nd circular proposal  EU: exposure concern to benzoates should be taken into account.  RU: Proposal should be clarified in the scope of benzoates consumption from all sources	Adopt at 1000

## Food Category No. 12.10 Protein products other than from soybeans

Corresponding commodity standards: 163-1981; 174-1989

Additive	INS Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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#### Food Category No. 13.0 Foodstuffs intended for particular nutritional uses

Corresponding commodity standards: 53-1981: Does not refer to food additives with the exception of salt substitutes.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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#### Food Category No. 13.1 Infant formulae, follow-up formulae, and formulae for special medical purposes for infants

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is on a case-by-case basis

Corresponding commodity standards: None; Multiple commodity standards correspond to subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
GUM ARABIC (ACACIA GUM)	414	GMP		4	Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Discontinue  EU, Indonesia, RU: Supports discontinuation  FoodDrinkEurope, ISDI: Note that INS 414 is permitted by CAC/GL 10-1979 Part D, in nutrient preparations, (max level 10 mg/kg ready to use food for infants and young children)	Discontinue

## Food Category No. 13.1.1 Infant formulae

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is justified on a case-by-case basis

<u>CX/FA 18/50/7 Appendix 5</u> <u>135</u>

Corresponding commodity standards: 72-1981: allows specific thickeners, emulsifiers, acidity regulators, antioxidants and packaging gases

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
TOCOPHEROLS	307a, b,	10	72	7	Antioxidant	2nd Circular Proposal: Adopt at 10 mg/kg. Add note "excluding INS numbers 307a and 307c." – aligns with CODEX STAN 72-1981  Colombia, EU, FoodDrinkEurope, ICGMA, Indonesia, ISDI, Malaysia, RU: supports the adoption  EU Specialty Food Ingredients: STAN 72-1981 only permits INS 307b which explains the limitation to exclude INS 307a and c.  Japan, Switzerland, India: 2nd Circular Proposal should be revised to 10 mg/L product ready for consumption, per CODEX STAN 72-1981 (1 mg/100mL)	Adopt at 10 mg/kg with Note 72 "on the ready-to- eat basis" and newnote "excluding INS numbers 307a and 307c."— aligns with CODEX STAN 72- 1981

## Food Category No. 13.1.2 Follow-up formulae

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is on a case-by-case basis

Corresponding commodity standards: 156-1987: allows specific thickening agents, emulsifiers, pH-adjusting agents, antioxidants and flavours

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
TOCOPHEROLS	307a, b,	30	72	7	Antioxidant	2nd Circular Proposal: Adopt at 30 mg/kg – aligns with CODEX STAN 156-1987  Colombia, EU, FoodDrinkEurope, ICGMA, ISDI, Malaysia: Support for proposal alignment with CS  Japan, Switzerland, India: 2nd Circular Proposal should be revised to 30 mg/L product ready for consumption per CODEX STAN 156-1987.  RU: Adopt at 10 mg/kg	Adopt at 30 mg/kg with Note 72.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						It is food supplement with established adequate level of consumption. Recommended level of daily intake tocopherols (vit E) for children before 3 year – 3-4 mg/ per person per day. RU: Adopt at 10 mg/kg	

## Food Category No. 13.1.3 Formulae for special medical purposes for infants

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is justified on a case-by-case basis

Corresponding commodity standards: 72-1981: allows specific thickeners, emulsifiers, acidity regulators, antioxidants and packaging gases

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
TOCOPHEROLS	307a, b,	10	72	7	Antioxidant	2nd Circular Proposal: Adopt at 10 mg/kg. Add note "excluding INS numbers 307a and 307c". – aligns with CODEX STAN 72-1981  EU, FoodDrinkEurope, ICGMA, Indonesia, ISDI, Malaysia, RU: Supports proposal  EU Specialty Food Ingredients: a use level of 3 mg/kg is unlikely to show any antioxidant effect in the finished product. STAN 72-1981 only permits INS 307b which explains the limitation to exclude INS 307a and c.  Japan, Switzerland, India: 2nd Circular Proposal should be revised to 10 mg/L product ready for consumption, per CODEX STAN 72-1981	Adopt at 10 mg/kg with Note 72 and new note "excluding INS numbers 307a and 307c". – aligns with CODEX STAN 72- 1981

## Food Category No. 13.2 Complementary foods for infants and young children

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is on a case-by-case basis

Corresponding commodity standards: 73-1981: allows specific thickening agents, emulsifiers, pH adjusting agents, antioxidants and flavours; 74-1981: allows specific emulsifiers, acidity regulators, antioxidants, raising agents, thickeners, anticaking agents and packaging gases.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
ASCORBYL ESTERS	304, 305	200	10, 15 & 187	2	Antioxidant	<ul> <li>2nd Circular Proposal: Adopt at 10 mg/kg with Notes 15 and 187 – aligns with CODEX STANS 73-1981 &amp; 74-1981</li> <li>Colombia: The use of ascorbyl esters on the 2nd Circular Proposal is considered relevant.</li> <li>EU: ML is CS is 2000 mg/kg. Believe is high compared to ADI. Questions fat content of foods and if child of 10 kg would exceed ADI by consuming 6 g.</li> <li>FoodDrinkEurope, Malaysia, RU: supports adoption</li> </ul>	Discuss further - corresponding standards allow use at 200 mg/kg with Notes 15 "On the fat or oil basis." and 187 "Ascorbyl palmitate (INS 304) only."
CARRAGEENAN	407	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	2nd Circular Proposal: Discontinue.  EU, FoodDrinkEurope, Indonesia, RU: Supports discontinuation	Discontinue – not listed in corresponding commodity standards
PROPYLENE GLYCOL ALGINATE	405	10000		4	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	2nd Circular Proposal: Discontinue.  EU, FoodDrinkEurope, Indonesia, RU: Supports discontinuation	Discontinue- not listed in corresponding commodity standards
SODIUM DIACETATE	262(ii)	GMP	319 & 320	7	Acidity regulator, Preservative, Sequestrant	2nd Circular Proposal: Discontinue.  EU, FoodDrinkEurope, Indonesia, RU: Supports discontinuation	Discontinue— not listed in corresponding commodity standards
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Discontinue.  EU, FoodDrinkEurope, Indonesia, RU: Supports discontinuation	Discontinue- not listed in corresponding commodity standards
TARTRATES	334, 335(ii), 337	5000	45	7	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular Proposal: Adopt at 5000 mg/kg including INS 334, 335(ii), 336(i), 336(ii) and 337, with notes 364, XS 73-1981 and new note "as residue in biscuits and rusks"   EU, FoodDrinkEurope, RU: Supports proposal   ISDI: Support adoption with inclusion of 226i and 336ii to fully align	Adopt at 5000 mg/kg including INS 334, 335(i), 335(ii), 336(i), 336(ii) and 337, with notes 364, XS 73-1981 and new note "as residue in biscuits and rusks"

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
TOCOPHEROLS	307a, b,	1000		7	Antioxidant	2nd Circular Proposal: Adopt at 300 mg/kg with Note 15  Colombia, FoodDrinkEurope, Indonesia, ISDI: Accepts alignment with CS  RU: there are no justification of safety ML = 300 mg/kg for for infants and young children  EU: ML in CS is 3000 mg/kg expressed on fat basis, Note 15 needs to be added. ML seems high, question fat content of food.	Adopt at 300 mg/kg with Note 15

# Food Category No. 13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1)

Corresponding commodity standards: 118-1979 (does not discuss food additives)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt at 1000 mg/kg      Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded      Chile, RU: supports to request info on technical justification and actual use.      EU: Can accept if tech just has been provided.      Japan: supports the 2nd circular proposal. used to prevent protein denaturation. The maximum use level is 1000 mg/kg.	Adopt at 1000 mg/kg
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	Request technical justification and info on actual use      Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded      Chile, RU: supports to request info on technical justification	Discontinue; no information on technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						and actual use. <u>EU</u> : not aware of tech just in this category	
PROPYLENE GLYCOL ALGINATE	405	1200		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	2nd Circular Proposal: Adopt  EU, FoodDrinkEurope, IFAC, RU: Supports proposal	Adopt
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		7	Emulsifier, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt at 1000 mg/kg</li> <li>Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded</li> <li>Chile, RU: supports to request info on technical justification and actual use.</li> <li>EU: Can accept if tech just has been provided.</li> <li>IFAC: Supports adoption</li> <li>Japan: supports the 2nd circular proposal. used to prevent protein denaturation. The maximum use level is 1000 mg/kg</li> </ul>	Adopt at 1000 mg/kg
STEAROYL LACTYLATES	481(i), 482(i)	2000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt  EU, FoodDrinkEurope, IFAC, RU: Supports proposal	Adopt
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt at 300 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)); Provisions for INS 473a and 474 are not in this FC, would need to be added.  Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded  In Brazilian legislation, INS 473 is allowed as emulsifier and stabilizer in enteral nutrition formulae (ready-to-eat), with	Adopt at 300 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)); Provisions for INS 473a and 474 are not in this FC, would need to be added.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ML of 0.03g/100g (300mg/kg).  EU, FoodDrinkEurope, RU: Supports proposal	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt at 300 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))</li> <li>Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded</li> <li>In Brazilian legislation, INS 473 is allowed as emulsifier and stabilizer in enteral nutrition formulae (ready-to-eat), with ML of 0.03g/100g (300mg/kg).</li> <li>EU, FoodDrinkEurope, RU: Supports proposal</li> </ul>	Adopt at 300 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))
SUCROGLYCERIDE S	474	5000			Emulsifier	2nd Circular Proposal: Request info on technical justification and actual use      Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded      Chile, EU, RU: Supports proposal	Discontinue; no information on technological justification provided
TARTRATES	334, 335(ii), 337	GMP	45	4	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular Proposal: Request further info on technical justification and actual use  Chile, EU, RU: Supports request for info on tech just and ML	Discontinue; no information on technological justification provided
TOCOPHEROLS	307a, b,	GMP		4	Antioxidant	2nd Circular Proposal: Adopt at 300 mg/kg  Brazil: Seeks for clarification on the ML of 300 mg/kg (isn't 30mg/kg?) In Brazilian legislation, tocopherols (INS 473) are allowed as antioxidant in dietetic foods intended for special medical purposes (modified formula for enteral nutrition for children under 3 years of age), with ML of 0.003g/100g (30mg/kg)	Adopt at 30 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						EU, FoodDrinkEurope: Supports adoption	
						RU: Supports proposal with ML up to 200 mg/kg Because it is food supplement (vit E) with established daily nor of consumption from all sources	

## Food Category No. 13.4 Dietetic formulae for slimming purposes and weight reduction

Corresponding commodity standards: 181-1991: allows food additives generally; 203-1995: allows food additives generally

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt at 1000 mg/kg  Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded  EU, FoodDrinkEurope, RU: Supports proposal  Japan: supports the 2 <sup>nd</sup> circular proposal. Polyglycerol esters of fatty acids are used to prevent protein denauturation at ML of denaturation. The maximum use level is 1000 mg/kg	Adopt at 1000 mg/kg
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	2nd Circular Proposal: Request further info on technical justification and actual use      Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded      Chile, EU: Supports to request further info on technical justification and actual use.	Discontinue; no information on technological justification provided
PROPYLENE GLYCOL ALGINATE	405	1200		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent,	2nd Circular Proposal: Adopt  EU, FoodDrinkEurope, IFAC, RU: Supports proposal	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
					Stabilizer, Thickener		
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt at 1000 mg/kg  EU, FoodDrinkEurope, IFAC, RU: Supports proposal  Japan: supports the 2nd circular proposal. Sorbitan esters of fatty acids are used to prevent protein denaturation. The maximum use level is 1000 mg/kg  Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded	Adopt at 1000 mg/kg
STEAROYL LACTYLATES	481(i), 482(i)	2000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt  EU, FoodDrinkEurope, IFAC, RU: Supports proposal  EU: Can accept if tech just has been provided.	Adopt
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Request further info on technical justification and actual use</li> <li>Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded</li> <li>Chile, EU, RU: Supports proposal</li> </ul>	Discontinue; no information on technological justification provided
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Request further info on technical justification and actual use      Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded      Chile, EU, RU: Supports proposal	Discontinue; no information on technological justification provided
SUCROGLYCERIDE S	474	5000			Emulsifier	2nd Circular Proposal: Request further info on technical justification and actual use      Brazil: Provision is for use in staple food, may be sole source of food, ADI may be exceeded      Chile, EU, RU: Supports proposal	Discontinue; no information on technological justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
TARTRATES	334, 335(ii), 337	GMP	45	4	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular Proposal: Request further information on numerical use levels – not a Table 3 additive  Chile, EU: Supports proposal  RU: Supports proposal only if ML is established	Discontinue; no information on technological justification provided
TOCOPHEROLS	307a, b,	GMP		4	Antioxidant	2nd Circular Proposal: Adopt at 200 mg/kg  EU, RU: Supports proposal at ML up to 200 mg/kg  FoodDrinkEurope: Increase allowed levels. To 300 mg/kg as for 13.5. Some products need slightly more than 200. This is required when we have higher levels of very sensitive oils –PUFA- added in powder form (recommended to avoid oxygenation that occurs when spraying liquid oils). Otherwise one would need to add synthetic antioxidant instead	Adopt at 300 mg/kg

# <u>Food Category No.</u> 13.5 Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6 Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		4	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  EU: Can accept if tech just has been provided.  FoodDrinkEurope: Supports proposal  IFAC: supports adoption of this provision.  RU: Supports proposal	Adopt
TOCOPHEROLS	307a, b,	GMP		4	Antioxidant	2nd Circular Proposal: Adopt at 300 mg/kg  Brazil: In Brazilian legislation, tocopherols (INS 307) are allowed as antioxidant in food supplements (only liquids), with ML of 0.03g/100g (300mg/kg), on fat basis.	Adopt at 300 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						EU, FoodDrinkEurope: Supports proposal	
						RU: Supports proposal with ML up to 200 mg/kg	

# <u>Food Category No.</u> 13.6 Food supplements

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	50000		4	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  Brazil: Seeks clarification on ML of 50 000 mg/kg. ML seems high. Allowed as emulsifiers in food supplements (liquids only), with ML of 0.5g/100g (5000mg/kg).  EU: the info on ML indicates 18.000 ppm  FoodDrinkEurope, IADSA: Supports proposal  Japan: used in food supplements to emulsify water-soluble extract and oil. Maximum use level is 18,000 mg/kg.  RU: ML level should be discussed. ML 50000 is to higher. ADI= 0-0,25 mg/kg bw	Adopt at 18,000 mg/kg
POLYVINYL ALCOHOL (PVA) – POLYETHYLENE GLYCOL (PEG) GRAFT COPOLYMER	1209	50000		2	Glazing agent, Stabilizer	2nd Circular Proposal: Adopt at 100,000 mg/kg with New Note "for use in capsule and tablet form"      EU, FoodDrinkEurope: Supports proposal      IADSA: Supports the 2nd circular proposal to adopt the provision at 100,000 mg/kg with New Note "for use in capsule and tablet form"	Adopt at 100,000 mg/kg with New Note "for use in capsule and tablet form"

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
		(33)				Supportive information:  JECFA Chemical Technical Assessment http://www.fao.org/3/a-az649e.pdf  JECFA summary report: http://www.fao.org/fileadmin/user_upload/agns/pdf/jecfa/Summary_report_of_the_80th_JECFA_meeting.pdf  FAO JECFA Monographs 17 - page 47 http://www.fao.org/3/a-i5080e.pdf  RU: ML level should be discussed. ML 100000 is to higher.	
PROPYLENE GLYCOL	1520	2000		4	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt with New Note "for use in capsule and tablet form"  EU: used as secondary food additive? Could the technological need be explained?  FoodDrinkEurope, IFAC: Supports adoption  IADSA: confirms that INS 1520 is used in food supplements as a primary additive (e.g. humectant in capsule shells) and a secondary additive (e.g. flavour). The additive is used in solid form including tablets, capsules and powders.  IADSA supports the 2nd circular proposal to adopt the provision at 2000 mg/kg. IADSA however requests that "capsule and tablet form" is replaced by 'solid forms' in the foot Note. The new Note would read "for use in solid forms"  RU: Supports proposal	Adopt with New Note "for use in capsule and tablet form"
PROPYLENE GLYCOL ALGINATE	405	1000		7	Bulking agent, Carrier, Emulsifier, Foaming	2nd Circular Proposal: Adopt	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
					agent, Gelling agent, Stabilizer, Thickener	EU, FoodDrinkEurope, IADSA, RU: Supports proposal	
SORBITAN ESTERS OF FATTY ACIDS	491-495	20000		4	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt at 5000 mg/kg with Note 364  EU, FoodDrinkEurope, IADSA, IFAC, RU: Supports proposal	Adopt at 5000 mg/kg with Note 364
SUCROSE ESTERS OF FATTY ACIDS	473	50000		4	Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt at 5000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU, FoodDrinkEurope, RU: Supports proposal  IADSA: supports the 2nd circular proposal to adopt the provision at 5000 mg/kg. The additives are used in food supplements to emulsify and stabilise emulsions. The additives are also used as glazing agents in coated tablets.  Japan: proposes that the maximum use level be changed to Sucrose esters of fatty acids are20000 mg/kg. This food additive is used in tablet-foam supplement as glazing agent. It provides protective coatings to prevent moisture absorption and to 20000 mg/kg, give smooth mouth feel.	Adopt at 20000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	50000		4	Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt at 5000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU, FoodDrinkEurope, RU: Supports proposal  IADSA: supports the 2nd circular proposal to adopt the provision at 5000 mg/kg. The additives are used in food supplements to emulsify and stabilise emulsions. The additives are also used as glazing agents in coated tablets.  Japan: used in tablet-foam supplement as glazing agent. It	Adopt at 20000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						provides protective coatings to prevent moisture absorption and to give smooth mouth feel. proposes that the maximum use level be changed to 20000 mg/kg. This food additive is used in tablet-form supplement up to 20000 mg/kg.	
SUCROGLYCERIDE S	474	50000			Emulsifier	2nd Circular Proposal: Adopt at 5000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU, FoodDrinkEurope, IADSA, RU: Supports proposal	Adopt at 20000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))
TARTRATES	334, 335(ii), 337	GMP	45	4	Acidity regulator, Eg/kgmulsifying salt, Sequestrant, Stabilizer	2nd Circular Proposal: Request information on use levels Brazil: supports adoption of a numerical use level, allowed as acidulant in food supplements (liquids and solids), with ML of 0.20g/100mL or 100mg, and INS 335ii is allowed as acidity regulator in food supplements (liquids only), with ML of 0.5g/100mL. EU, Chile: Supports to request information on use levels. IADSA: Levels up to 5000 mg/kg have been reported to be used in food supplements. INS 334, 335(ii) and 337are used as primary additives and additives in nutrients RU: Supports proposal only if ML is established	Adopt at 5000 mg/kg
TOCOPHEROLS	307a, b,	150		4	Antioxidant	2nd Circular Proposal: Adopt at 300 mg/kg with New Note "Except for use at 6,000 mg/kg, singly or in combination, on the basis of fish oil or algal oil content."  Brazil: Allowed in food supplements, with the following ML: Liquids:	Adopt at 2000 mg/kg with New Note "Except for use at 6,000 mg/kg, singly or in combination, on the basis of fish oil or algal oil content."

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
		(mg/kg)				307 and 307b: 0.03g/100mL (300mg/L).  Would like to make the following correction: "In Brazilian legislation, tocopherol is allowed as antioxidant in food supplements, with the following ML: Solids: 307: 0.15g/100g (1500mg/kg and not 150 mg/kg) 307b: 0.2g/100g (2000mg/kg and not 200mg/kg)"  Canada: Supports Brazil's justification. Notes that fish oils as a food ingredient are permitted to contain up to 6,000 mg/kg of tocopherol (see FC 02.1.3 "Lard, tallow, fish oil, and other animal fats," Note 358) Suggests a new note be added of "Except for use at 6,000 mg/kg on the basis of fish oil or algal oil content."  EU, FoodDrinkEurope: Supports proposal  EU Specialty Food Ingredients: reasonable use level for food supplements is 1000 mg/kg to take into account the diversity of food supplements and the susceptibility of varying constituents in a food supplement against oxidative degradation.  GOED: Supports adoption with new note per 2 <sup>nd</sup> Circular Proposal; however, given that the Standard for Fish Oils adopted by CAC40 does not include algal oils, should algal oils be included in the note? GOED is not opposed to its inclusion, but raises the issue for clarification  IADSA:  Levels used up to 1500 to 2000 mg/kg have reported to be used in food supplements.  IADSA supports the revised recommendation of Brazil.  IADSA proposes to adopt the 2nd circular proposal at 2000 mg/kg with New Note "Except for use at 6,000 mg/kg,	
						Levels used up to 1500 to 2000 mg/kg have reported to be used in food supplements.  IADSA supports the revised recommendation of Brazil.  IADSA proposes to adopt the 2nd circular proposal at 2000	

ng/kg)			-
		content."  RU: Supports proposal only for ML=150 mg/kg	

### Food Category No. 14.0 Beverages, excluding dairy products

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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### Food Category No. 14.1 Non-alcoholic ("soft") beverages

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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#### Food Category No. 14.1.1 Water

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is not justified on a general basis

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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#### Food Category No. 14.1.2 Fruit and vegetable juices

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators is justified on a case-by-case basis. The use of emulsifiers, stabilizers, and thickeners is **not** justified on a general basis

Corresponding commodity standards: None, 247-2005 applies to subcategories 14.1.2.1 and 14.1.2.3

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000		2	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Discontinue. Move to subcategories for consideration  EU, ICBA, ICGM,A, RU: Supports discontinuation; supports move to subcategories for consideration.	Current recommendation in all subcategories is Hold pending reply from CCPFV as per REP17/FA para 14(ii)
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	2000		2	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Discontinue. Move to subcategories for consideration</li> <li>EU, ICBA, ICGM,A, RU: Supports discontinuation; supports move to subcategories for consideration.</li> </ul>	Current recommendation in all subcategories is Hold pending reply from CCPFV as per REP17/FA para 14(ii)
XANTHAN GUM	<del>415</del>	3000		2	Emulsifier, Foaming agent, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Discontinue. Move to subcategories for consideration</li> <li>EU, ICBA, ICGM,A, RU: Supports discontinuation; supports move to subcategories for consideration.</li> </ul>	Current recommendation in all subcategories is Hold pending reply from CCPFV as per REP17/FA para 14(ii)

# Food Category No. 14.1.2.1 Fruit juice

Horizontal approach(FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators, emulsifiers, stabilizers, and thickeners is justified on a case by case basis

Corresponding commodity standards: 247-2005: allows food additives in Tables 1 and 2 and also lists specific processing aids

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
CALCIUM LACTATE	327	1200	336	2	Acidity regulator, Emulsifying salt, Firming agent, Flour treatment agent, Thickener	<ul> <li>2nd Circular Proposal: Request further information on justification for use – acidity regulators justified on case-by-case basis, not listed in CS 247-2005</li> <li>Chile: Supports to request further information on justification for use –acidity regulators justified on case-by-case basis, not listed in CS 247-200.</li> <li>EU, Switzerland, RU: Does not agree use of any additive not naturally present in juice due to potential change in characteristic of juice.</li> </ul>	Discuss further; multiple Table 3 acidity regulators are adopted in this food category at GMP

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA, India: Supports adoption as an acidity regulator (It's ADI is not specified)	
						ICGMA: Supports adoption as an acidity regulator at 1200 mg/kg Maximum Use Level	
						Calcium lactate, INS 327, is included in Table 3 of the GFSA and received a JECFA ADI of "NOT LIMITED", 1974. The use of calcium lactate as a regulator of acidity in fruit juices, particularly citrus fruit juices, provides a number of advantages to assist in producing consumer accepted juices. The calcium ion provides excellent buffering potential. The use of calcium lactate provides the additional benefit of helping to prevent browning associated with the production of fruit juices, citrus in particular. Its use allows for consumer accepted and preferred fruit juices, particularly citrus juices.	
						IFU, Poland: The Polish Association of Juice Producers (KUPS) comments. We do not support adoption. We only see the technological need to use of this additive with the addition of gellan gum. The KUPS is opposed to the use of gellan gum therefore we see no technological need for the use of calcium lactate. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005).	
GELLAN GUM	418	200	336	2	Glazing agent, Stabilizer	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)      EU: accepts holding the provision pending reply from CCPFV. However, the EU maintains its view that this additive is not needed and justified and its use might affect the characteristic of the product and mislead the consumer.      ICBA: Supports immediate adoption as a stabilizer at a Maximum Use Level of 1000 mg/kg      ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						CCFA 49 (IFAC). Having multiple options for stabilizers in fruit juices allows for greater innovation to meet consumer demands and expectations. Gellan gum provides excellent stabilization and particle suspension and does not impart a flavor or taste when used as a stabilizer in fruit juices. Gellan gum has no numerical ADI of NOT SPECIFIED, a Maximum Use Level of 1000 mg/kg is requested. Further delay on this provision awaiting response from the CCPFV will have a negative impact on trade. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	
TRISODIUM CITRATE	331(iii)	500	336	2	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)      EU: accepts holding the provision pending reply from CCPFV. However, the EU maintains its view that this additive is not needed and justified.      ICBA: Supports immediate adoption at a Maximum Use Level of 500 mg/kg  ICBA notes that technological use justification has been provided previously, CCFA 46th Meeting GFSA Report. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2nd circular	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.	
						IFU, Poland, RU, Switzerland: opposed to the approval of this thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)</li> <li>Colombia: The use of pectin by GMP is relevant and not with a specific DMU</li> <li>EU, Poland, RU, Switzerland: Supports proposal</li> <li>FoodDrinkEurope, IFU: supports use of this thickener/ stabilizer</li> <li>ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg</li> <li>ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). Further delay on this provision awaiting response from the CCPFV will have a negative impact on trade. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.</li> <li>ICGMA: Although ICGMA can accept the 2<sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.</li> <li>Japan: Supports 2<sup>nd</sup> circular proposal; Pectins are used in</li> </ul>	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						mix juice as stabilizer. Maximum use level is 3,000 mg/kg.	
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	2000			Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  EU: accepts holding the provision pending reply from CCPFV. However, the EU maintains its view that this additive is not needed and justified and its use might affect the characteristic of the product and mislead the consumer.  ICGMA: Although ICGMA can accept the 2nd circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  ICBA: Supports immediate adoption at a Maximum Use Level of 2000 mg/kg  ICBA notes that technological use justification has been provided previously, CCFA 46th Meeting GFSA Report. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)      EU: accepts holding the provision pending reply from CCPFV. However, the EU maintains its view that this additive is not needed and justified and its use might affect the characteristic of the product and mislead the consumer.      EU Specialty Food Ingredients, ICBA: supports immediate adoption.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

# Food Category No. 14.1.2.2 Vegetable juice

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators is justified in this FC on a general basis, emulsifiers, stabilizers, and thickeners are **not** justified in this FC on a general basis

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)     Brazil, EU, Switzerland, RU: Supports proposal     Colombia: The use of pectin by GMP is relevant and not with a specific DMU     FoodDrinkEurope, IFU, Poland: supports use of this thickener/	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  Japan: supports 2 <sup>nd</sup> circular proposal. Pectins are used in fruit and vegetable mix juice as stabilizer. Maximum use level is 3,000 mg/kg.	
PHOSPHATES	338; 339(i)- (iii); 340(i)- (iii); 341(i)- (iii); 343(i)- (iii); 450(i)- (iii),(v)- (vii), (ix); 451(i),(ii); 452(i)- (v); 542	1000	33	7	Acidity regulator, Antioxidant, Sequestrant	<ul> <li>2nd Circular Proposal: Adopt</li> <li>Colombia: Additive used in the food industry as an acid, acidulant and alkalizing regulator by means of GMP</li> <li>EU, RU, Switzerland: does not support proposal</li> <li>ICBA: Supports immediate adoption at a Maximum Use Level of 1000 mg/kg</li> <li>ICBA notes that technological use justification has been provided previously, CCFA 46th Meeting GFSA Report. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.</li> <li>ICGMA, IFAC, India, PAPA: supports the EWG proposals.</li> <li>IFU, Poland: opposes the proposal. If phosphate is to enhance the use of benzoates then they are not approved for the use in vegetable juice. We therefore oppose the approval of phosphate</li> </ul>	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						addition. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.  We do not think approval at step 7 is correct. Furthermore an addition of phosphates would adulterate the corresponding AIJN Code of Practice reference figure significantly, thus interfering authenticity analysis results.  2nd Circular Proposal: Adopt	
TARTRATES	334, 335(ii), 337	4000	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	Colombia: Additive used in the food industry as an acid, acidity regulator and acidulant, with DMU of 3 g/kg  EU: for consistency CCPFV should be consulted.  ICBA: Supports immediate adoption at a Maximum Use Level of 4000 mg/kg  Supports the EWG proposal based on the horizontal approach.  ICGMA, India, Indonesia: supports the adoption  IFU, Poland, RU, Switzerland: We oppose the use of tartrate in vegetable juice. They are only approved in fruit juices as an acidity regulator for grape juices only. See notes 128 and 129. Tartaric acid is not predominant in vegetable juices therefore we do not see the technological need to adopt the use of tartrates. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not think approval at step 7 is correct.	Adopt
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	2000			Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	2nd Circular Proposal: Request further info on use and technical justification  Chile, EU: Agrees with request for additional information  ICBA: Supports adoption at 2000 mg/kg Maximum Use Level  Sodium carboxymethyl cellulose, INS 466, (CMC) is included in Table 3 of the GFSA and received a JECFA ADI of "NOT	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
		(mg/kg)				SPECIFIED", 1989. The development and distribution of consumer acceptable vegetable juices can be a challenge because of the instability of solids such as pulp and proteins. The use of CMC alone or in combination with other stabilizers such as pectin, gellan gum, or guar gum in vegetable juices helps to prevent stratification. The use of CMC allows for technological innovation and the greater availability of consumer accepted vegetable juices across the spectrum of the global market place. Technological justification was also previously provided, CCFA 46th Meeting GFSA Report.  ICGMA: Although ICGMA can accept the 2nd circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, Poland, Switzerland, RU: KUPS is opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	REP17/FA para 14(ii)  EU: Accepts holding pending reply from CCPFV  EU Specialty Food Ingredients: supports immediate adoption.  ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.	
						IFU, Poland, Switzerland, RU: KUPS is opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

## Food Category No. 14.1.2.3 Concentrates for fruit juice

Horizontal approach: (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): acidity regulators, emulsifiers, stabilizers, and thickeners: case by case basis

**Corresponding commodity standards: 247-2005**: allows specific antifoaming agents, clarifying agents, filtration aids, flocculating agents, enzyme preparations and packaging gases.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  EU, Switzerland: Supports proposal  FoodDrinkEurope, IFU, Poland: supports use of this thickener/stabilizer  ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  RU: Does not support proposal. There not technological justification. Proposal should be discontinued. Use of this FA in this FC could mislead consumers.	
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	2000			Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  EU: accepts holding it pending reply from CCPFV  ICBA: Supports immediate adoption at a Maximum Use Level of 2000 mg/kg  ICBA notes that technological use justification has been provided previously, CCFA 46th Meeting GFSA Report. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2nd circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, Poland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.  RU: Does not support proposal. There not technological justification. Proposal should be discontinued. Use of this FA in this FC could mislead consumers.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						Switzerland: Does not agree use of any additive not naturally present in juice due to potential change in characteristic of juice	
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  EU: accepts holding it pending reply from CCPFV  EU Specialty Food Ingredients: supports immediate adoption.  ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Food Category No. 14.1.2.4 Concentrates for vegetable juice

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): The use of acidity regulators is justified in this FC on a general basis. Emulsifiers, stabilizers, and thickeners are **not** justified in this FC on a general basis

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  Colombia: The use of pectin by GMP is considered relevant, and not with a specific DMU  EU, Switzerland: Supports proposal  FoodDrinkEurope, IFU, Poland: Supports adoption  ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  RU: Does not support proposal. There not technological justification. Proposal should be discontinued. Use of this FA in this FC could mislead consumers.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)
PHOSPHATES	338; 339(i)- (iii); 340(i)- (iii); 341(i)- (iii); 342(i)- (ii); 343(i)- (iii);	1000	33 & 127	7	Acidity regulator, Antioxidant, Sequestrant	2nd Circular Proposal: Adopt     EU: for consistency CCPFV should be consulted.      Colombia: Additive used in the food industry as an acid, acidulant and alkalizing regulator by means of GMP      ICBA: Supports immediate adoption at a Maximum Use Level of 1000 mg/kg  Phosphate ingredients can assist in improving the shelf life of	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
	450(i)- (iii),(v)- (vii), (ix); 451(i),(ii) ; 452(i)- (v); 542					beverages via a sequestration action. Additionally, the acid regulatory function of a number of phosphate ingredients can help provide a crisp sharp taste and assist in retention of intrinsic ascorbic acid. Having multiple options for phosphate ingredients for use in vegetable juices allows for greater flexibility and innovation to meet consumer demands and expectations. The JECFA GROUP MTDI of 70 mg/kg bw (as P) supports the Maximum Use Level of 1000 ppm.  ICGMA, IFAC, India PAPA: supports the EWG proposal.  IFU, Poland, RU, Switzerland: We opposes this proposal. If the use of phosphate is to enhance the use of benzoates then they are not approved for the use in concentrates for vegetable juice. We therefore oppose the approval of phosphate addition. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005).  We do not think approval at step 7 is correct. Furthermore an addition of phosphates would adulterate the corresponding AIJN Code of Practice reference figure significantly, thus interfering authenticity analysis results.	
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	2000			Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Colombia: Support adoption at max level for the functional classes listed      EU: accepts holding it pending reply from CCPFV      ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.      ICBA: Supports immediate adoption at a Maximum Use Level of 2000 mg/kg      ICBA notes that technological use justification has been	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						provided previously, CCFA 46 <sup>th</sup> Meeting GFSA Report.  IFU, Poland, RU, Switzerland: Opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.  2nd Circular Proposal: Adopt	
TARTRATES	334, 335(ii), 337	4000	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	Colombia: Additive used by the food industry with the technological functions of acidifier, acidity regulator and acidulant, with DMU of 3g / kg  EU: for consistency CCPFV should be consulted.  ICBA: Supports immediate adoption at a Maximum Use Level of 4000 mg/kg  ICBA supports the EWG proposal based on the horizontal approach.  ICGMA, India: Supports adoption  IFU, Poland, RU, Switzerland: We do not understand the recommendation to approve the use of tartrates. They are only approved in fruit juices as an acidity regulator for grape juices only. See notes 128 and 129. Tartaric acid is not predominant in vegetable juices therefore we do not see the technological need to adopt the use of tartrates. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005).  We do not think approval at step 7 is correct.	Adopt
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  Colombia: Support adoption at max level for the functional classes listed	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						EU: accepts holding it pending reply from CCPFV	
						EU Specialty Food Ingredients: supports immediate adoption.	
						ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg	
						ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.	
						<u>ICGMA</u> : Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.	
						IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

### Food Category No. 14.1.3 Fruit and vegetable nectar

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): AR: case by case basis, ES&T: not justified in this FC on a general basis

Corresponding commodity standards: None, 247-2005 applies to subcategories 14.1.3.1 and 14.1.3.3

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	2 <sup>nd</sup> Circular Proposal	EWG Final Proposal
PECTINS	440	3000		2	Emulsifier, Gelling agent, Glazing agent,	2nd Circular Proposal: Disconsideration	scontinue. Move to subcategories for	Recommendation in all subcategories is
PEOTINO	110	0000		=	Stabilizer, Thickener	Colombia, EU, ICBA, ICGN		Hold pending reply from CCPFV as per

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	2 <sup>nd</sup> Circular Proposal	EWG Final Proposal
						subcategories for considera  China: Allows in this FC at		REP17/FA para 14(ii)
XANTHAN GUM	4 <del>15</del>	3000		2	Emulsifier, Feaming agent, Stabilizer,	2nd Circular Proposal: Disconsideration China: Allows in this FC at	scontinue. Move to subcategories for GMP	Recommendation in all subcategories is Hold pending reply from CCPFV as per
					Thickener	EU, ICBA, ICGMA, Indones discontinuation	sia, RU: Supports move; supports	REP17/FA para 14(ii)

# Food Category No. 14.1.3.1 Fruit nectar

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II):: AR and ES&T: case by case basis

Corresponding commodity standards: 247-2005: allows specific antifoaming agents, clarifying agents, filtration aids, flocculating agents, enzyme preparations and packaging gases.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)      Colombia: The use of pectin by GMP is considered relevant, and not with a specific DMU      EU, Switzerland, RU: Supports proposal      ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, FoodDrinkEurope, Poland: supports adoption	
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)</li> <li>EU: accepts holding it pending reply from CCPFV</li> <li>EU Specialty Food Ingredients: supports immediate adoption.</li> <li>ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg</li> <li>ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). Further delay on this provision awaiting response from the CCPFV will have a negative impact on trade. Numerous countries including Australia, Brazil, Chile, China, Columbia, Ecuador, Egypt, Japan, Nigeria, Pakistan, Peru, Philippines currently allow addition to Fruit Nectars. It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.</li> <li>ICGMA: Although ICGMA can accept the 2<sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.</li> <li>IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the</li> </ul>	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

# Food Category No. 14.1.3.2 Vegetable nectar

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): AR: justified in this FC on a general basis; ES&T: case by case basis

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)      Colombia: The use of pectin by GMP is considered relevant, and not with a specific DMU      EU, Switzerland, RU: Supports proposal      FoodDrinkEurope, IFU, Poland: supports use of this thickener/ stabilizer      ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PHOSPHATES	338; 339(i)- (iii); 340(i)- (iii); 341(i)- (iii); 343(i)- (iii); 450(i)- (iii),(v)- (vii), (ix); 451(i),(ii); 452(i)- (v); 542	1000	33	7	Acidity regulator, Antioxidant, Sequestrant	2nd Circular Proposal: Adopt as per horizontal approach  Colombia: Additive used in the food industry as an acid, acidulant and alkalizing regulator by means of GMP  EU: for consistency CCPFV should be consulted.  ICBA: Supports immediate adoption at a Maximum Use Level of 1000 mg/kg  Phosphate ingredients can assist in improving the shelf life of beverages via a sequestration action. Additionally, the acid regulatory function of a number of phosphate ingredients can help provide a crisp sharp taste and assist in retention of intrinsic ascorbic acid. Having multiple options for phosphate ingredients for use in vegetable juices allows for greater flexibility and innovation to meet consumer demands and expectations. The JECFA GROUP MTDI of 70 mg/kg bw (as P) supports the Maximum Use Level of 1000 ppm.  IFAC, ICGMA, India, PAPA,: Supports adoption  IFU, Poland, RU, Switzerland: opposed to the use of phosphates. If the proposal is to enhance the use of benzoates then they are not approved for the use in vegetable nectar. We therefore oppose the approval of phosphate addition. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005).  We do not think approval at step 7 is correct. Furthermore an addition of phosphates would adulterate the corresponding AIJN Code of Practice reference figure significantly, thus interfering authenticity analysis results.	Adopt
TARTRATES	334, 335(ii), 337	1600	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Adopt at 3000 mg/kg  Colombia: Additive used by the food industry with the technological functions of acidifier, acidity regulator and acidulant, with DMU of 3g / kg  EU, RU: for consistency CCPFV should be consulted.	Adopt at 4000 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA: Supports adoption at a Maximum Use Level of 4000 mg/kg  Tartrates can provide taste advantages through acid regulation. ICBA supports inclusion of all listed tartrates. Having multiple options for tartrate ingredients for use in concentrates for vegetable nectars allows for greater flexibility and innovation to meet consumer demands and expectations. The JECFA GROUP ADI of 30 mg/kg bw for tartaric acid and its sodium, potassium and potassium sodium salts supports the Maximum Use Level of 4000 ppm. Additionally, products may already be in the global market place utilizing tartrates up to 4000 ppm.  ICGMA, India: Supports adoption.  IFU, Poland, Switzerland: opposed to the proposal. Tartrates are only approved in fruit juices as an acidity regulator for grape juices only. See notes 128 and 129. Tartaric acid is not predominant in vegetable juices therefore we do not see the technological need to adopt the use of tartrates. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not think approval at step 7 is correct.	
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  Colombia: Support adoption at max level for the functional classes listed  EU, RU: accepts holding it pending reply from CCPFV  EU Specialty Food Ingredients: supports immediate adoption.  ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive IN	Max S Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
	(IIIg/kg)				provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  IFU, Poland, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

Food Category No. 14.1.3.3 Concentrates for fruit nectar

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): AR and ES&T: case by case basis

**Corresponding commodity standards: 247-2005**: allows specific antifoaming agents, clarifying agents, filtration aids, flocculating agents, enzyme preparations and packaging gases.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)      Colombia: The use of pectin by GMP is considered relevant, and not with a specific DMU      EU, FoodDrinkEurope, IFU, Poland, RU, Switzerland: Supports proposal      ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision	
						pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.	
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)</li> <li>Colombia: Support adoption at max level for the functional classes listed</li> <li>EU: Supports holding pending reply from CCPFV</li> <li>EU Specialty Food Ingredients: supports immediate adoption.</li> <li>ICGMA: Although ICGMA can accept the 2<sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.</li> <li>ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg</li> <li>ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). Further delay on this provision awaiting response from the CCPFV will have a negative impact on trade. Numerous countries including Australia, Brazil, Chile, China, Columbia, Ecuador, Egypt, Japan, Nigeria, Pakistan, Peru, Philippines currently allow addition to Fruit Nectars. It is</li> </ul>	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting	
						IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

# <u>Food Category No.</u> 14.1.3.4 Concentrates for vegetable nectar

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): AR: justified in this FC on a general basis; ES&T: case by case basis

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PECTINS	440	3000			Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)</li> <li>Colombia: The use of pectin by GMP is considered relevant, and not with a specific DMU</li> <li>EU, Switzerland, RU: Supports proposal</li> <li>EU Specialty Food Ingredients: No apparent rationale for the use of Xanthan gum as a foaming agent in fruit nectars.</li> <li>ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg</li> <li>ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.</li> <li>ICGMA: Although ICGMA can accept the 2<sup>nd</sup> circular recommendation in the spirit of consensus, we note significant</li> </ul>	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.	
						IFU, FoodDrinkEurope, Poland: supports adoption	
PHOSPHATES	338; 339(i)- (iii); 340(i)- (iii); 341(i)- (iii); 343(i)- (iii); 450(i)- (iii),(v)- (vii), (ix); 451(i),(ii); 452(i)- (v); 542	1000	33 & 127	7	Acidity regulator, Antioxidant, Sequestrant	2nd Circular Proposal: Adopt  EU: for consistency CCPFV should be consulted.  ICBA: Supports immediate adoption at a Maximum Use Level of 1000 mg/kg  Phosphate ingredients can assist in improving the shelf life of beverages via a sequestration action. Additionally, the acid regulatory function of a number of phosphate ingredients can help provide a crisp sharp taste and assist in retention of intrinsic ascorbic acid. Having multiple options for phosphate ingredients for use in vegetable juices allows for greater flexibility and innovation to meet consumer demands and expectations. The JECFA GROUP MTDI of 70 mg/kg bw (as P) supports the Maximum Use Level of 1000 ppm.  IFAC, ICGMA, PAPA: Supports adoption.  IFU, Poland, RU, Switzerland: opposes the proposal to use phosphate. If the use of phosphate is for the intention to support the functionality of benzoates then the notes 33, 40 and 122 should apply. This is in line with approval in food	Adopt
TARTRATES	334, 335(ii), 337	1600	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	category 14.1.2.1 Fruit juice  2nd Circular Proposal: Adopt EU: for consistency CCPFV should be consulted.  ICBA: Supports immediate adoption at a Maximum Use Level of 4000 mg/kg  Tartrates can provide taste advantages through acid regulation. ICBA supports inclusion of all listed tartrates. Having multiple options for tartrate ingredients for use in	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						concentrates for vegetable nectars allows for greater flexibility and innovation to meet consumer demands and expectations. The JECFA GROUP ADI of 30 mg/kg bw for tartaric acid and its sodium, potassium and potassium sodium salts supports the Maximum Use Level of 4000 ppm.  ICGMA, Indonesia: Supports adoption.  IFU, Poland, RU, Switzerland: opposes the proposal. Tartrates are only approved in fruit juices as an acidity regulator for grape juices only. See notes 128 and 129. Tartaric acid is not predominant in vegetable juices therefore we do not see the technological need to adopt the use of tartrates. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard	
XANTHAN GUM	415	3000			Emulsifier, Foaming agent, Stabilizer, Thickener	for Fruit Juices and Nectars (CODEX STAN 247-2005).  2nd Circular Proposal: Hold pending reply from CCPFV as per REP17/FA para 14(ii)  EU: accepts holding the provision pending reply from CCPFV.  EU Specialty Food Ingredients: supports immediate adoption.  ICGMA: Although ICGMA can accept the 2 <sup>nd</sup> circular recommendation in the spirit of consensus, we note significant technological justification supporting use has been provided. We remain extremely concerned that holding this provision pending a reply from CCPFV (which may not meet for at least 3 years) will negatively impact trade.  ICBA: Supports immediate adoption at a Maximum Use Level of 3000 mg/kg  ICBA notes that technological use justification has been provided previously, ICBA Comments to the First Circular and CRD8 of CCFA 49 (IFAC). It is likely that the CCPFV will not meet soon and likely will not have a reply for some time after its next meeting.	Hold pending reply from CCPFV as per REP17/FA para 14(ii)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						IFU, Poland, RU, Switzerland: opposed to the approval of this stabeliser/thickener. Approval of this additive contradicts the quality and authenticity requirements set in the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005). We do not see a technological need.	

<u>Food Category No.</u> 14.1.4 Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	10		7	Emulsifier, Humectant	<ul> <li><u>EU</u>: opposes – ADI very low. A child of 20kg would reach the ADI by drinking 200ml. No technological justification provided.</li> <li><u>FoodDrinkEurope</u>, <u>ICGMA</u>: supports adoption.</li> <li><u>ICBA</u>: Supports immediate adoption at a Maximum Use Level of 10 mg/kg</li> <li>Dioctyl Sodium Sulfosuccinate (DSS) can provide an important emulsification function for fruit flavored water-based flavored beverages. Limited regulatory acceptance has been granted for use of DSS in this category of beverages. DSS was notified to the US FDA as a GRAS (GRN 6) for use in water-based beverages. The US FDA did not have any questions, https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154917.htm (December 1998).</li> <li><u>RU</u>: There should be given risk estimation because ADI 0-0.1 mg/kg bw. So on one liter of drink could contain INS 480 in quantity higher than ADI.</li> </ul>	Adopt with new Note "For use in fruit flavored water-based beverages only"
ETHYL MALTOL	637	200		7	Flavour enhancer	<ul> <li>2nd Circular Proposal: Adopt</li> <li>EU: does not support: Excessive ML a child of 20 kg would reach the ADI by drinking 200ml! Used as flavouring or a flavor enhancer? Technological justification provided?</li> </ul>	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						FoodDrinkEurope, ICGMA: supports adoption.  ICBA: Supports immediate adoption at a Maximum Use Level of 200 mg/kg  ICBA notes that Ethyl Maltol's use a Flavour has been reviewed and accepted by JECFA. The use of Ethyl Maltol as a Flavour enhancer will add technological advantages to beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants by intensifying flavor and taste attributes. Its use and level of use as a flavour enhancer would be minor compared to its use and level of use as a flavouring based on its sensorial properties.  RU: There should be given risk estimation because ADI 0-2 mg/kg bw. So on one liter of drink could contain INS 637 in	
MALTOL	636	200		7	Flavour enhancer	quantity higher than ADI.  2nd Circular Proposal: Adopt  EU: does not support. No justification apart from the statement "support adoption" was provided. Excessive ML a child of 20 kg would reach the ADI by drinking 100ml!  FoodDrinkEurope, ICGMA: supports adoption.  ICBA: Supports immediate adoption at a Maximum Use Level of 200 mg/kg  ICBA notes that Maltol's use a Flavour has been reviewed and accepted by JECFA. The use of Maltol as a Flavour enhancer will add technological advantages to beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants by intensifying flavor and taste attributes. Its use and level of use as a flavour enhancer would be minor compared to its use and level of use as a flavouring based on its sensorial properties.  RU: There should be given risk estimation because ADI 0-2 mg/kg bw. So on one liter of drink could contain INS 636 in	Adopt

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
		1				quantity higher than ADI.	
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	9000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  China, FoodDrinkEurope, ICGMA: Supports adoption  EU: strongly opposes: Excessive ML a child of 20 kg would reach the ADI by drinking 56ml! In addition, the EU is not aware of the technological need  ICBA: Supports immediate adoption at a Maximum Use Level of 9000 mg/kg  The technological advantages provided by Polyglycerol Esters of Fatty Acids will add to the ability to innovate in beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants. The JECFA ADI of 0 – 25 mg/kg bw for polyglycerol esters of fatty acids supports the Maximum Use Level of 9000 ppm.  Japan: supports 2nd circular proposal. Polyglycerol esters of fatty acids are used in lactic drink to prevent separation of cream. Maximum use level is 2,000 mg/kg.  RU: There should be given risk estimation because ADI 0-25 mg/kg bw. So on one liter of drink could contain INS 475 in quantity higher than ADI.	Request information on types of products and use levels in subcategories
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	2nd Circular Proposal: Adopt  EU: does not support Excessive ML a child of 20 kg would reach the ADI by drinking 30ml! In addition, the EU is not aware of the technological need  FoodDrinkEurope, ICGMA: supports adoption.  ICBA: Supports immediate adoption at a Maximum Use Level of 5000 mg/kg  The technological advantages provided by Polyglycerol Esters of Interesterified Ricinoleic Acid will add to the ability to	Request information on use levels in subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						innovate in beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants. The JECFA ADI of 0 – 7.5 mg/kg bw for polyglycerol esters of interesterified ricinoleic acid supports the Maximum Use Level of 5000 ppm. <u>RU</u> : There should be given risk estimation because ADI 0-7,5 mg/kg bw. So on one liter of drink could contain INS 476 in quantity higher than ADI.	
POLYOXYETHYLEN E STEARATES	430, 431	500		7	Emulsifier	2nd Circular Proposal: Adopt  EU: no technological justification provided  FoodDrinkEurope, ICGMA: supports adoption  ICBA: Supports immediate adoption at a Maximum Use Level of 500 mg/kg  The technological advantages provided by Polyoxyethylene Stearates will add to the ability to innovate in beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants. The JECFA ADI of 0 – 25 mg/kg bw as a total of polyoxyethylene (8) and (40) stearates supports the Maximum Use Level of 500 ppm.	Adopt
PROPYLENE GLYCOL ALGINATE	405	500		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	2nd Circular Proposal: Adopt  China: Supports adoption, also allows in 14.1.4.2 at 6000  FoodDrinkEurope, IFAC, Indonesia: Supports adoption  EU: Questions if tech just has been provided. Believe 33 mg/kg is sufficient  ICBA: Supports adoption at a Maximum Use Level of 500 mg/kg  Propylene Glycol Alginate can provide emulsification that will add to the ability to innovate in beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants. Numerous countries allow its use in water-	Request information on use level in subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						based beverages at 500 ppm including Argentina, Brazil, Canada, Chile, Indonesia, Japan, Korea, Mexico, Morocco, Philippines, Poland, Romania, Russia, Turkey, and United States. The JECFA ADI of 0 – 70 mg/kg bw for propylene glycol alginate supports the Maximum Use Level of 500 ppm.  ICGMA: Supports adoption, but notes the information that has	
						been provided to us indicates the ML necessary to achieve the desired technological effect is 3000 mg/kg and that 500 mg/kg is not sufficient. Request the ML be revised to 3000 mg/kg.	
						<u>Japan</u> : supports the 2nd proposal; used in carbonated drinks fallen within FC 14.1.4.1 to stabilize generating foams in the final product.	
						2nd Circular Proposal: Adopt  EU: Could accept if tech just has been provided	Adopt
SODIUM DIACETATE	262(ii)	150		7	Acidity regulator, Preservative, Sequestrant	FoodDrinkEurope, ICGMA: supports adoption.  ICBA: Supports adoption at a Maximum Use Level of 150 mg/kg	
						The use of Sodium diacetate in some types of water-based beverages provides another preservation option for innovation with limited impact on taste. The JECFA ADI of 0 – 15 mg/kg bw sodium diacetate supports the Maximum Use Level of 150 ppm.	
						2nd Circular Proposal: Adopt China: Supports adoption, also allows in 14.1.4.2 at 6000	Discuss use and use levels in subcategories.
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		7	Emulsifier, Stabilizer	FoodDrinkEurope, IFAC, ICGMA: supports adoption  EU: opposes. Excessive ML a child of 20 kg would reach the ADI by drinking 100ml. In addition, the EU is not aware of the technological need	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg  Sorbitan Esters of Fatty Acids can provide emulsification that will add to the ability to innovate in beverages included in FC 14.1.4 by providing for more options for consumer acceptable flavor variants. Often, Sorbitan Esters of Fatty Acids are used in combination with other emulsifiers to provide optimum function and thus limit the use levels. The JECFA GROUP ADI of 0 – 25 mg/kg bw as the sum of the sorbitan esters of lauric, oleic, palmitic and stearic acid supports the Maximum Use Level of 5000 ppm.  RU: There should be given risk estimation because ADI 0-25 mg/kg bw. So on one liter of drink could contain INS 441-495	
STEAROYL LACTYLATES	481(i), 482(i)	2000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	in quantity higher than ADI.  2nd Circular Proposal: Adopt  China, FoodDrinkEurope, IFAC: Supports adoption  EU, RU: opposes due to safety (exposure) concerns. The intake calculations indicate the exceedance of the ADI for this additive and the additive is not authorized in flavoured drinks in the EU (the use is limited only to powders for the preparation of hot beverages respectively). The use in flavoured drinks would be a significant addition to the existing exposure. Child of 20kg reaches the ADI by drinking 200ml.  ICBA: supports adoption at a Maximum Use Level of 2000 mg/kg  Stearoyl lactylates are particularly useful in powdered beverages to provide emulsification upon reconstitution with water. The JECFA ADI of 0 – 20 mg/kg bw supports the use of stearoyl lactylates at 2000 ppm.  ICGMA: Supports adoption, but notes that a 5,000 mg/kg usage level is necessary to achieve the desired technological effect. We have also been advised that numerous products exist in global commerce at the higher usage level and	Discuss use and use level in subcategories

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						adopting 2000 mg/kg would negatively impact trade in these products	
TARTRATES	334, 335(ii), 337	5000	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Adopt  China, FoodDrinkEurope, ICGMA: Supports adoption  EU: has the technological need been provided? ML seems to be excessive (a 20 kg child will reach the ADI by drinking 120ml)  ICBA: Supports adoption at a Maximum Use Level of 5000 mg/kg  Tartrates provide for innovation especially in fruit flavored beverages as an acidity regulator and by providing flavour enhancement and crisp taste. The JECFA GROUP ADI of 0 – 30 mg/kg bw for L(+)-tartaric acid and its sodium, potassium, and potassium sodium salts supports the Maximum Use Level of 5000 ppm.  Japan: supports 2nd circular proposal. Tartrates are used as acidity regulator. Maximum use level is 800 mg/kg  RU: Does not support proposal. ML is so higher	Adopt
TOCOPHEROLS	307a, b,	1000	15	7	Antioxidant	2nd Circular Proposal: Adopt at 200 mg/kg  China: Supports adoption, allows in 14.1.4.2 at 2000  EU, RU: does not support: ADI could be exceeded for children  ICBA: Supports adoption at a Maximum Use Level of 200 mg/kg  As an antioxidant, Tocopherols are permitted for use in water-based beverages in a number of countries including Argentina, Canada, China, Colombia, Indonesia, Japan, Korea, Mexico, Morocco, Philippines, Poland, Romania, Turkey, Unites States, and Vietnam. The JECFA GROUP ADI of 0.15 – 2 mg/kg bw	Adopt at 200 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						for INS 307a, b, c supports the Maximum Use Level of 200 ppm	
						ICGMA: Supports adoption at 1,000 mg/kg. 200 mg/kg is not sufficient to achieve the desired technological effect and another member has indicated they allow 2000 mg/kg in this food category in their regulations.	
						Japan: Supports proposal to adopt at 200 mg/kg	

## Food Category No. 14.1.4.1 Carbonated water-based flavoured drinks

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PROPYLENE GLYCOL	1520	3000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 1000 mg/kg  EU: secondary food additive use?  FoodDrinkEurope, ICGMA, RU: supports adoption.  ICBA: Supports adoption at a Maximum Use Level of 1000 mg/kg  The JECFA GROUP ADI of 0 – 25 mg/kg bw for propylene glycol supports the Maximum Use Level of 1000 ppm.	Adopt at 1000 mg/kg
PROPYLENE GLYCOL ALGINATE	405	500			Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	See comments in FC 14.1.4  Japan: support adoption; used in carbonated drinks fallen within FC 14.1.4.1 to stabilize generating foams in the final product.	Request information on use levels in this subcategory of 14.1.4
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	9000			Emulsifier, Stabilizer		Request information on use levels in this subcategory of 14.1.4
POLYGLYCEROL	476	5000			Emulsifier	See comments in FC 14.1.4	Request information

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
ESTERS OF INTERESTERIFIED RICINOLEIC ACID							on use levels in this subcategory of 14.1.4
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000			Emulsifier, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
STEAROYL LACTYLATES	481(i), 482(i)	2000			Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
SUCROSE ESTERS OF FATTY ACIDS	473	1000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt at 1500 mg/kg</li> <li>China, FoodDrinkEurope, ICGMA: Supports adoption, allows in 14.1.4 at 1500</li> <li>EU, RU: why this additive is needed? Flavoured drinks could be still important source of the exposure</li> <li>ICBA: Supports adoption at a Maximum Use Level of 1500 mg/kg</li> <li>The emulsification properties of Sucrose Esters of Fatty Acids allow for greater innovation in fruit flavored beverages employing oils for flavoring and especially useful in clear beverage applications. The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids and sucroglycerides supports the Maximum Use Level of 5000 ppm.</li> </ul>	Adopt at 1500 mg/kg
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	1000			Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt at 5000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))      EU: opposes – exposure concern; 20kg child reaches the ADI by drinking 120 ml. No technological justification was provided.      FoodDrinkEurope, ICGMA: Supports proposal      ICBA: Supports adoption at a Maximum Use Level of 5000	Discuss further

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
		(gg)				mg/kg with Note 348  Products may have already been placed in numerous markets with up to 5000 ppm. The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids, sucroglycerides and sucrose oligoesters type I and II supports the Maximum Use Level of 5000 ppm.  RU: Adopt with ML of 2nd Circular Proposal = 1000 mg/kg because ADI 0-30 mg/kg bw  2nd Circular Proposal: Adopt at 5000 mg/kg;	Discuss further
SUCROGLYCERIDE S	474	1000			Emulsifier	with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) <u>EU</u> : exposure concern; 20kg child reaches the ADI by drinking 120 ml.  No technological justification was provided. <u>FoodDrinkEurope, ICGMA, RU</u> : Supports proposal <u>ICBA</u> : Supports adoption at a Maximum Use Level of 5000 mg/kg with Note 348  Products may have already been placed in numerous markets with up to 5000 ppm. The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids, sucroglycerides and sucrose oligoesters type I and II supports the Maximum Use Level of 5000 ppm.	
TARTRATES	334, 335(ii), 337	5000	45		Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
TOCOPHEROLS	307a, b,	1000	15		Antioxidant	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4

<u>Food Category No.</u> 14.1.4.2 Non-carbonated water-based flavoured drinks, including punches and ades

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PROPYLENE GLYCOL	1520	3000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 1000 mg/kg  EU: secondary food additive use?  ICBA: supports adoption at a Maximum Use Level of 1000 mg/kg  The JECFA GROUP ADI of 0 – 25 mg/kg bw for propylene glycol supports the Maximum Use Level of 1000 ppm.  ICGMA, Malaysia, RU: Supports adoption	Adopt at 1000 mg/kg
PROPYLENE GLYCOL ALGINATE	405	500			Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	See comments in FC 14.1.4  China: allowed at 6,000 mg/kg	Discuss use levels in this subcategory of 14.1.4
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	9000			Emulsifier, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000			Emulsifier	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000			Emulsifier, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
STEAROYL LACTYLATES	481(i), 482(i)	2000			Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) and New Note "for use in aniseed-based, diary-based, coconut and almond	Discuss further

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
	INS	Level	Notes		INS Functional Class	drinks"  China: Supports adoption, allows in 14.1.4 at 1500  EU: opposes – exposure concern; 20kg child reaches the ADI by drinking 120 ml.  FoodDrinkEurope, ICGMA: Supports proposal  ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg with Note 348  The emulsification properties of Sucrose Esters of Fatty Acids allow for greater innovation in fruit flavored beverages employing oils for flavoring and especially useful in clear beverage applications. The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids and sucroglycerides supports the Maximum Use Level of 5000 ppm.  Indonesia: proposes ML of 750 mg/kg  Japan: proposes modifying New Note to read as "for use in aniseed-based, diary-based, coconut and almond drinks, and ready-to-drink coffee and tea drinks with or without milk or milk solids" since this food additive is also used in ready-to-drink coffee and tea drinks with or without milk or milk solids to prevent oil separation. Japan: also proposes the maximum use level be reduced to 3000 mg/kg.  RU: Adopt with ML of = 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification  2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II	Discuss further
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	(INS 473a) and sucroglycerides (INS 474)) <u>EU</u> : opposes – exposure concern; 20kg child reaches the ADI by drinking 120 ml. No technological justification was provided.	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						FoodDrinkEurope, ICBA, ICGMA: Supports adoption  RU: Adopt with ML of = 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification  2nd Circular Proposal: Adopt;	Discuss further
SUCROGLYCERIDE S	474	5000			Emulsifier	with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) <u>EU</u> : opposes – exposure concern; 20kg child reaches the ADI by drinking 120 ml. No technological justification was provided. <u>FoodDrinkEurope, ICBA, ICGMA</u> : Supports adoption <u>RU</u> : Adopt with ML of = 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification	
TARTRATES	334, 335(ii), 337	5000	45		Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
TOCOPHEROLS	307a, b,	1000	15		Antioxidant	See comments in FC 14.1.4 China: allows at 2000 mg/kg	Request information on use levels in this subcategory of 14.1.4

## No. 14.1.4.3 Concentrates (liquid or solid) for water-based flavoured drinks

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PROPYLENE GLYCOL	1520	200000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 1000 mg/kg  EU: secondary food additive use? No technological justification was provided.	Adopt at 1000 mg/kg
						ICBA: supports adoption at a Maximum Use Level of 1000	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						mg/kg based on finished product formulation as consumed.  The JECFA GROUP ADI of 0 – 25 mg/kg bw for propylene glycol supports the Maximum Use Level of 3000 ppm.  Products may have already been placed in numerous markets with up to 3000 ppm  ICGMA, Indonesia: Supports adoption  Malaysia: Support adoption of 1000 mg/kg but with Note 381 (As consumed). mitigate  RU: Agrees with adopt at 1000 mg/kg. There are not technological justification	
PROPYLENE GLYCOL ALGINATE	405	500			Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	See comments in FC 14.1.4	Discuss use levels in this subcategory of 14.1.4
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	9000			Emulsifier, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000			Emulsifier	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000			Emulsifier, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
STEAROYL LACTYLATES	481(i), 482(i)	2000			Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	See comments in FC 14.1.4	Request information on use levels in this subcategory of 14.1.4
SUCROSE ESTERS OF FATTY ACIDS	473	10000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)); and New Note "for	Discuss further

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						use in powders for the preparation of hot beverages"  China: Supports adoption, allows in 14.1.4 at 1500  EU: opposes – exposure concern; 20kg child reaches the ADI by drinking 60 ml. No technological justification was provided.  FoodDrinkEurope, ICGMA: Supports proposal  ICBA: supports adoption at a Maximum Use Level of 10000 mg/kg based on finished product formulation as consumed without addition of New Note "for use in powders for the preparation of hot beverages".  The emulsification properties of Sucrose Esters of Fatty Acids allow for greater innovation in fruit flavored beverages employing oils for flavoring. The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids and sucroglycerides supports the Maximum Use Level of 10000 ppm.  RU: Adopt with ML of = 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	10000			Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt at 50000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU: opposes – exposure concern. ML expressed before dilution? No technological justification was provided.  FoodDrinkEurope, ICGMA: Supports proposal  ICBA: supports adoption at a Maximum Use Level of 50000 mg/kg with Note 348 based on concentrated product formulation.  The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids, sucroglycerides and sucrose oligoesters	Discuss further

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						type I and II supports the Maximum Use Level of 50000 ppm for concentrates  RU: Adopt with ML of 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification	
SUCROGLYCERIDE S	474	10000			Emulsifier	2nd Circular Proposal: Adopt at 50000 mg/kg; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU: opposes – exposure concern. ML expressed before dilution? No technological justification was provided.  ICBA: supports adoption at a Maximum Use Level of 50000 mg/kg with Note 348 based on concentrated product formulation.  FoodDrinkEurope, ICGMA: Supports proposal  RU: Adopt with ML of 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification	Discuss further
TARTRATES	334, 335(ii), 337	5000	45		Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant		Request information on use levels in this subcategory of 14.1.4
TOCOPHEROLS	307a, b,	1000	15		Antioxidant		Request information on use levels in this subcategory of 14.1.4

Food Category No. 14.1.5 Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa

Horizontal approach (FA/45 CRD2 Appendix IV, FA/46 CRD 2 Appendix II): AR and ES&T: justified in this food category on a general basis, with Note 160 "For use in ready-to-drink products and pre-mixes for ready-to-drink products only"

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
ETHYL MALTOL	637	200		7	Flavour enhancer	<ul> <li><u>EU</u>: does not support. Used as a flavor enhancer?         Technological justification? A 20 kg child reaches the ADI by drinking 200ml.         </li> <li><u>FoodDrinkEurope, ICGMA, Malaysia</u>: Supports adoption         </li> <li><u>ICBA</u>: Supports immediate adoption at a Maximum Use Level of 200 mg/kg         </li> <li>ICBA notes that Ethyl Maltol's use a Flavour has been reviewed and accepted by JECFA. The use of Ethyl Maltol as a Flavour enhancer will add technological advantages to beverages by providing for more options for consumer acceptable flavor variants by intensifying flavor and taste attributes especially fruity and caramel tastes. Its use and level of use as a flavour enhancer would be minor compared to its use and level of use as a flavouring based on its sensorial properties.         </li> <li><u>RU</u>: There should be given risk estimation because ADI 0-2 mg/kg bw. So on one liter of drink could contain INS 637 in quantity higher than ADI.</li> </ul>	Adopt
MALTOL	636	200		7	Flavour enhancer	2nd Circular Proposal: Request further info on technical justification and actual use level  Chile, EU: supports request further info on technical justification and actual use level.  FoodDrinkEurope, ICGMA: Supports adoption  ICBA: Supports immediate adoption at a Maximum Use Level of 200 mg/kg  ICBA notes that Ethyl Maltol's use a Flavour has been reviewed and accepted by JECFA. The use of Ethyl Maltol as a Flavour enhancer will add technological advantages to beverages by providing for more options for consumer acceptable flavor variants by intensifying flavor and taste attributes, especially fruity and caramel tastes. Its use and level of use as a flavour	Discuss further

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	enhancer would be minor compared to its use and level of use as a flavouring based on its sensorial properties.  RU: There should be given risk estimation because ADI 0-2 mg/kg bw. So on one liter of drink could contain INS 636 in quantity higher than ADI.  2nd Circular Proposal: Adopt at 9000 mg/kg with Note 160  China: allows in 14.1.5 at 10,000  EU: does not support. Technological justification? A 20 kg child reaches the ADI by drinking 56ml. EU does not see the technological need for this additive  ICBA: Supports adoption at a Maximum Use Level of 9000 mg/kg with Note 160  The emulsification properties provided by Polyglycerol Esters of Fatty Acids will add to the ability to innovate in beverages by providing for more options for consumer acceptable flavor variants. The JECFA ADI of 0 – 25 mg/kg bw for polyglycerol esters of fatty acids supports the Maximum Use Level of 5000 ppm.  FoodDrinkEurope, ICGMA, Japan, Malaysia: Supports proposal. used in coffee, coffee mixed with cream and black tea mixed with cream to prevent separation of cream.	Adopt at 10000 mg/kg with Note 160 "For use in ready-to-drink products and pre-mixes for ready-to-drink products only."
						RU: There should be given risk estimation because ADI 0-25 mg/kg bw. So on one liter of drink could contain INS 475 in quantity higher than ADI in case of children. There are not technological justification	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	2nd Circular Proposal: Adopt with Note 160  EU: opposes. Technological justification? A 20 kg child reaches the ADI by drinking 30ml! EU does not see the technological need for this additive  FoodDrinkEurope, ICGMA, Malaysia: Supports adoption	Adopt with Note 160

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg with Note 160  The technological advantages provided by Polyglycerol Esters of Interesterified Ricinoleic Acid will add to the ability to innovate in beverages by providing for more options for consumer acceptable flavor variants. The JECFA ADI of 0 – 7.5 mg/kg bw for polyglycerol esters of interesterified ricinoleic acid supports the Maximum Use Level of 5000 ppm  RU: There should be given risk estimation because ADI 7,5 mg/kg bw. So on one liter of drink could contain INS 636 in	
PROPYLENE GLYCOL ALGINATE	405	10000		4	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	<ul> <li>quantity higher than ADI. There are not technological justification</li> <li>2nd Circular Proposal: Adopt with Note 160</li> <li>China, FoodDrinkEurope, ICGMA, IFAC, Japan, Malaysia: Supports adoption as proposed. used as a foam stabilizer in cappuccino beverages.</li> <li>EU: opposes. Technological justification? A 20 kg child reaches the ADI by drinking 140ml! EU does not see the technological need for this additive</li> <li>ICBA: supports adoption at a Maximum Use Level of 10000 mg/kg with Note 160</li> <li>Propylene Glycol Alginate can provide emulsification that will add to the ability to innovate in beverages by providing for more options for consumer acceptable flavor variants. Numerous countries allow its use in water-based beverages at 10000 ppm including Argentina, Brazil, Canada, Chile, Indonesia, Japan, Korea, Mexico, Morocco, Philippines, Poland, Romania, Russia, Turkey, and United States. The JECFA ADI of 0 – 70 mg/kg bw for propylene glycol alginate supports the Maximum Use Level of 10000 ppm</li> <li>RU: Does not agrees with proposal. ML is so higher. There are not technological justification</li> </ul>	Adopt with Note 160
PROTEASE FROM ASPERGILLUS	1101(i)	GMP		7	Flavour enhancer, Flour treatment agent,	2nd Circular Proposal: Adopt with Note 160	Adopt with Note 160

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
ORYZAE VAR.					Stabilizer	EU, RU: no technological justification provided	
						FoodDrinkEurope, ICGMA, Malaysia: Supports adoption	
						ICBA: supports adoption at a Maximum Use Level of GMP with Note 160	
						Protease from Aspergillus oryzae can provide flavour enhancement in protein containing beverages. The JECFA ADI of ACCEPTABLE supports GMP as the use level.	
						2nd Circular Proposal: Adopt at 2000 mg/kg	Adopt at 2000 mg/kg
						<u>Japan</u> : used to prevent creaming or coagulation of milk fat in milk-added beverages and to prevent oil separation. Maximum use level is 2,000 mg/kg.	
						EU: Believe ML of 500 mg/kg is sufficient	
						ICGMA, IFAC, Malaysia: Supports adoption	
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		7	Emulsifier, Stabilizer	ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg with Note 348	
						The JECFA GROUP ADI of 0 – 25 mg/kg bw as the sum of the sorbitan esters of lauric, oleic, palmitic and stearic acid supports the Maximum Use Level of 5000 ppm. Products may have already been placed in numerous markets with up to 5000 ppm.	
						RU: There should be given risk estimation because ADI 0-25 mg/kg bw. So on one liter of drink could contain INS 441-495 in quantity higher than ADI. There are not technological justification/	
					Emulsifier, Flour	2nd Circular Proposal: Adopt at 5000 mg/kg with Note 2 and 160	Adopt at 5000 mg/kg with Note 2 "On the dry ingredient, dry weight,
STEAROYL LACTYLATES	481(i), 482(i)	2000	2	7	treatment agent, Foaming agent, Stabilizer	China, FoodDrinkEurope, ICGMA, IFAC, Malaysia: Supports adoption as proposed	dry mix or concentrate basis"and Note 160
						<u>EU</u> : has exposure concerns on INS 481, 482. ML of 2000ppm should be sufficient. The use needed only in powders for	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						preparation of hot beverages.  ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg with Note 2 and 160  Stearoyl lactylates are particularly useful in powdered beverages to provide emulsification upon reconstitution with water. The JECFA ADI of 0 – 20 mg/kg bw supports the use of stearoyl lactylates at 5000 ppm.  RU: There should be given risk estimation because ADI 0-25 mg/kg bw. So on one liter of drink could contain INS 441-495 in quantity higher than ADI. There are not echnological justification	
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))</li> <li>EU: has exposure concerns on INS 473-474.         A 20 kg child reaches the ADI by drinking 120ml. ML and use needs to be restricted.     </li> <li>FoodDrinkEurope, ICGMA, Malaysia: Supports adoption</li> <li>ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg with Note 348</li> <li>The emulsification properties of Sucrose Esters of Fatty Acids allow for greater innovation in fruit flavored beverages employing oils for flavoring. The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids and sucroglycerides supports the Maximum Use Level of 5000 ppm.</li> <li>Japan: supports the 2<sup>nd</sup> circular proposal. used in coffee mixed with cream and black tea mixed with cream to prevent separation of cream.         They are also used to prevent oil separation in coffee and tea concentrates.         Maximum use level is 5,000 mg/kg. Suggests         Japan suggests removing Note 160 "For use in ready-to-drink     </li> </ul>	Adopt with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	products and pre-mixes for ready-to-drink products only" since this food additive is used in concentrates fallen within this food category.  RU: Adopt with ML of 1000 mg/kg because ADI 0-30 mg/kg bw. There are not technological justification  2nd Circular Proposal: Adopt; with Note 160 and Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  China: Allows in this FC at 15,000  EU: has exposure concerns on INS 473-474. A 20 kg child reaches the ADI by drinking 120ml. ML and use needs to be restricted.  Japan: used in ready-to-drink coffee to prevent oil separation. Maximum use level is 1,000 mg/kg.  FoodDrinkEurope, ICGMA, Malaysia: Supports adoption  ICBA: supports adoption at a Maximum Use Level of 5000 mg/kg with Note 160 and Note 348  The JECFA GROUP ADI of 0 – 30 mg/kg bw for sucrose esters of fatty acids, sucroglycerides and sucrose oligoesters type I and II supports the Maximum Use Level of 5000 ppm  RU: There are not technological justification  2nd Circular Proposal: Adopt;	Adopt; with Note 160 and Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))
SUCROGLYCERIDE S	474	5000			Emulsifier	with Note 160 and Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))  EU: has exposure concerns on INS 473-474.  A 20 kg child reaches the ADI by drinking 120ml. ML and use needs to be restricted.  FoodDrinkEurope, ICBA, ICGMA, Malaysia: Supports	with Note 160 and Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						adoption	
						RU: There are not technological justification	

#### Food Category No. 14.2 Alcoholic beverages, including alcohol-free and low-alcoholic counterparts

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	<del>10</del>		7	Emulsifier, Humectant	2nd Circular Proposal: Discontinue. Move to subcategories for consideration  EU, ICGMA, RU: supports second circular proposal.	Discontinue. (For all subcategories no tech justification has been provided)
PROPYLENE GLYCOL	<del>1520</del>	50000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Discontinue. Move to subcategories for consideration  EU, ICGMA, RU: supports second circular proposal.  RU: (from first circular) ML should be up to 3000 mg/kg.	Discontinue. (For all subcategories no tech justification has been provided)

#### Food Category No. 14.2.1 Beer and malt beverages

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	10		7	Emulsifier, Humectant	2nd Circular Proposal: Adopt  EU, RU: Was technological need provided? Why we need emulsifiers in beer?	Do not move from FC 14.2
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	500		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  EU, RU: does see the rational for adoption. Was technological need provided? Why we need emulsifiers in beer?	Discontinue – no tech justification provided

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						FoodDrinkEurope: Supports proposal	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000		7	Emulsifier	2nd Circular Proposal: Adopt  EU, RU: does see the rational for adoption. Was technological need provided? Why we need emulsifiers in beer?  FoodDrinkEurope: Supports proposal	Discontinue – no tech justification provided
PROPYLENE GLYCOL	1520	50000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 3000 mg/kg  EU, RU: Was technological need provided? Why we need emulsifiers in beer?	Do not move from FC 14.2
PROPYLENE GLYCOL ALGINATE	405	3000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	<ul> <li>2nd Circular Proposal: Adopt</li> <li>China, FoodDrinkEurope, IFAC: Supports adoption</li> <li>EU, RU: has technological justification been provided? Is the ML of 3000 ppm justified?</li> <li>Japan: supports the 2<sup>nd</sup> circular proposal. Propylene glycol alginate is used as stabilizer (foam stabilizer).</li> </ul>	Adopt
TARTRATES	334, 335(ii), 337	2000	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Adopt  EU: has technological justification been provided?  FoodDrinkEurope, Indonesia, RU: Supports adoption	Adopt

## Food Category No. 14.2.2 Cider and perry

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	10			Emulsifier, Humectant	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Do not move from 14.2
ETHYL MALTOL	637	100		7	Flavour enhancer	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Discontinue – no tech justification provided
MALTOL	636	250		7	Flavour enhancer	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Discontinue – no tech justification provided
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Discontinue – no tech justification provided
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000		7	Emulsifier	2nd Circular Proposal: Adopt <u>EU</u> : no technological justification was provided – discontinue	Discontinue – no tech justification provided
PROPYLENE GLYCOL	1520	50000			Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 3000 mg/kg  EU: no technological justification was provided – discontinue	Do not move from 14.2
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) Provisions for INS 473a and 474 are not in this FC, would need to be added.	Discontinue – no tech justification provided. Do not add provisions for INS 473A and 474.
						<u>EU</u> : no technological justification was provided – discontinue	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – related to proposal for INS 473	Discontinue/Do not add provision
SUCROGLYCERIDE S	474	5000			Emulsifier	EU: no technological justification was provided – discontinue  2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))- – related to proposal for INS 473	Discontinue/Do not add provision

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						<b>EU</b> : no technological justification was provided – discontinue	
TARTRATES	334, 335(ii), 337	2000	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue  RU: Supports adoption	Adopt

#### Food Category No. 14.2.3 Grape wines

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	This food category and its subcategories are not within the mandate of working group.
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#### Food Category No. 14.2.4 Wines (other than grape)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	10			Emulsifier, Humectant	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Do not move from FC 14.2
ETHYL MALTOL	637	100		7	Flavour enhancer	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Discontinue- no tech justification provided
MALTOL	636	250		7	Flavour enhancer	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Discontinue- no tech justification provided
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	500		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Discontinue- no tech justification provided
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000		7	Emulsifier	2nd Circular Proposal: Adopt <u>EU</u> : no technological justification was provided – discontinue	Discontinue- no tech justification provided
PROPYLENE	1520	50000			Emulsifier, Glazing	2nd Circular Proposal: Adopt at 3000 mg/kg	Do not move from FC

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
GLYCOL					agent, Humectant	Ellens technological justification was provided discontinue	14.2
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	EU: no technological justification was provided – discontinue  2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)); Provisions for INS 473a and 474 are not in this FC, would need to be added.	Discontinue- no tech justification provided
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	EU: no technological justification was provided – discontinue  2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – related to proposal for INS 473  EU: no technological justification was provided – discontinue	Discontinue/Do not add provision
SUCROGLYCERIDE S	474	5000			Emulsifier	2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – Related to proposal for INS 473  EU: no technological justification was provided – discontinue	Discontinue/Do not add provision
TARTRATES	334, 335(ii), 337	GMP	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Request information on numerical use levels – not a Table 3 additive  Chile: Supports request for numerical use level  EU: no technological justification was provided – discontinue  Japan: L-Tartaric acid is used up to 6,600 mg/kg as acidity regulator.  RU: Supports adoption	Adopt at 6,600 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	500		7	Emulsifier, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt</li> <li>EU: no technological justification was provided – discontinue</li> <li>RU: Does not support proposal, use of food additives in this FC could mislead consumers. It is adulteration</li> </ul>	Discontinue – no tech justification provided
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)); Provisions for INS 473a and 474 are not in this FC, would need to be added.</li> <li>EU: no technological justification was provided – discontinue</li> <li>RU: Does not support proposal, use of food additives in this FC could mislead consumers. It is adulteration</li> </ul>	Discontinue – no tech justification provided
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	5000			Emulsifier, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – related to proposal for INS 473</li> <li>EU: no technological justification was provided – discontinue</li> <li>RU: Does not support proposal, use of food additives in this FC could mislead consumers. It is adulteration</li> </ul>	Discontinue/do not add provision
SUCROGLYCERIDE S	474	5000			Emulsifier	<ul> <li>2nd Circular Proposal: Adopt;</li> <li>with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – related to proposal for INS 473</li> <li>EU: no technological justification was provided – discontinue</li> <li>RU: Does not support proposal, use of food additives in this FC</li> </ul>	Discontinue/do not add provision

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						could mislead consumers. It is adulteration	
DIOCTYL SODIUM SULFOSUCCINATE	480	10		7	Emulsifier, Humectant	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Do not move from FC 14.2
PROPYLENE GLYCOL	1520	50000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 3000 mg/kg  EU: no technological justification was provided – discontinue	Do not move from FC 14.2
TARTRATES	334, 335(ii), 337	GMP	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Request information on numerical use levels – not a Table 3 additive  EU: no technological justification was provided – discontinue  Chile: Supports request for tech just and ML  RU: Does not support proposal, use of food additives in this FC could mislead consumers. It is adulteration	Discontinue – no tech justification provided

### Food Category No. 14.2.6 Distilled spirituous beverages containing more than 15% alcohol

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	10			Emulsifier, Humectant	2nd Circular Proposal: Adopt  EU: no technological justification was provided – discontinue	Do not move from FC 14.2
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt</li> <li>EU: has the technological justification been provided? Aware of the need only for emulsified liqueurs</li> </ul>	Discontinue – no tech justification provided
PROPYLENE GLYCOL	1520	50000			Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 3000 mg/kg  EU: no technological justification was provided – discontinue	Do not move from FC 14.2
PROPYLENE GLYCOL ALGINATE	405	10000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	<ul><li>2nd Circular Proposal: Adopt</li><li>EU: has the technological justification been provided? Aware of the need only for emulsified liqueurs</li></ul>	Discontinue – no tech justification provided

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						IFAC: Supports adoption	
STEAROYL LACTYLATES	481(i), 482(i)	8000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt  EU: Aware of the need only for emulsified liqueurs  IFAC: Supports adoption	Discontinue – no tech justification provided
SUCROSE ESTERS OF FATTY ACIDS	473	5000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt  EU: Not justified in whisky	Adopt with New Note "not for use in Whisky"
TARTRATES	334, 335(ii), 337	3000	45	7	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Adopt  EU: Not justified in whisky	Adopt with New Note "not for use in Whisky"

# <u>Food Category No.</u> 14.2.7 Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low alcoholic refreshers) Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
DIMETHYL DICARBONATE	242	250	18	2	Preservative	2nd Circular Proposal: Adopt  EU: has the technological need been provided?	Discontinue, no tech justification provided
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt</li> <li>EU: has the technological need been provided?</li> <li>Japan: supports the 2nd circular proposal. Polyglycerol esters of fatty acids are used as emulsifier.</li> </ul>	Adopt
STEAROYL LACTYLATES	481(i), 482(i)	8000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt  EU: has the technological need been provided?  IFAC: Supports adoption	Discontinue, no tech justification provided
DIOCTYL SODIUM SULFOSUCCINATE	480	10		7	Emulsifier, Humectant	2nd Circular Proposal: Adopt  EU: has the technological need been provided?	Do not move from FC 14.2

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PROPYLENE					Emulaifier Clazing	2nd Circular Proposal: Adopt	Do not move from FC 14.2
GLYCOL	1520	50000		7	Emulsifier, Glazing agent, Humectant	EU: has the technological need been provided?	14.2
						2nd Circular Proposal: Adopt	Adopt at 4,000 mg/kg
						Ellipse the technological peed been provided?	
	334,				Acidity regulator,	EU: has the technological need been provided?	
TARTRATES	335(ii),	3000	45	7	Antioxidant, Flavour	Indonesia: supports adoption	
	337				enhancer, Sequestrant	Japan, proposes maximum use level he changed to 4,000	
						Japan: proposes maximum use level be changed to 4,000 mg/kg.	
						L-Tartrate is used up to 4,000mg/kg as acidity regulator.	
						2nd Circular Proposal: Adopt	Adopt
T0000UED010	307a, b,	4.50		_		EU: has the technological need been provided?	
TOCOPHEROLS	C C	150		/	Antioxidant		
						Japan: supports the 2 <sup>nd</sup> circular proposal. Tocopherols are	
						used as antioxidant.	

## <u>Food Category No.</u> 15.0 Ready-to-eat savouries

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000		7	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt      EU: ML quite high; 20kg child reaches the ADI by eating 50g. What is specific with the emulsifier that it cannot be addressed by Table 3 additives?      FoodDrinkEurope: Supports proposal      ICGMA: Supports adoption. Emulsifiers and stabilizers like polyglycerol esters of fatty acids are used to improve interaction with starch granules in the doughs used to produce savory	Discuss use in subcategories

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						snacks. They improve dough performance through cooking and allows the snack to retain a desired level of moisture through transportation and storage which contributes to softness of the snack.  Japan: Polyglycerol esters of fatty acids are used in fabricated potato chips, fallen within FC 15.1, to give crispness. The maximum use level is 1000 mg/kg.  Japan suggests that this draft provision be moved to FC 15.1 unless any other products covered by other subcategories are specified.	
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000		7	Emulsifier	2nd Circular Proposal: Adopt  EU: What is specific with the emulsifier that it cannot be addressed by Table 3 additives?  FoodDrinkEurope: Supports proposal  ICGMA: Supports adoption. Polyglycerol esters of interesterified ricnoleic acid are used to improve interaction with starch granules in the doughs used to produce savory snacks. They improve dough performance through cooking and allows the snack to retain a desired level of moisture through transportation and storage which contributes to softness of the snack	Discuss use in subcategories
TARTRATES	334, 335(ii), 337	2000	45	4	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	2nd Circular Proposal: Adopt  EU: Could accept if tech just has been provided  FoodDrinkEurope, Indonesia: Supports proposal  ICGMA: Supports adoption. Tartrates help to adjust the acidity of certain savory snacks while preventing oxidation that can impact taste and quality.	Adopt

Food Category No. 15.1 Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000			Emulsifier, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt</li> <li>EU: ML quite high; 20kg child reaches the ADI by eating 50g. What is specific with the emulsifier that it cannot be addressed by Table 3 additives?</li> <li>FoodDrinkEurope: Supports proposal</li> <li>ICGMA: Supports adoption. Emulsifiers and stabilizers like polyglycerol esters of fatty acids are used to improve interaction with starch granules in the doughs used to produce savory snacks. They improve dough performance through cooking and allows the snack to retain a desired level of moisture through transportation and storage which contributes to softness of the snack.</li> <li>Japan: Polyglycerol esters of fatty acids are used in fabricated potato chips, fallen within FC 15.1, to give crispness. The maximum use level is 1000 mg/kg.</li> <li>Japan suggests that this draft provision be moved to FC 15.1 unless any other products covered by other subcategories are specified.</li> </ul>	Adopt at 1000 mg/kg
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000			Emulsifier	2nd Circular Proposal: Adopt  EU: What is specific with the emulsifier that it cannot be addressed by Table 3 additives?  FoodDrinkEurope: Supports proposal  ICGMA: Supports adoption. Polyglycerol esters of interesterified ricnoleic acid are used to improve interaction with starch granules in the doughs used to produce savory snacks. They improve dough performance through cooking and allows the snack to retain a desired level of moisture through transportation and storage which contributes to softness of the snack	Adopt
PROPYLENE GLYCOL	1520	300		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt  EU: Questions tech need, if use as SFA	Adopt

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Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
PROPYLENE GLYCOL ALGINATE	405	3000		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Stabilizer, Thickener	FoodDrinkEurope, IFAC: Supports adoption  ICGMA: Supports adoption. Propylene glycol provides a humectant and emulsifying function in the production of potato or cereal dough used to make extruded chips and other savory snacks. This improves dough performance through cooking and allows the snack to retain a desired level of moisture through transportation and storage.  2nd Circular Proposal: Adopt  EU: Questions tech need. Aware of need only for cereal and potato-based snacks  FoodDrinkEurope: Supports proposal  ICGMA: Supports adoption. Propylene glycol alginate helps to emulsify dough and interact with starch granules. This provides results in a desirable and consistent product with a softer	Adopt
SODIUM DIACETATE	262(ii)	500		7	Acidity regulator, Preservative, Sequestrant	texture.  2nd Circular Proposal: Adopt  China: Allows in this FC at 1000  EU: Could accept if tech just has been provided  FoodDrinkEurope: Supports proposal  ICGMA: supports adoption. Sodium diacetate helps preserve snack foods throughout their shelf life by inhibiting microbial growth.	Adopt at 1000 mg/kg
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000		4	Emulsifier, Stabilizer	2nd Circular Proposal: Adopt  EU: Questions if tech just has been provided. Not aware of need  FoodDrinkEurope, IFAC: Supports adoption  ICGMA: supports adoption. Sorbitan esters of fatty acids helps	Adopt at 300 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						to emulsify dough and interact with starch granules. This provides results in a desirable and consistent product with a softer texture.  Japan: supports 2 <sup>nd</sup> circular proposal. Sorbitan esters of fatty acids are used to prevent retrogradation in potato snacks from potato dough. Maximum use level is 300 mg/kg.	
STEAROYL LACTYLATES	481(i), 482(i)	5000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	2nd Circular Proposal: Adopt     EU: Questions if tech just has been provided. Not aware of need     FoodDrinkEurope, IFAC: Supports adoption     ICGMA: supports adoption. Stearoyl lactylates form bonds with gluten to improve dough strength for certain cereal based savory snacks that are baked.	Adopt
SUCROSE ESTERS OF FATTY ACIDS	473	10000		7	Emulsifier, Foaming agent, Glazing agent, Stabilizer	<ul> <li>2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))</li> <li>EU: exposure concerns – ML quite high; 20kg child ADI reached by consuming 60g. There are no alternatives? Use should be restricted</li> <li>FoodDrinkEurope: Supports proposal</li> <li>ICGMA: supports adoption. Sucrose esters of fatty acids helps to emulsify dough and interact with starch granules. This provides results in a desirable and consistent product with a softer texture</li> <li>Japan: supports 2<sup>nd</sup> circular proposal.</li> <li>Sucrose esters of fatty acids are used in rice crackers (senbei) and potato snacks from potato dough to prevent cracking and</li> </ul>	Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						give crispness. Maximum use level is 10000 mg/kg.	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	10000			Emulsifier, Glazing agent, Stabilizer	2nd Circular Proposal: Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – related to proposal for INS 473  EU: exposure concerns – ML quite high; 20kg child ADI reached by consuming 60g. There are no alternatives? Use should be restricted  FoodDrinkEurope: Supports proposal  ICGMA: supports adoption. Sucrose oligoesters helps to emulsify dough and interact with starch granules. This provides results in a desirable and consistent product with a softer texture.	Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))
SUCROGLYCERIDES	474	10000			Emulsifier	2nd Circular Proposal: Adopt     with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474)) – related to proposal for INS 473      EU: exposure concerns – ML quite high; 20kg child ADI reached by consuming 60g. There are no alternatives? Use should be restricted      FoodDrinkEurope: Supports proposal      ICGMA: supports adoption. Sucroglyceride helps to emulsify dough and interact with starch granules. This provides results in a desirable and consistent product with a softer texture.	Adopt; with Note 348 (Singly or in combination: sorbitan esters of fatty acids (INS 473), sucrose oligoesters, typel and type II (INS 473a) and sucroglycerides (INS 474))
TOCOPHEROLS	307a, b,	200		7	Antioxidant	2nd Circular Proposal: Adopt  EU: Could accept if tech just has been provided	Adopt at 200 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
						China, RU: Supports adoption  FoodDrinkEurope, ICGMA: Supports proposal; Tocopherols prevent oxidation of certain savory snacks to prevent development of undesirable flavors or textures.  Japan: supports 2 <sup>nd</sup> circular proposal. used in potato chips (crisps) and potato products from potato dough to prevent oxidation during their shelf life.  Japan would like to correct the maximum use level of 150 mg/kg commented in the 1 <sup>st</sup> circular to 100 mg/kg.	

#### Food Category No. 15.2 Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruit)

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000			Emulsifier, Stabilizer	See discussion in FC 15.0	Discuss use in this subcategory
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000			Emulsifier	See discussion in FC 15.0	Discuss use in this subcategory
PROPYLENE GLYCOL	1520	50000		7	Emulsifier, Glazing agent, Humectant	2nd Circular Proposal: Adopt at 5000 mg/kg  EU: could the technological need be explained?  FoodDrinkEurope: Supports proposal  RU: Does not support proposal. ML should be up to 3000 mg/kg  USA: Allowed in nuts and nut products at a ML of 5%	Adopt at 5000 mg/kg

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
TOCOPHEROLS	307a, b,	1500		7	Antioxidant	2nd Circular Proposal: Adopt at 200 mg/kg  EU, RU: Supports proposal for ML up to 200 mg/kg  Japan: supports 2 <sup>nd</sup> circular proposal. used in sugar coated almond to prevent oxidation during its shelf life.	Adopt at 200 mg/kg

Food Category No. 15.3 Snacks - fish based

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	2nd Circular Proposal/EWG Comments	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	10000			Emulsifier, Stabilizer	See discussion in FC 15.0	Discuss use in this subcategory
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	1000			Emulsifier	See discussion in FC 15.0	Discuss use in this subcategory

Food Category No. 16.0 Prepared foods

Additive	_	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	There are no provisions under discussion in this Food Category; included for information purposes only
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#### **EWG General Comments**

#### **EU general comments:**

The EU welcomes and appreciates the approach that in determining the initial recommendations priority was given to alignment with corresponding Codex commodity standards and the decision of the physical working groups (p-WGs) to the 45th and 46th CCFA as to the justification of emulsifiers, stabilizer, thickeners, or acidity regulators in specific food categories.

However, the horizontal approach for EST and acidity regulators was developed and applied to Table 3 additives, i.e. additives of very low toxicity for which the exposure should not represent a hazard to health. In the EU's view "the horizontal justification" cannot be extrapolated to the additives with the numerical ADIs and the technological justification for each additive with the numerical ADI shall be required to see whether there is a need and advantage when comparing to Table 3 additives. The EU believes that it is an important consideration taking into account that some food additives are proposed for inclusion in numerous food categories (e.g. INS 473, 474, 475, 476, 481-482, 491-495), there are already many adopted provisions for these additives in the GSFA and there might be a concern from the overall exposure.

The EU appreciates further discussion on the food additive provisions. The EU draws the attention that certain substances under discussion have very low ADIs, therefore, the uses and use levels need to be carefully considered (e.g. INS 476 ADI = 7,5 mg/kg bw/d; INS 480 ADI = 0,1 mg/kg bw/d; INS 520 PTWI = 2 mg/kg bw/w; INS 636 ADI = 1 mg/kg bw/d and INS 637 ADI = 2 mg/kg bw/d).

In addition, there are many provisions for other food additives which might lead to the exposure concerns when the overall exposure is taken into account. The EU would like to inform other EWG members about its exposure concerns as regards INS 473-474 and INS 481-482. The EFSA opinions indicate the ADIs being exceeded based on more restrictive number of provisions than currently under the discussion. See

INS 473-474: <a href="http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2658/epdf">http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2658/epdf</a> INS 481-482: <a href="http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3144/epdf">http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3144/epdf</a>

#### Israel general comments:

Israel supports the IFU position and opposes the proposal to add emulsifiers, stabilizers, thickeners such as xanthan gum, gellan gum and cellulose gum or other foreign substances to any type of fresh natural fruit and vegetable juices, other than those naturally present in the fruit itself.

We do not see a technical need to allow these additives in juices. This standpoint represents the position of Israel's manufacturers and has been ascertained by Israel's Codex Alimentarius Contact Point as representing the consensus of the country's juice manufacturers.

The technical regulations and standards governing the manufacture and processing of fruit juices in Israel determine that it is forbidden to add food additives, appearance improvers or any type of thickeners to pure fruit juice.

#### ICGMA, IFAC general comments:

Support for adoption of nisin in this food category. To provide additional technological justification, egg proteins are heat sensitive; egg whites in particular are unstable at the temperature range essential for effective pasteurization. Nisin provides an effective control regime for bacteria that may

In recognition of the impact of heat on the functionally and nutritional properties of liquid egg products, most countries have limited mandatory heat pasteurization regimes to primarily target elimination of microbial pathogen. While these conditions can kill 99% of the bacteria present, studies examining the cause of spoilage in commercial liquid egg products found that non-pathogenic thermophiles and endospores of spore formers such as Bacillus cereus may survive the heat treatment. Many of these surviving bacteria are capable of growth at refrigeration temperatures.

The shelf life of pasteurized liquid egg products typically varies from 10 - 11 days, depending on the initial load, the pasteurization regime, and the storage conditions. Studies show that the use of nisin preparation can help prevent/reduce outgrowth of spoilage bacteria, thereby extending the shelf life of liquid egg products and reducing food waste due to spoilage.

We also wish to note the October 2006 adopted Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on the safety in use of nisin as a food additive in an additional category of liquid eggs and on the safety of nisin produced using a modified production process as a food additive (EFSA Journal (2006) 314b, 1-8, available: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2006.314b/epdf) which permits the use of nisin in liquid egg products and includes a section "Case of need." This section supports the above noted technological justification and states the following:

According to the present EU legislation requirements, the liquid whole egg is pasteurised at temperatures of not lower than 64.4 0C for at least 2.5 minutes. The heat process guarantees an approximate 99% killing of the bacteria present in the raw liquid whole egg. Surviving bacteria may include both Gram-negative and Gram-positive species and are capable of growth even at refrigeration temperatures. The variable shelf life of pasteurised liquid egg products (10-11 days), which depends on the initial load, the pasteurization, and the storage conditions can be increased by the use of nisin. Bacillus cereus, which also is a common contaminant of liquid whole egg is not controlled by other preservatives such as sorbate and benzoate. The petitioner has provided data that demonstrate the efficacy of nisin in preserving liquid eggs.

We believe this additional information should address questions about technological need in pasteurized products and support earlier technological justification provided by ICGMA and others

## Appendix 6: Proposed draft provisions related to FC 01.1.2 (Other fluid milks (plain)) with the exception of food additives provisions with the function of colour and sweetener

- Among several topics, CCFA49 requested the EWG on the GSFA to CCFA50 to discuss:
- Draft provisions for food additives related to FC 01.1.2

#### **Background**

- 2. CCFA48 revised the structure, title and descriptor of food category 01.1 (*Fluid milk and milk products*) and its subcategories. CCFA48 also considered that the scope of the revised food category 01.1 and its subcategories 01.1.1 (*Fluid milk (plain)*), 01.1.3 (*Fluid buttermilk (plain)*), and 01.1.4 (*Flavoured fluid milk drinks*) had not substantially changed from the scope of the corresponding historical food categories, and therefore determined that it was not necessary to revoke and/or discontinue the provisions in the historical food categories, but rather to place those provisions in the corresponding revised food categories.<sup>2</sup> However, CCFA48 also noted that there are no provisions for the use of food additives in the new food category 01.1.2 (*Other fluid milks (plain)*) as the scope of the new food category did not correspond to the scope of a historical food category. Therefore, CCFA48 requested that proposals for inclusion of food additive provisions in the new food category 01.1.2 be submitted in response to the circular letter requesting proposals for new and/or revision of adopted food additive provisions.<sup>3</sup>
- 3. The circular letter requesting proposals for new and/or revision of adopted food additive provisions issued in advance of CCFA49 included a specific request for proposals for food additive provisions in the new food category 01.1.2.4 Responses to the circular letter were compiled for CCFA49<sup>5</sup> and discussed by the physical working group (PWG) on the GSFA to CCFA49.6 If multiple proposals for provisions in the same food category were submitted for the same food additive, the PWG only discussed the proposal with the higher use level. The PWG recommended that specific provisions proposed for food category 01.1.2 be included in the GSFA at Step 2.7
- 4. CCFA49 agreed to the recommendation of the PWG to include the specific provisions proposed for food category 01.1.2 in the GSFA at Step 2. CCFA49 also requested that the EWG on the GSFA to CCFA50 consider the proposed draft provisions in food category 01.1.2 (with the exception of those provisions for food additives with the function of colour or sweetener)<sup>8</sup> and prepare recommendations for those provisions.<sup>9</sup>

#### **Working Document**

5. The EWG issued two circulars for comment. The provisions under discussion are presented in the format of food category 01.1.2 in Table 2 of the GSFA. This document presents proposals (adopt, adopt with revision) for the provisions under discussion based upon a consensus approach taking into account comments on the first and second circulars by members of the EWG. These recommendations are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification.

<sup>&</sup>lt;sup>1</sup> REP 17/FA, para. 109.

<sup>&</sup>lt;sup>2</sup> REP 16/FA, paras 78-86.

<sup>&</sup>lt;sup>3</sup> Rep 16/FA, para. 86.

<sup>&</sup>lt;sup>4</sup> CL 2016/8-FA

<sup>&</sup>lt;sup>5</sup> CX/FA 17/49/9, FA49 CRD 12, FA49 CRD19.

<sup>&</sup>lt;sup>6</sup> FA/49 CRD2

<sup>&</sup>lt;sup>7</sup> FA/49 CRD2 Annex 5.

<sup>&</sup>lt;sup>8</sup> FA/49 CRD2 Annex 5 contained a provision for the use of lutein esters from Tagetes erecta (INS 161b(iii)) in food category 01.1.2. Since this food additive has the technological function of "colour" the provision for INS 161b(iii) is not included in this working document.

<sup>&</sup>lt;sup>9</sup> REP 17/FA paras 88 and 109.

## Food Category No. 01.1.2 (Other fluid milks (plain)):

**Descriptor:** Includes all plain fluid milk, excluding products of food categories 01.1.1 Fluid milk (plain), 01.1.3 Fluid buttermilk (plain), and 01.2 Fermented and renneted milk products (plain). Includes, but is not limited to, plain recombined fluid milks, plain reconstituted fluid milks, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks, lactose reduced milk, and plain milk-based beverages. In this food category, plain products contain no added flavouring nor other ingredients that intentionally impart flavour, but may contain other non-dairy ingredients.

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
ACETIC AND FATTY ACID ESTERS OF GLYCEROL	472a	GMP	Emulsifier, Sequestrant, Stabilizer	Use in non- flavoured vitamin and mineral fortified fluid milks only	Initial country comment:  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks  Comments to EWG:  EFEMA: Emulsifiers help to form stable emulsions even in technologically challenging emulsions (i.e. fortified formula). This improves the mouthfeel (sensory/texture) and shelf life (prevents sedimentation) of the milk.  EU: is the need related to fortification? Could be the technological effect described? See 2 <sup>nd</sup> Circular General Comment below  FoodDrinkEurope: Supports this additive at GMP and for the mentioned functional classes  Japan: Supports the proposal with the proposed note. Acetic and fatty acid esters of glycerol are used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.  Chile: Supports adoption	Adopt as listed
ASCORBIC ACID, L-	300	GMP	Antioxidant		Initial country comment:  Thailand: Used as antioxidant in milk products such as recombined milk, reconstituted milk and vitamin and mineral fortified milk. It helps to prevent oxidation of fat and vitamins and maintain products quality throughout shelf life. It is used to keep quality and enhance stability of milk products. Its use does not change the nature of products and disguise the effects of the use of faulty raw materials which could mislead consumer.  China: Using in fluid milk, to keep quality in shelf life, and to protect product from developing a rancid off taste and/or off-flavor.  Comments to EWG:  Brazil: See General Comment	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					<u>EU</u> : could it be explained why the natural antioxidants of milk (e.g. tocopherols, beta-carotne, phospholipids) are not sufficient? There is no effect of the use ascorbic acid on the sensory properties of milk (taste)? Only needed in vitamin and mineral fortified milk? See 2 <sup>nd</sup> Circular General Comment below	
					<u>FoodDrinkEurope</u> : Supports this additive at GMP and for the mentioned functional classes.	
CAROB BEAN GUM	410	GMP	Emulsifier, Stabilizer, Thickener		Initial country comment:  Thailand: Used to stabilize colloidal suspension and prevent sedimentation of solid particles in milk (e.g. milk protein and fortified minerals) during storage period. Moreover, it also helps to improve the viscosity of product as per consumer preferences. Carob bean gum is usually used in combination with other EST at an optimized ratio. It is not used to disguise the effects of the use of faulty raw materials.  Comments to EWG:  Brazil: See General Comment below  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below  EU Specialty Food Ingredients: Support adoption. For use in UHT treated or sterilized, recombined and reconstituted milk as a stabilizer. Gelation of UHT milk during storage is a major factor limiting its shelf life. The gel which forms, is a matrix of aggregated protein complexes. Protein complexes are formed because of changes in the protein structure caused by the UHT treatment. Carob bean gum stabilize these protein complexes, so that matrix formation is delayed and consequently shelf life of the milk is extended.  FoodDrinkEurope: Supports this additive at GMP and for the mentioned functional classes.  ICGMA, IFAC: Supports listing this provision with FC 01.1.2 given the rationale provided by Thailand. Carob bean gum is used in UHT treated or sterilized, recombined and reconstituted milk as a stabilizer. Gelatin of UHT milk during storage is a major factor limiting shelf life. The gel which	Adopt as listed

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					forms is a matrix of aggregated protein complexes. Protein complexes are formed because of changes in the protein structure caused by the UHT treatment. Carob bean gum stabilizes these protein complexes so that the matrix formation is delayed and consequently, the shelf life is extended.	
					Chile: Supports adoption	
					<u>EU Specialty Foods, ICGMA, IFAC:</u> supports the 2 <sup>nd</sup> circular proposal. Generally, Carob bean gum would be used in combination with other emulsifiers, stabilizers, and thickeners in recombined and reconstituted UHT milk. Other EST (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Carob bean gum provides stabilization of proteins during processing and storage. Also, carob bean gum compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk.	
					South Africa: Supports adoption.  For use in UHT treated or sterilized, recombined and reconstituted milk as a stabilizer. Gelation of UHT milk during storage is a major factor limiting its shelf life. The gel which forms, is a matrix of aggregated protein complexes. Protein complexes are formed because of changes in the protein structure caused by the UHT treatment. Carob bean gum stabilize these protein complexes, so that matrix formation is delayed and consequently shelf life of the milk is extended	
CARRAGEENAN	407	GMP	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener		Initial country comment:  Thailand: Added to aid the suspension of solid particles in milk products, prevent water-fat separation and protein sedimentation, especially in recombined milk and vitamin and mineral fortified formula. In milk system, carrageenan has the property of reacting with proteins which can increase the stability of products. Moreover, it also helps to improve the viscosity of product as per consumer preferences. Carrageenan is used usually in combination with other EST at an optimized ratio.  China: To stabilize the fluid milk products, creating a thixotropic network together with dairy proteins, which can keep solids suspended, I.e. vitamin-mineral complexes in fortified milk products.  Japan: Used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.	Adopt as listed

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Comments to EWC:  Brazil: See General Comment below  Chille: Helps to maintain the stability of the product over time after having undergone UHT thermal processing, and help maintain cocoa suspensions (chocolate milk), vitamin and mineral mixtures. In some cases, its helps to maintain the suspensions of colorants and flavorings.  Columbia: As a stabilizer for unit milk-based drinks with BPM doses. As a stabilizer in milk-based beverages; Retains water and prevents phase separation, and may increase viscosity depending on the dose, has a technological function similar to that performed in the categories o1.2.1.1 Fermented milk (natural / simple) without heat treatment after fermentation and o1.2.1.2 Fermented (natural / simple) milks heat-treated after fermentation and o1.2.1.2 Fermented (natural / simple) milks heat-treated after fermentation on the unservice of milk. See 2 <sup>nd</sup> Circular General Comment below.  EU Specialty Food Ingredients, FoodDrinkEurope: Support adoption. Agree with tech. justifications  ICGMA: supports depotion. Carrageenan has a unique functionality as a stabilizer and thickener in dairy products given its interaction with casein. It is commonly used to suspend vitamins and minerals in fortified milks.  IFAC: Supports the listing of this provision with FC 01.1.2 given the rationale provided by Thailand, China and Japan  Japan: Supports the proposal. Carrageenan is used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.  NZ: Supports use at GMP.  Carrageenan is added to suspend particles in fluid milk to prevent sedimentation. Carrageenan is acted to suspend particles in fluid milk to prevent sedimentation. Carrageenan is acted to suspend. Carrageenan can be used in combination with other stabilizers to improve the stability during shelf life. Carrageenan can be used to improve the viscosity to improve
life Carrageenan can be used to improve the viscosity to improve

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					Chile: Supports adoption  EU Specialty Foods, ICGMA, IFAC: supports the 2 <sup>nd</sup> circular proposal. In response to the general comments from the EU and Brazil on the use of stabilizers in this food category, would like to provide the following clarification:  Carrageenan would be used in combination with other emulsifiers, stabilizers, and thickeners in recombined and reconstituted UHT milk. Other emulsifiers, stabilizers, and thickeners (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Carrageenan provides stabilization of proteins during processing and storage. Also, carrageenan compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk  South Africa: Supports adoption  Initial country comment:	
CITRIC ACID	330	GMP	Acidity regulator, Antioxidant, Colour retention agent, Sequestrant	For use in non- flavoured mineral fortified fluid milks only	Japan: Used to adjust pH to prevent degradation of protein in non-flavoured iron fortified fluid milks.  EWG Comments: EU: needed only for iron fortified fluid milks? Why?  Japan: Supports the proposal with the proposed note.  Chile, FoodDrinkEurope: support adoption as listed	Adopt as listed
CITRIC AND FATTY ACID ESTERS OF GLYCEROL	472c	GMP	Antioxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer	Use in non- flavoured vitamin and mineral fortified fluid milks only	Initial country comment:  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  EWG comments:  EFEMA: Emulsifiers help to form stable emulsions even in technologically challenging emulsions (i.e. fortified formula). This improves the mouthfeel (sensory/texture) and shelf life (prevents sedimentation) of the milk.  EU: is the need related to fortification? Could be the technological need more elaborated? See 2 <sup>nd</sup> Circular General Comment below  Food Drink Europe: Supports this additive at GMP and for the mentioned functional classes.	Adopt as listed

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
DIACETYLTARTARI C AND FATTY ACID ESTERS OF GLYCEROL	<b>INS</b> 472e	Level	Functional	Use in non-flavoured vitamin and mineral fortified fluid milks only	Initial country comment/eWG comments  Japan: Supports the proposal with the proposed note.  Chile: Supports adoption  Initial country comment:  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  EWG Comments:  EFEMA: Support adoption. For use in recombined and reconstituted milk as stabilizer. Due to the anionic properties of diacetyltartaric and fatty acid esters of glycerol, the additive will stabilize and prevent protein aggregation during heat treatment. Preventing protein aggregation helps to stabilize the product during shelf life and to avoid precipitation. Furthermore, emulsifiers help to form stable emulsions even in technologically challenging emulsions (i.e. fortified formula). This improves the mouthfeel (sensory/texture) and shelf life (prevents sedimentation) of the milk.  EU: is the need related to fortification? Could be the technological need more elaborated? See 2 <sup>nd</sup> Circular General Comment below  ICGMA, IFAC: Supports adoption. When used in recombined and reconstituted milk as stabilizer, the additive will stabilize and prevent protein aggregation during heat treatment due to the anionic properties of diacetyltartaric and fatty acid esters of glycerol. Preventing protein aggregation helps to stabilize the product during shelf life and to avoid precipitation which is undesirable for consumers.  Japan: Supports the proposal with the proposed note.  FoodDrinkEurope: supports adoption as listed and Note  ICGMA: Supports 2 <sup>nd</sup> circular proposal	eWG proposal  Adopt as listed
					South Africa: Supports adoption For use in recombined and reconstituted milk as stabilizer. Due to the anionic properties of diacetyltartaric and fatty acid esters of glycerol, the additive will stabilize and prevent protein aggregation during heat treatment. Preventing protein aggregation helps to stabilize the product during shelf life and to avoid precipitation.	

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
GELLAN GUM	418	GMP	Thickener, Stabilizer		Initial country comment:  Thailand: Used to enhance the stability of fluid milks, especially in recombined milk, reconstituted milk and vitamin and mineral fortified formula. It helps to stabilize colloidal suspension and prevent sedimentation of solid particles in milk (e.g. milk protein and fortified minerals) during storage period. It also helps to improve the viscosity of product as per consumer preferences and enhance the organoleptic properties. Gellan gum is usually used in combination with other EST at an optimized ratio.  China: To stabilize and prevent protein aggregation, fouling in UHT heat exchanger. When used in non-flavored vitamin and mineral fortified fluid milk, gellan could provide excellent suspension of insoluble particles without adding excessive mouthfeel viscosity or impacting flavor.  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  EWG comments:  Brazil: See General Comment  Columbia: As a stabilizer for use in milk based drinks by BPM.  As a stabilizer in milk-based beverages; Retains water and prevents phase separation, and may increase viscosity depending on the dose, has a technological function similar to that performed in the categories o1.2.1.1 Fermented milk (natural / simple) without heat treatment after fermentation and 01.2.1.2 Fermented (natural / simple) milks heat-treated after fermentation  FoodDrinkEurope: Supports this additive at GMP and for the mentioned functional classes  ICGMA, IFAC: Supports adoption. Gellan Gum stabilizes through a number of functionalities, I.e. by giving steric stabilization through interaction with proteins; by increasing viscosity of the continuous phase and thereby reducing creaming rates, and finally by increasing protein load in the fat globule membranes and thereby reducing risk of coalescence in the fat phase. Gellan Gum is furthermore able to create a thixotropic network together with dairy proteins, which can keep solids suspended, I.e. vitamin-mineral complexes in fortified products.	Adopt as listed

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
		(mg/kg)	Class		Japan: Supports the proposal. Gellan gum is used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  NZ: Supports the use at GMP. Gellan gum is added to suspend particles in fluid milk to prevent sedimentation. Interacts with the milk proteins and thus form a network that keeps the particles suspended. Can be used in combination with other stabilizers to improve the stability during shelf life. Can be used to improve the viscosity to improve mouthfeel.  Chile: Supports adoption  EU: See 2 <sup>nd</sup> Circular General Comment below  EU Specialty Foods, ICGMA, IFAC: supports the 2 <sup>nd</sup> circular proposal. In response to EU and Brazil, the following clarification is provided: Gellan gum would be used in combination with other emulsifiers, stabilizers, and thickeners in recombined and reconstituted UHT milk. Other emulsifiers, stabilizers, and thickeners (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Gellan gum provides stabilization of proteins during processing and storage. Also, gellan gum compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk.  South Africa: Supports adoption	
					Gellan Gum can stabilize o/w emulsions through a number of functionalities, I.e. by giving steric stabilization through interaction with proteins; by increasing viscosity of the continuous phase and thereby reducing creaming rates, and finally by increasing protein load in the fat globule membranes and thereby reducing risk of coalescence in the fat phase. Gellan Gum is furthermore able to create a thixotropic network together with dairy proteins, which can keep solids suspended, I.e. vitamin-mineral complexes in fortified products.	
GUAR GUM	412	GMP	Emulsifier, Stabilizer, Thickener		Initial country comment:  Thailand: Used to stabilize colloidal suspension and prevent sedimentation of solid particles in milk (e.g. milk protein and fortified minerals) during storage period. Moreover, it helps to improve the viscosity of product as per consumer preferences. It also contributes to the organoleptic property by improving mouthfeel. Guar gum is usually used in combination with other EST at an optimized ratio.	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					EWG comments:  Brazil: See General Comment  Columbia: As a stabilizer for use in milk-based drinks with BPM.	
					As a stabilizer in milk-based beverages; Retains water and prevents phase separation, and can increase viscosity depending on the dose, has a technological function similar to that performed in the categories 01.2.1.1 Fermented milk (natural / simple) without heat treatment after fermentation and 01.2 .1.2 Fermented (natural / simple) milks heat-treated after fermentation	
					<u>EU</u> : concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below	
					<u>EU Specialty Food Ingredients, FoodDrinkEurope</u> : Supports this additive at GMP and for the mentioned functional classes	
					<u>Chile</u> : Supports adoption	
					ICGMA, IFAC: Supports adoption. Information provided by our members is consistent with the technological justification provided by Thailand In response to the general comments from the EU and Brazil: Guar gum would be used in combination with other emulsifiers, stabilizers, and thickeners in recombined and reconstituted UHT milk. Other emulsifiers, stabilizers, and thickeners (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Guar gum provides stabilization of proteins during processing and storage. Also, guar gum compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk.	
					South Africa: Supports adoption	
GUM ARABIC	414	GMP	Bulking agent, Carrier, Emulsifier,	Use in non- flavoured vitamin and mineral	Initial country comment: <u>Japan</u> : Used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.	Adopt as listed
GOW ANADIO	414	GWIF	Glazing agent, Stabilizer, Thickener	fortified fluid milks only	EWG comments: <u>Brazil</u> : See General Comment	Auopi as lisieu
					Columbia: As a stabilizer for use in milk-based drinks with BPM doses.	

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					As a stabilizer in milk-based beverages; Retains water and avoids phase separation, has a technological function similar to that which it performs in categories 01.2.1.1 Fermented (natural / simple) milk without heat treatment after fermentation and 01.2.1.2 Fermented (natural / simple) fermented milks Thermally after fermentation	
					<u>EU</u> : concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below	
					<u>FoodDrinkEurope</u> : Supports this additive at GMP and for the mentioned functional classes	
					<u>IFAC</u> : Supports adoption. Information provided by our members is consistent with the technological justification provided by Japan	
					Japan: Supports the proposal with the proposed note	
					Chile: Supports adoption	
					Initial country comment:  Thailand: It prevents sedimentation of solid particles in milk (e.g. milk protein and fortified minerals) during storage period. Moreover, it helps to enhance the viscosity of product as per consumer preferences. It also contributes to the organoleptic property by improving mouthfeel.	
					EWG Comments: <u>Brazil</u> : See comment above	
HYDROXYPROPYL STARCH	1440	GMP	Emulsifier, Stabilizer, Thickener		Columbia: As a thickener for use in milk-based drinks by BPM. As a stabilizer in milk-based beverages; Retains water and prevents phase separation, and may increase viscosity depending on the dose, has a technological function similar to that performed in the categories 01.2.1.1 Fermented milk (natural / simple) without heat treatment after fermentation and 01.2 .1.2 Fermented (natural / simple) milks heat-treated after fermentation	Adopt as listed
					<u>EU</u> : concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below	
					FoodDrinkEurope: Supports this additive at GMP and for the mentioned functional classes.	

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
LACTIC AND FATTY ACID ESTERS OF GLYCEROL	472b	GMP	Emulsifier, Sequestrant, Stabilizer	Use in non- flavoured vitamin and mineral fortified fluid milks only	Initial country comment:  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  EWG comments:  EFEMA: Emulsifiers help to form stable emulsions even in technologically challenging emulsions (i.e. fortified formula). This improves the mouthfeel (sensory/texture) and shelf life (prevents sedimentation) of the milk.  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below  FoodDrinkEurope: Supports proposal  Japan: Supports the proposal with the proposed note. Lactic and fatty acid esters of glycerol are used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.  Chile: Supports adoption	Adopt as listed
LECITHIN	322(i)	GMP	Antioxidant, Emulsifier		Initial country comment:  Thailand: Added to fluid milk to prevent separation of water and oil phase, especially in recombined milk and reconstituted milk. It also helps to stabilize the colloidal suspension of products and prevents sedimentation of solid particles in milk (e.g. milk protein and fortified minerals) during storage period. In addition, lecithin aids in homogenisation process.  China: Used to create a stable fat globule membrane and improve the heat stability of recombined and reconstituted milk products.  Japan: Used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.  EWG comments: Chile: Helps to maintain the stability of the product over time after having undergone UHT thermal processing, and help maintain cocoa	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					suspensions (chocolate milk), vitamin and mineral mixtures. In some cases, its helps to maintain the suspensions of colorants and flavorings.	
					<u>EU Specialty Food Ingredients. FoodDrinkEurope</u> : Support adoption. Agree with tech. justifications.	
					ICGMA, IFAC: Supports adoption. Information provided by our members is consistent with the technological justification provided by Thailand, China, and Japan.	
					<u>Japan</u> : Supports the proposal. Lecithin is used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.	
					<u>NZ</u> : Supports use at GMP. Lecithin is added to improve fat particle stability. Covers the fat droplets created, for example during homogenization, and prevents them from coalescing again during shelf life and thus cause creaming	
					<u>EU</u> : See 2 <sup>nd</sup> Circular General Comment below	
					Malaysia, South Africa: Support adoption	
MICROCRYSTALLIN E CELLULOSE (CELLULOSE GEL)	460(i)	GMP	Anticaking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener		Initial country comment:  Thailand: Used as emulsifier and stabilizer in recombined and reconstituted milk as well as vitamin and mineral fortified milk. It provides good colloidal suspension and prevent sedimentation of solid particles in milk system (e.g. milk protein and fortified minerals) during storage period. It is used in recombined and reconstituted milk to prevent separation of water and oil phase. In addition, microcrystalline cellulose also helps to improve the viscosity of product and create satisfactory mouth feel as per consumer preferences. Microcrystalline cellulose is either used individually or in combination with other EST at an optimized ratio.  China: Suspend colloids or particles in milk, such as milk protein and mineral in fortified products. It could also increase viscosity of the continuous water phase and thereby reducing creaming or sediment rates.	Adopt as listed
					<u>Japan</u> : Used to prevent sedimentation in non-flavoured mineral fortified fluid milk	
1					EWG Comments::	

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
			Class		Brazil: See General Comment  Chile: Helps to maintain the stability of the product over time after having undergone UHT thermal processing, and help maintain cocoa suspensions (chocolate milk), vitamin and mineral mixtures. In some cases, its helps to maintain the suspensions of colorants and flavorings.  Columbia: As a stabilizer for use in milk-based drinks with BPM doses. As a stabilizer in milk-based beverages to ensure product stability over the shelf life, it retains water and prevents phase separation, and can increase viscosity depending on the dose, has a technological function similar to that in the categories 01.2.1.1 Fermented milks (natural / simple) without heat treatment after fermentation and 01.2.1.2 Fermented milks (natural / simple) heat-treated after fermentation  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below  FoodDrinkEurope: Supports this additive at GMP and for the mentioned functional classes  ICGMA, IFAC: Supports adoption. Information provided by our members is consistent with the technological justification provided by Thailand, China, and Japan.  Japan: supports the proposal. Microcrystalline cellulose is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. This additive is also used in non-flavoured witamin fortified fluid milks for the	
					NZ: Supports use at GMP.  Microcrystalline cellulose is added to suspend particles in fluid milk to prevent sedimentation. It creates a network that keeps the particles suspended and is often used in combination with other stabilizers to improve the stability during shelf life. Microcrystalline cellulose can be used to improve the viscosity to improve mouthfeel  EU Specialty Foods, ICGMA, IFAC: supports the 2 <sup>nd</sup> circular proposal.	
					In response to the general comments from the EU and Brazil: Cellulose gel would be used in combination with other emulsifiers,	

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					stabilizers, and thickeners in recombined and reconstituted UHT milk.  Other emulsifiers, stabilizers, and thickeners (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Cellulose gel provides stabilization of proteins during processing and storage. Also, cellulose gel compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk.	
MONO- AND DI- GLYCERIDES OF FATTY ACIDS	471	GMP	Emulsifier, Stabilizer, Antifoaming agent		Initial country comment:  Thailand: Used as emulsifier and stabilizer in products subject to food category 01.1.2. It helps to enhance stability of recombined and reconstituted products, especially for high fat content formula (milk fat, vegetable oil and DHA are added) by keeping the fat and water from separation. It also prevents the sedimentation of fine particle and increases colloidal stability of vitamin and mineral fortified formula.  Moreover, it is used to reduce foam formation during processing. The excessive foam has an effect on further process (e.g. packing) which could lead to the poor quality of final products. Mono- and di-glyceride of fatty acids are usually used in combination with other EST at an optimized ratio.  China: Have a significant impact on the interfacial tension between water and oil phase and as such is very important for facilitating emulsification in recombined products. Can prevent powdery mouthfeel and gritty texture and is used for controlling the emulsifier/protein ratio in emulsion membranes. This is important for shelf life of the products.  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  EWG comments:  Columbia:  As an emulsifier / stabilizer for use in milk-based drinks with BPM doses It guarantees the stability of the emulsion, allowing no separation of grease during the life and prevents the sedimentation of fine particles, also increases the colloidal stability and prevents the sedimentation of fine particles in products fortified with vitamins and minerals.  It has a technological function similar to that in categories 01.2.1.1 Fermented milk (natural / simple) without heat treatment after fermentation and 01.2.1.2 Fermented milk (natural / simple) heat-treated	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					after fermentation	
					<b>EFEMA:</b> Support adoption. For use in recombined and reconstituted milk as stabilizer. Due to the anionic properties of diacetyltartaric and fatty acid esters of glycerol, the additive will stabilize and prevent protein aggregation during heat treatment. Preventing protein aggregation helps to stabilize the product during shelf life and to avoid precipitation. Furthermore, emulsifiers help to form stable emulsions even in technologically challenging emulsions (i.e. fortified formula). This improves the mouthfeel (sensory/texture) and shelf life (prevents sedimentation) of the milk.	
					<u>EU</u> : the natural emulsification properties of milk are not sufficient? Would a product containing vegetable oil still be considered "Other fluid milk"? See 2 <sup>nd</sup> Circular General Comment below	
					<u>FoodDrinkEurope</u> : Supports this additive at GMP and for the mentioned functional classes	
					ICGMA, IFAC: Supports adoption given rationale provided by Thailand, China, and Japan. Mono- and diglycerides facilitate emulsification and enhance stability both in low fat and in high fat recombined and reconstituted products.	
					<u>Japan</u> : Supports the proposal <u>Chile, FoodDrinkEurope</u> : Supports adoption	
					EFEMA: supports adoption as listed. We would also like to reiterate our technical justification for INS 471 in this food category as the comments mentioned refer to INS 472e: Mono- and diglycerides facilitate emulsification and enhance stability both in low fat and in high fat recombined or reconstituted products.  Furthermore, especially in recombined milk products, the "willingness" of the milk protein to form stable emulsions is negatively influenced.  Emulsifiers help to form stable emulsions even in technologically challenging emulsions (i.e. recombined formula, especially recombined formula with high for content or fortified formula). This improves the	
					formula with high fat content or fortified formula). This improves the mouthfeel (sensory/texture) and shelf life (prevents sedimentation) of the milk.  Emulsifiers lower the surface tension of a liquid and thus break arising bubbles.	

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					South Africa: Supports adoption. Mono- and diglycerides facilitate emulsification and enhance stability both in low fat and in high fat recombined and reconstituted products.	
NITROGEN	941	GMP	Packing gas		Initial country comment:  Thailand: Used as packing gas for fluid milk products subject to food category 01.1.2. It is flushed to final products during filling step  EWG comments: Columbia: It is given as an adjuvant for beverages based on milk and other milk, helps maintain sensory characteristics, as there is no oxygen to prevent the oxidation of fat.  Chile, FoodDrinkEurope, Malaysia: Support adoption as listed	Adopt as listed
PECTIN	440	GMP	Emulsifier, Stabilizer, Thickener		Initial country comment:  Thailand: Added to aid the suspension of solid particles (e.g. milk protein and fortified minerals) and to avoid the sedimentation during the shelf life. It is currently used in fluid milk products such as recombined milk, reconstituted milk (high protein formula) and fortified vitamins and minerals milks. Also helps to improve the viscosity of products and create satisfactory mouth feel as per consumer preferences. Pectin is either used individually or in combination with other EST at an optimized ratio.  EWG comments:  Brazil: See General Comment.  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below.  Chile, FoodDrinkEurope: Supports adoption as listed.  IFAC: Supports the listing of this provision with FC 01.1.2 given the rationale provided by Thailand	Adopt as listed
PHOSPHATES	338; 339(i) -(iii); 340(i) -(iii); 341(i)	5000	Acidity regulator, Sequestrant, Stabilizer	Note 33: As phosphorous; Note 227, For use in sterilized and UHT treated milks only; and	Initial country comment:  Thailand: Used as acidity regulator to adjust the pH of milk thus enhance protein stability. It is also required as stabilizer to prevent protein sedimentation during UHT and sterilization process. Moreover, phosphates form chelate complexes with polyvalent metal ions (e.g. iron and zinc) which can prevent the oxidation of fat in milk. In vitamin and	Adopt at 5000 without Note 227

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
	-(iii); 342(i) -(ii); 343(i) -(iii); 450(i) - (iii),(v) -(vii), (ix); 451(i) ,(ii); 452(i) - (v); 542		Class	Note for singly or in combination	mineral fortified formula, phosphates are added to enhance stability by reducing the interfacial tension between liquid and solid.  China: Could reduce the interfacial tension between liquid/solid, especially for using in the process of UHT milk as keep quality during the UHT process. It also could preserve the quality of milk by using as moisture conservative.  EWG comments:  Columbia: For use in category 01.1.2 Other liquid milk (natural / simple) in the products Other liquid milks and milk-based drinks sterilized and UHT only It becomes necessary to add phosphates to prevent the coagulation of proteins during the sterilization or ultrapasteurization process. The proportion of milk salt concentrations play an important role in the thermal stability of dairy products, calcium and magnesium ions tend to destabilize the protein system, while phosphates stabilize it. It has a technological function equal to that it performs in category 01.1.1 Liquid milk (natural / simple), where it is already authorized for references with ultra-high temperature (UHT) treatments, sterilized.  EU: why is ML of 5000 ppm needed? In FC 01.1.1 ML 1500 ppm is sufficient. See 2nd Circular General Comment below  FoodDrinkEurope: adoption as listed without note  IFAC: Supports adoption given rationale provided by Thailand and China.  Japan: proposes Note 227 be deleted since phosphates are used not only in sterilized and UHT treated milks but also in non-flavoured vitamin and mineral fortified fluid milks. Disodium diphosphate (INS 450(i)) is used in non-flavoured mineral fortified milks bisodium diphosphate (INS 450(i)) is used in non-flavoured mineral fortified milks. Disodium diphosphate improve protein stability in sterilized products (e.g. concentrated products like recombined evaporated milks/REM). It also improves the stability during shelf life (reducing sedimentation) and reduces fouling during UHT process by chelating polyvalent minerals like calcium	
	1		1	1	Capports adoption as listed	

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
POLYDEXTROSE	1200	GMP	Stabilizer, Thickener		Initial country comment:  Thailand: Used as thickener to improve organoleptic properties of milk products and increase viscosity of product as per consumer preferences. It also helps to enhance the stability of milk, especially vitamin and mineral fortified formula.  China: Added to low/reduced fat milks, contributing to mouthfeel and the perception of creaminess, thereby increasing organoleptic acceptability to consumers.  EWG comments:  Brazil: This additive will have an impact on the viscosity of the product, changing the character of fortified milk and misleading the consumer; disagreeing with what is proposed in section 3.2 of the GSFA.  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below  EU Specialty Food Ingredients, FoodDrinkEurope: Support adoption as listed and note.  ICGMA, IFAC: Supports adoption. Polydextrose imparts a smoother texture and richer consistency to milk products, particularly in reduced sugar/fat products. Study data indicates that impact on viscosity is process and formula dependent.  No change in viscosity was noted in  heat treated UHT products: up to 3.5%  pasteurized plain products: up to 1.8%  pasteurized sugar sweetened products: up to 3%  At higher levels, sensory data show that milk products containing polydextrose were perceived as less watery i.e. had more body and a better mouthfeel	Adopt as listed
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	1000	Emulsifier, Stabilizer		South Africa: Supports adoption  Initial country comment: China: It can impact the surface tension between water and oil phase to help the formation of emulsion in recombined milk products. Polyglycerol esters of fatty acids can also reduce fat creaming. And keep the product stable during the shelf life, especially for recombined whole milk products.  Japan: Used in non-flavoured vitamin and mineral fortified milk to stabilize	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					calcium or iron which are used for fortification.  EWG comments:  EU: the natural emulsification properties of milk are not sufficient or affected in recombined milk? Needed only in iron or calcium fortified milk? See 2 <sup>nd</sup> Circular General Comment below  EFEMA: Support adoption. Agree with technical justifications.  FoodDrinkEurope: supports adoption as listed without note  Chile, South Africa: Supports adoption  Initial country comment:  Japan: Used in non-flavoured mineral fortified milk to prevent	
POTASSIUM CARBONATE	501(i)	GMP	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener	Use in non- flavored vitamin and mineral fortified milks only	EWG comments:  Brazil: See General Comment  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below  Chile, FoodDrinkEurope: Supports adoption as listed and note.  Japan: Supports the proposal. Potassium carbonate is used to prevent denaturation of protein during pasteurization in non-flavoured mineral fortified fluid milks. This additive is also used in vitamin fortified fluid milks for the same purpose	Adopt as listed
POTASSIUM HYDROXIDE	525	GMP	Acidity regulator	227: For use in sterilized and UHT treated milks only	Initial country comment:  Thailand: Widely use as acidity regulator. It is used to adjust the pH of milk enhancing protein stability of sterilized and UHT treated milk.  Potassium hydroxide is alkali agent that does not adversely affect the taste and smell of milk products. In addition, using of potassium salt is more suitable when compared to sodium salt because the sodium salt may cause excessive amount of sodium in milk products. Potassium hydroxide is permitted in FC 13.1.1 "Infant formulae".  EWG comments:  Columbia: As a regulator of acidity in beverages based on sterilized milks and UHT, it is used to adjust the pH of the milk that improves the stability	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					of the protein. Potassium hydroxide is an alkaline agent that does not adversely affect the taste and smell of dairy drinks. It is used in 01.4.3 Curd cream (natural / simple), 13.2 Supplementary foods for infants and young children, among others  NZ: Supports use at GMP. Potassium hydroxide is added as an acidity regulator to adjust pH to improve protein stability and thus reduce sedimentation during shelf life. Adding potassium hydroxide (or in combination with sodium hydroxide) can improve the overall mineral balance in liquid milk products already containing high amounts of sodium  Chile, FoodDrinkEurope: Support adoption as listed.	
PROPYLENE GLYCOL ALGINATE	405	4000	Emulsifier, Stabilizer, Thickener		EU: See 2 <sup>nd</sup> Circular General Comment below  Initial country comment:  China: Stabilizes milk protein by providing steric stabilization. Propylene glycol alginate can interact with milk proteins and adsorbed on the surface of casein micelles with a functionality of stabilization in recombined milk. As the molecule of propylene glycol alginate contains both of hydrophobic and hydrophilic groups, it also has interfacial activity and is helpful to stabilize the recombined products during shelf life.  Comments to first circular:  Brazil: See General Comment  EU: concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below  ICGMA: Supports adoption. Information provided by our members is consistent with the technological justification provided by China  Chile, ICGMA: Supports adoption as listed	Adopt as listed
SODIUM ASCORBATE	301	GMP	Antioxidant		Initial country comment:  Thailand: Used as antioxidant in fluid milk such as recombined milk, reconstituted milk and non-flavoured vitamin and mineral fortified milk. It helps to prevent oxidation of fat and vitamins, and maintain products quality throughout shelf life. The use of sodium ascorbate together with tocopherols shows a synergistic effect.	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					<u>China</u> : Using in fluid milk, to keep quality in shelf life, and to protect product from developing a rancid off taste and/or off-flavor.	
					EWG comments: <u>Brazil</u> : Understands as inadequate the provision of antioxidants in the already-reconstituted and recombined milk. Brazil understands that it is technologically justified to use antioxidants in milk powder. However, from the moment of reconstitution (recombination), Brazil considers that the generated product is similar to the whole milk, for which there is no technological justification for adding antioxidants, tolerating only the antioxidants transferred from the milk powder. Also, whole milk already has natural antioxidants that already guarantee the stability of the product.	
					Columbia: As a stabilizer for use in milk-based drinks with BPM doses. As a stabilizer in milk-based beverages to ensure product stability over the shelf life, it retains water and prevents phase separation, and can increase viscosity depending on the dose, has a technological function similar to that in the categories 01.2.1.1 Fermented milks (natural / simple) without heat treatment after fermentation and 01.2.1.2 Fermented milks (natural / simple) heat-treated after fermentation	
					<u>EU</u> : could it be explained why the natural antioxidants of milk (e.g. tocopherols, beta-carotene, phospholipids) are not sufficient? Is there no effect of the use ascorbic acid on the sensory properties of milk (taste)? Only needed in vitamin and mineral fortified milk? See 2 <sup>nd</sup> Circular General Comment below	
					<u>NZ</u> : Supports use at GMP.  Sodium ascorbate is added as an antioxidant to prevent oxidation of fat, vitamins or other oxidation sensitive nutrients and thus maintain the quality of the liquid milk throughout the shelf life. It can be used in combinations with other antioxidants	
					Chile, FoodDrinkEurope: Supports adoption as listed.	
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM		GMP	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent,		Initial country comment:  Thailand: Used as emulsifier, stabilizer in fluid milk such as recombined milk, reconstituted milk and vitamin and mineral fortified fluid milk. It provides good colloidal suspension and prevent sedimentation of solid particles in milk system (e.g. milk protein and	Adopt as listed

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
			Humectant, Stabilizer, Thickener		fortified minerals) during storage period. It is used in recombined and reconstituted milk to prevent separation of water and oil phase. Moreover, CMC also helps to improve the viscosity of product as per consumer preferences. CMC is either used individually or in combination with other EST at an optimized ratio.	
					<u>China</u> : Stabilizes milk by increasing viscosity of the continuous water phase and thereby reducing creaming or sediment rates in fortified milk products, such as calcium fortified.	
					<u>Japan</u> : Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.	
					EWG comments: <u>Brazil</u> : See General Comment	
					<u>Chile</u> : Helps to maintain the stability of the product over time after having undergone UHT thermal processing, and help maintain cocoa suspensions (chocolate milk), vitamin and mineral mixtures. In some cases, its helps to maintain the suspensions of colorants and flavorings.	
					<u>EU</u> : concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below	
					ICGMA, IFAC: Supports adoption. Information provided by our members is consistent with the technological justification provided by Thailand, China, and Japan.	
					<u>Japan</u> : Supports the proposal. Sodium carboxymethyl cellulose is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. This additive is also used in vitamin fortified fluid milks for the same purpose.	
					<u>NZ</u> : Supports use at GMP. Carboxymethyl cellulose is added to suspend particles in fluid milk to prevent sedimentation. It creates a network that keeps the particles suspended and is often used in combination with other stabilizers to improve the stability during shelf life. Carboxymethyl cellulose can be used to improve the viscosity to improve mouthfeel.	

SUCROGLYCERIDE S 474				EU Specialty Foods, ICGMA, IFAC: supports the 2 <sup>nd</sup> circular proposal. In response to the general comments from the EU and Brazil: Cellulose gum would be used in combination with other emulsifiers,	
				stabilizers, and thickeners in recombined and reconstituted UHT milk.  Other emulsifiers, stabilizers, and thickeners (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Cellulose gum provides stabilization of proteins during processing and storage. Also, cellulose gum compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk	
				<u>Chile, South Africa, FoodDrinkEurope</u> : Supports adoption Initial country comment:	
	1000	Emulsifier	Note 348: Singly or in combination: Sucrose esters of fatty acids (INS 473), sucrose oligoesters, type I and type II (INS 473a) and sucroglycerides (INS 474).	Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  Comments to first circular:  EU: is the need related to fortification? Could the technological effect be described? Used as an emulsifier?  Japan: Supports the proposal with Note 348. Sucroglycerides share the ADI with Sucrose esters of fatty acids (INS 473) and Sucrose oligoesters type I and II (INS 473a). Sucrose esters of fatty acids are used to prevent sedimentation in non-flavoured mineral fortified fluid milks  EWG comments:  Chile, FoodDrinkEurope: Supports adoption as listed  EU: See 2 <sup>nd</sup> Circular General Comment below	Adopt with new note "for use in vitamin and mineral fortified milks only"
				South Africa: Supports adoption Initial country comment:	
SUCROSE ESTERS OF FATTY ACIDS 473	1000	Emulsifier, Foaming agent, Glazing agent, Stabilizer	Note 348	China: It can impact the surface tension between water and oil phase to help the formation of emulsion in recombined products and calcium fortified milk products. Can reduce fat creaming. This is very helpful for shelf life of the products  Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  EWG comments:	Adopt as listed

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					<u>EU</u> : the natural emulsification properties of milk are not sufficient or affected in recombined milk? See 2 <sup>nd</sup> Circular General Comment below	
					<u>EU Specialty Food Ingredients</u> : Support adoption. Agree with tech. justifications.	
					<u>ICGMA</u> : Supports adoption. Information provided by our members is consistent with the technological justification provided by China and Japan.	
					<u>Japan</u> : Supports the proposal with Note 348. Sucrose esters of fatty acids are used to prevent sedimentation in non-flavoured mineral fortified fluid milks.  Sucrose esters of fatty acids share the ADI with Sucroglycerides (INS)	
					474) and Sucrose oligoesters type I and II (INS 473a).	
					Chile, FoodDrinkEurope, ICGMA: Supports adoption as listed	
					Initial country comment: <u>Japan</u> : Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.	
SUCROSE OLIGOESTERS,	473a	1000	Emulsifier, Glazing agent,	Note 348	EWG comments: <u>EU</u> : is the need related to fortification? Could the technological effect be described?	Adopt with new note" for use in vitamin and mineral fortified milks
TYPE I AND II			Stabilizer		<u>Japan</u> : Supports the proposal with Note 348. Sucrose oligoesters type I and II share the ADI with Sucrose esters of fatty acids (INS 473) and Sucroglycerides (INS 474). Sucrose esters of fatty acids are used to prevent sedimentation in non-flavoured mineral fortified fluid milks	only"
					<u>Chile, FoodDrinkEurope</u> : supports adoption as listed  Initial country comment:	
TOCOPHEROLS (D- ALPHA- TOCOPHEROL,	307a,				China: Could keep products' quality in shelf life, and to protect product from developing a rancid off taste and/or off-flavor.	
TOCOPHEROL TOCOPHEROL CONCENTRATED, MIXED, DI-ALPHA- TOCOPHEROL	307b, 307c	200	Antioxidant		EWG Comments: <u>Brazil</u> : Understands as inadequate the provision of antioxidants in the already-reconstituted and recombined milk. Brazil understands that it is technologically justified to use antioxidants in milk powder. However, from the moment of reconstitution (recombination), Brazil considers that the	Adopt as listed

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					generated product is similar to the whole milk, for which there is no technological justification for adding antioxidants, tolerating only the antioxidants transferred from the milk powder. Also, whole milk already has natural antioxidants that already guarantee the stability of the product.  Eu: milk naturally contains certain level of tocopherols – it is not sufficient? See 2 <sup>nd</sup> Circular General Comment below  Nz: supports use at ML = 200mg/kg and in particular, supports the use of tocopherol concentrated mixed (INS 307b). Tocopherols are added as an antioxidant to prevent oxidation of fat, vitamins or other oxidation sensitive nutrients and thus maintain the quality of the liquid milk throughout the shelf life. Can be used in combinations with other antioxidants.  Chile, FoodDrinkEurope: supports adoption as listed	
TRISODIUM CITRATE	331(iii	GMP	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer		Initial country comment:  Thailand: Used to enhance stability of milk products by forming chelate complexes with polyvalent metal ions (e.g. iron and zinc) which can prevent the oxidation of fat in milk. It is also required as stabilizer to prevent sedimentation of protein.  China: Could help to prevent protein denature and maintain a good stability during the manufacture processing of the products in FC 1.1.2.  Japan: Used to adjust pH to prevent sedimentation in non-flavoured mineral fortified fluid milks  EWG comments:  Columbia: For use in category 01.1.2 Other liquid milk (natural / simple) in the products Other liquid milks and milk-based drinks sterilized and UHT only. It fulfills the technological function of stabilizer of the protein, during the heat treatment. It has an unspecified ADI and poses no appreciable risk to the health of consumers.  It has a technological function similar to that it plays in the categories:  - 01.1.4 Flavored liquid dairy drinks  - 01.3 Condensed milk and similar products  - 01.2.1.2 Fermented milk (natural / simple) heat-treated after fermentation  - 01.4.1 Pasteurized cream (natural / plain)	Adopt as listed

Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					- 01.4.2 Sterilized and UHT creams, whipping cream creams and creams with reduced fat content (natural / plain)	
					<u>EU Specialty Food Ingredients</u> : Support adoption. Agree with tech. justifications.	
					ICGMA: Supports adoption. Information provided by our members is consistent with the technological justification provided by Thailand, China, and Japan.	
					<u>Japan</u> : Supports the proposal. Trisodium citrate is used to adjust pH to prevent sedimentation in non-flavoured mineral fortified fluid milks	
					<u>Chile, South Africa, FoodDrinkEurope</u> : Supports supports adoption as listed.	
					<u>EU</u> : See 2 <sup>nd</sup> Circular General Comment below	
XANTHAN GUM	415	GMP	Emulsifier, Foaming agent, Stabilizer, Thickener		Initial country comment:  Thailand: Used as emulsifier, stabilizer in fluid milk such as recombined milk, reconstituted milk and vitamin and mineral fortified fluid milk. It provides good colloidal suspension and prevent sedimentation of solid particles in milk system (e.g. milk protein and fortified minerals) during storage period. It also helps to improve the viscosity of product and mouthfeel as per consumer preferences. Xanthan gum is either used individually or in combination with other EST at an optimized ratio.  China: Stabilizes fluid milk products by giving steric stabilization through interaction with proteins. It also helps to keep solids suspended, I.e. vitamin-mineral complexes in fortified products.  Japan: Used to prevent sedimentation in non-flavoured mineral fortified	Adopt as listed
			mickener		fluid milks.  EWG comments:  Brazil: See General Comment  Columbia: As a stabilizer for use in milk-based drinks with BPM doses. As a stabilizer in milk-based beverages; Retains water and avoids phase separation and can increase viscosity depending on the dose, has a technological function similar to that performed in the categories 01.2.1.1	

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Additive	INS	Max Level (mg/kg)	INS Functional Class	Proposed Notes	Initial country comment/eWG comments	eWG proposal
					Fermented milk (natural / simple) without heat treatment after fermentation and 01.2. 1.2 Fermented milk (natural / simple) heat-treated after fermentation	
					<u>EU</u> : concerned with the use of thickeners which have impact on the nature of milk. See 2 <sup>nd</sup> Circular General Comment below	
					<u>Chile, EU Specialty Food Ingredients, FoodDrinkEurope</u> : Support supports adoption as listed.	
					<u>ICGMA, IFAC</u> : Supports adoption. Information provided by our members is consistent with the technological justification provided by Thailand, China, and Japan.	
					<u>Japan</u> : Supports the proposal. Xanthan gum is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. Xanthan gum is also used in non-flavoured vitamin fortified fluid milks for the same purpose	
					EU Specialty Foods, ICGMA, IFAC: supports the 2 <sup>nd</sup> circular proposal. In response to the general comments from the EU and Brazil: Xanthan gum would be used in combination with other emulsifiers, stabilizers, and thickeners in recombined and reconstituted UHT milk. Other emulsifiers, stabilizers, and thickeners (for example mono- and diglycerides of fatty acids) control fat crystallization and prevent creaming during storage. Xanthan gum provides stabilization of proteins during processing and storage. Also, xanthan gum compensates for loss of mouthfeel, which is characteristic for recombined and reconstituted UHT milk when compared to fresh milk.	
					South Africa: Supports adoption	

#### **EWG General Comments**

### **Brazil General Comment:**

Does not support adoption. agrees with EU 1<sup>st</sup> circular general comment. Brazil agrees with the technological justification regarding the addition of emulsifiers to avoid the sedimentation of solid particles. However, the thickening characteristic of this additive will invariably have an impact on the viscosity of the product, changing the character of fortified milk and may mislead the consumer; disagreeing with what is proposed in section 3.2 of the GSFA. In time, in this appendix there is proposed the use of several other emulsifiers additives that do not have thickening action; and therefore would achieve the desired technological objective (eg, INS 472a, 472e, 472b, 475, 474, 473 and 473a).

In Brazil, a tropical country, the use of citrates and phosphates is fully adequate to ensure the stability of UHT milk under storage conditions at room temperature (which is often higher than 30 °C).

Brazil also emphasizes that, for the consumers in general, it is difficult to discern through food labeling the purpose and the technological functions of the additives. It is difficult to know which additives could be de-characterizing food's integrity.

Finally, Brazil observes that does not oppose the approval of new additives for these products, provided they comply with the principles established in the GSFA.

#### EU General 1st circular General Comment:

The EU recalls that the primary purpose for the revision of the category 01.1 and its subcategories was the correct placement of certain products (recombined and reconstituted milks) and an indication of a possible different technological need for food additives linked with these products. The EU acknowledges the discussion on the food additives provisions listed in Appendix 6, however, would like to express its concern especially on the use of thickeners. Thickeners are substances increasing the viscosity and therefore having a direct impact on the nature of the product. In the EU's view a product with modified viscosity could not be regarded as milk anymore

# EU General 2<sup>nd</sup> Circular General Comment:

In the EU there is no category such as "other fluid milks". However, the EU acknowledges that there might be different products (not available on the EU market) and therefore there might be some specific need for food additives. However, in such cases the technological need needs to be explained clarifying why the food additive is needed to be added to milk (which is normally a complete stable foodstuff not requiring food additives).

The food category refers to fluid milk, therefore, the use of additives shall not affect the nature of the products (i.e. nature of milk). For this reason the EU is generally opposing to the use of thickeners. In addition, the category 01.1.2 covers different fluid milks possibly having different needs. Therefore, in the EU's view any provision suggested for the adoption should be specific (for specific fluid milks as outlined in the descriptor) reflecting the specific technological justification provided, otherwise the EU could not support the adoption.

#### **IDF General Comment:**

IDF recognises the range and diversity of products throughout the world that fall into the new FC 01.1.2 (Other fluid milks (plain)) (Other fluid milks (plain)) and understands that there are important technological needs for emulsifiers, stabilizers and antioxidants in this category due to the nature of products such as reconstituted and recombined milks. This appears to be particularly true where these reconstituted and recombined products are subjected to "room temperatures" during the summer months in tropical and subtropical areas of the world. These products generally contain blends of milk proteins, milk fats and other dairy-based ingredients which had been separated in another area of the world, shipped to the receiving country as ingredients and then recombined or reconstituted. These products, when all dairy-based ingredients have been blended together, have a higher likelihood of various components settling out or oxidizing, making them less desired by consumers. The use of emulsifiers, stabilizers and antioxidants can reduce oxidation and the settling out of various components. We believe that clear product labelling should allow consumers and purchasers to make informed decisions on whether to purchase such products or not.