



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-First Session

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): PROVISIONS FOR COLOURS IN THE STEP PROCESS IN FOOD CATEGORIES 05.2, 05.3 AND 05.4; PROVISIONS IN TABLE 1 AND 2 OF THE GSFA IN FOOD CATEGORIES 01.0 THROUGH 16.0; PROPOSED DRAFT PROVISIONS IN TABLE 3 FOR GUM GHATTI (INS 419) AND TAMARIND SEED POLYSACCHARIDE; THE TECHNOLOGICAL JUSTIFICATION FOR THE USE OF PRESERVATIVES AND ANTICAKING AGENTS FOR SURFACE TREATMENT OF MOZZARELLA WITH HIGH MOISTURE; REQUEST FOR AND COMPILE INFORMATION ON AVAILABLE RELEVANT DIETARY EXPOSURE DATA AND THE ACTUAL USE LEVEL AND TECHNOLOGICAL JUSTIFICATION FOR CERTAIN FOOD ADDITIVES IN FOOD CATEGORIES 14.1.4 AND 14.1.5 (REPORT OF THE EWG ON THE GSFA)

Prepared by the United States of America with the assistance of Australia, Brazil, Canada, Chile, China, Columbia, Costa Rica, Dominican Republic, European Union, Guatemala, India, Indonesia, Ireland, Japan, Korea, Malaysia, Mexico, New Zealand, Norway, Paraguay, Peru, Philippines, Russian Federation, Saudi Arabia, South Africa, Spain, Switzerland, Thailand, Uganda, Zimbabwe, American Beverage Association, Calorie Control Council (CCC), Comité Européen des Fabricants de Sucre (CEFS), European Food Emulsifier Manufacturers Association (EFEMA), EU Specialty Food Ingredients, FoodDrinkEurope, Food Industry Asia (FIA), International Association for the Development of Natural Gums, 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 Confectionery Association (ICA/IOCCC), International Council of Grocery Manufacturer Associations (ICGMA), International Dairy Federation (IDF), International Food Additives Council (IFAC), Institute of Food Technologists (IFT), International Fruit and Vegetable Juice Association (IFU), International Glutamate Technical Committee (IGTC), International Organization of the Flavor Industry (IOFI), International Special Dietary Foods Industries (ISDI), Natural Food Colours Association (NATCOL), US Dairy Export Council, and World Processing Tomato Council (WPTC)

Introduction

1. CCFA50 agreed to establish an EWG to provide recommendations to CCFA51 on the following topics:¹
 - (i) Draft and proposed draft provisions for colours in the Step process in food categories 05.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 05.3 (Chewing gum), 5.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces);
 - (ii) All remaining draft and proposed draft provisions in Table 1 and 2 of the GSFA in food categories 01.0 through 16.0, with the exception of those additives with technological functions of colour (excluding those provisions discussed in point (i)) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from CCSCH, CCPFV or CCFO;
 - (iii) Proposed draft provisions in Table 3 for gum ghatti (INS 419) and, pending assignment of an INS number, tamarind seed polysaccharide (see Appendix IX, parts A.2);
 - (iv) The technological justification for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content covered by the *Standard for Mozzarella* (CXS 262-2006); and
 - (v) Request for and compile information on available relevant dietary exposure data for dioctyl sodium sulfosuccinate (INS 480), polyglycerol esters of fatty acids (INS 475), sodium stearoyl lactylate (INS 481(i)), calcium oleyl lactylate (INS 482(ii)) and the actual use level and technological justification in Food Category 14.1.4 for dioctyl sodium sulfosuccinate (INS 480), polyglycerol esters of fatty acids (INS 475), sodium stearoyl

¹ REP 18/FA, para. 112.

lactylate (INS 481(i)), calcium oleyl lactylate (INS 482(ii)) and in food category 14.1.5 for polyglycerol esters of fatty acids (INS 475), sodium stearyl lactylate (INS 481(i)) and calcium oleyl lactylate (INS 482(ii)) for consideration by the electronic working group to formulate recommendations on the provisions for these additives in those food categories.

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 4), topic iii (Appendix 5), topic iv (Appendix 6), and topic v (Appendix 7).

- Provision for trisodium citrate in FC 01.1.1 is presented in Appendix 2.

- Proposed draft provisions related to FC 01.1.2 (Other fluid milks (plain)) with the technological function of emulsifier and stabilizer are presented in Appendix 3.

Appendix 1- Draft and proposed draft provisions for colours in the Step process in food categories 05.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 05.3 (Chewing gum), 05.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces)

1. Among several topics, CCFA50 requested the EWG on the GSFA to the CCFA51 to discuss:¹
 - Provisions for colours in the Step process in food categories 05.2, 05.3 and 05.4

Introduction

2. The Chair of the PWG on the GSFA to CCFA50 proposed the EWG on the GSFA to CCFA51 work on recommendations for draft and proposed draft provisions for colours in the Step process in food categories 05.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 05.3 (Chewing gum), 5.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces.² CCFA50 agreed to this proposed and subsequently included this work in the mandate of the EWG on the GSFA to CCFA51.¹

Working Document

3. The EWG issued three circulars for comment. The current document contains 2 annexes.
4. Annex 1 presents a summary of comments provided by the EWG on the application of criteria in Section 3.2 of the Preamble of the GSFA to the general use of colours in FCs 05.2.1, 05.2.2, 05.2.3, 05.3, and 05.4.
5. Annex 2 presents proposals for each draft and proposed draft provisions for colours in food categories 05.2 and its subcategories, 05.3 and 05.4. In Annex 2, the provisions are presented in the format of Table 2 of the GSFA. When a food additive provision from a parent food category is considered in the corresponding subcategories, the provision is indicated in the subcategory in **bolded** font with no Step indicated in the "Step/Adopted" column.
6. A full compilation of comments submitted for Appendix 1 (Colours) to the three circulars are available as at [here](#).

¹ REP 18/FA, para. 112(i).

² CCFA50 CRD2.

Annex 1 – Summary of comments submitted to the first circular on the application of criteria in Section 3.2 of the Preamble of the GSFA to the general use of colours in FCs 05.2.1, 05.2.2, 05.2.3, 05.3, and 05.4

Tech justification

All comments submitted to the 1st circular agreed that colours are used in general in foods across the food categories under discussion. Several comments noted that 40th CCFA had already designated that colours are technologically justified in these food categories. Comments noted that colour was used to improve the organoleptic properties of the food in all food categories under discussion and that there are already adopted provisions for colours in these food categories. Comments noted that the use of colours was designated in the food category descriptor for FC 5.2.1, 5.2.2, and 5.2.3.

Comments noted food in FC 5.2.1, 5.2.2, are generally made from water and sugar (simple syrup), colours are necessary to distinguish product. During manufacturing process (boiling) of hard candies, volatile natural pigments if present in the ingredients gets depleted through evaporation. Hence food colours are required to restore colors lost during the processing. For FC 05.2.3 bulk of ingredients are inherently off-white or beige. For 05.3 the base ingredients tend to not result in very colourful or readily distinguishable products. For 05.4 it was noted that sugar-based toppings are lacking in colour.

Specifically for FC 05.2.3, one Member stated that in their country's category system this food category includes pasta with edible seed, with or without sugar, which does allow the use of colours. However, it was not clear if FC 05.2.3 in the GSFA is the appropriate FC for such products.

Specifically for FC 05.4, one member stated that in their country's category system this food category includes "confectionary baths" and colours were not included in confectionary baths containing cocoa. However, it should be noted that this product may be considered Chocolate Sauce which is included in FC 05.1.2.

Advantage

All comments submitted to the 1st circular agreed that the use of colours in all of these FCs has multiple advantages. These advantages applied in general to foods across these food categories. Advantages include: The base ingredients tend to not result in very colourful or readily distinguishable products. Colours are used to impart colours to products across this food category to differentiate products, as well as to restore colour that may have been lost in processing. Colour is often used to differentiate products by taste.

Misleading the consumer

All comments submitted to the 1st circular agreed that the use of colours in all of these FCs does not mislead the consumer. Comments noted that these are highly processed foods where the use of colours does not change their nature, consumers expect colours to be added to these foods, and that colours have been traditionally added to these products. Multiple EWG members noted that food ingredients are required to be listed on the food label, and that some Codex Members have specific labeling requirements for colours.

Draft and proposed draft provisions for colours in the Step process in food categories 05.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 05.3 (Chewing gum), 05.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces)

When a food additive provision from a parent food category is considered in the corresponding subcategories the provision is indicated in the subcategory in **bolded** font with no Step indicated in the "Step/Adopted" column.

Category No. 05.0 (Confectionery)

Corresponding commodity standards: commodity standards correspond to subcategories 05.1.1, 05.1.3, 05.1.4, and 05.2.2

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
CARAMEL II - SULFITE CARAMEL	150b	50000	183	4	Colour	Discuss use in subcategories (discontinue if adopted in subcategories)

Category No. 05.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4)

Corresponding commodity standards: CODEX STAN 309R-2011 corresponds to subcategory 05.2.2 - only allows acidity regulators and emulsifiers listed in Table 3.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	200	185	4	Colour	Discuss use in subcategories (discontinue if adopted in subcategories (as appropriate))
AZORUBINE (CARMOISINE)	122	300	-	7	Colour	
BRILLIANT BLACK (BLACK PN)	151	300	-	7	Colour	
BROWN HT	155	300	-	7	Colour	
CURCUMIN	100(i)	300	-	7	Colour	
LUTEIN FROM TAGETES ERECTA	161b(i)	300	-	4	Colour	
QUINOLINE YELLOW	104	300	-	7	Colour	
TARTRAZINE	102	300	-	7	Colour	
ZEAXANTHIN,	161h(i)	300	-	4	Colour	

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
SYNTHETIC						

Category No. 05.2.1 (Hard candy)

Corresponding commodity standards: none

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	200	8	4	Colour	Adopt at 200 mg/kg
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	200	185		Colour	Adopt at 30 mg/kg with New Note: "Except for use at 200 mg/kg in hard candy with hard panned sugar coating."
AZORUBINE (CARMOISINE)	122	300			Colour	Adopt at 50 mg/kg. with New Note: "Except for use at 300 mg/kg in candies with red fruit flavour."
BRILLIANT BLACK (BLACK PN)	151	300			Colour	Adopt at 100 mg/kg
BROWN HT	155	300			Colour	Adopt at 50 mg/kg.
CAMEL II - SULFITE CAMEL	150b	50000	183		Colour	Adopt at 50,000 mg/kg with removal of Note 183.
CURCUMIN	100(i)	300			Colour	Adopt at 150 mg/kg with New Note: "Except for use at 300 mg/kg in candies with yellow fruit flavour."
LUTEIN FROM TAGETES ERECTA	161b(i)	300			Colour	Hold provision until additive has been considered for inclusion in Table 3.
LYCOPENE, TOMATO	160d(i)	50000		3	Colour	Discontinue.
PAPRIKA EXTRACT	160c(ii)	95	39	2	Colour	Adopt at 100 mg/kg.
QUINOLINE YELLOW	104	300			Colour	Adopt at 100 mg/kg. with New Note: "Except for use at 300 mg/kg in lemon flavored candies."
TARTRAZINE	102	300			Colour	Adopt at 300 mg/kg.
ZEAXANTHIN, SYNTHETIC	161h(i)	300			Colour	Hold provision until additive has been considered for inclusion in Table 3.

Category No. 05.2.2 (Soft candy)

Corresponding commodity standards: CODEX STAN 309R-2011: allows acidity regulators and emulsifiers listed in Table 3

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
AMARANTH	123	100		7	Colour	Discontinue.
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	200	8	4	Colour	Adopt at 200 mg/kg.
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	200	185		Colour	Adopt at 30 mg/kg with New Note: "Except for use at 200 mg/kg in milk toffees."
AZORUBINE (CARMOISINE)	122	300			Colour	Adopt at 100 mg/kg.
BRILLIANT BLACK (BLACK PN)	151	300			Colour	Adopt at 100 mg/kg
BROWN HT	155	300			Colour	Adopt at 50 mg/kg
CARAMEL II - SULFITE CARAMEL	150b	50000	183		Colour	Adopt at 50,000 mg/kg with removal of Note 183.
CURCUMIN	100(i)	300			Colour	Adopt at 150 mg/kg.
LUTEIN FROM TAGETES ERECTA	161b(i)	300			Colour	Hold provision until additive has been considered for inclusion in Table 3.
LYCOPENE, TOMATO	160d(i)	5000		3	Colour	Discontinue.
PAPRIKA EXTRACT	160c(ii)	95	39	2	Colour	Adopt at 100 mg/kg.
QUINOLINE YELLOW	104	300			Colour	Adopt at 100 mg/kg
TARTRAZINE	102	300			Colour	Adopt at 300 mg/kg.
ZEAXANTHIN, SYNTHETIC	161h(i)	300			Colour	Hold provision until additive has been considered for inclusion in Table 3.

Category No. 05.2.3 (Nougats and marzipans)

Corresponding commodity standards: none

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	100	8	4	Colour	Adopt at 200 mg/kg.
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	200	185		Colour	Adopt at 30 mg/kg.
AZORUBINE (CARMOISINE)	122	300			Colour	Adopt at 50 mg/kg.
BRILLIANT BLACK (BLACK PN)	151	300			Colour	Adopt at 100 mg/kg.
BROWN HT	155	300			Colour	Adopt at 50 mg/kg
CARAMEL II - SULFITE CARAMEL	150b	50000	183		Colour	Adopt at 50,000 mg/kg with removal of Note 183.
CURCUMIN	100(i)	300			Colour	Adopt at 150 mg/kg.
LUTEIN FROM TAGETES ERECTA	161b(i)	300			Colour	Hold provision until additive has been considered for inclusion in Table 3.
PAPRIKA EXTRACT	160c(ii)	95	39	2	Colour	Adopt at 100 mg/kg.
QUINOLINE YELLOW	104	300			Colour	Adopt at 100 mg/kg.
TARTRAZINE	102	300			Colour	Adopt at 300 mg/kg.
ZEAXANTHIN, SYNTHETIC	161h(i)	300			Colour	Hold provision until additive has been considered for inclusion in Table 3.

Category No. 05.3 (Chewing gum)

Corresponding commodity standards: none

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
AMARANTH	123	300		7	Colour	Adopt at 100 mg/kg.
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	500	8	4	Colour	Adopt at 50 mg/kg.
ANNATTO EXTRACTS,	160b(ii)	500	185	4	Colour	Adopt at 50 mg/kg.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
NORBIXIN-BASED						
AZORUBINE (CARMOISINE)	122	300		7	Colour	Adopt at 100 mg/kg.
BRILLIANT BLACK (BLACK PN)	151	300		7	Colour	Adopt at 300 mg/kg.
BROWN HT	155	300		7	Colour	Adopt at 300 mg/kg.
CARAMEL II - SULFITE CARAMEL	150b	50000	183		Colour	Adopt at 20,000 mg/kg with removal of Note 183.
CURCUMIN	100(i)	700		7	Colour	Adopt at 300 mg/kg with New Note "Except for use at 700 mg/kg to provide brigher coloring in yellow fruit or spice flavoured chewing gum."
LYCOPENE, TOMATO	160d(i)	50000		3	Colour	Discontinue.
PAPRIKA EXTRACT	160c(ii)	60	39	2	Colour	Adopt at 150 mg/kg.
QUINOLINE YELLOW	104	300		7	Colour	Adopt at 30 mg/kg with new note "Except for use at 300 mg/kg in lemon and citrus flavoured products."
TARTRAZINE	102	300		7	Colour	Adopt at 300 mg/kg.
ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Hold provision until additive has been considered for inclusion in Table 3.

Category No. 05.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces)

Corresponding commodity standards: none

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
AMARANTH	123	300		7	Colour	Adopt at 100 mg/kg.
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	50	8	4	Colour	Adopt at 50 mg/kg.
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	1000	185	4	Colour	Adopt at 25 mg/kg with New Note: "Except for use at 100 mg/kg in sugar-based icings."

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
AZORUBINE (CARMOISINE)	122	500		7	Colour	Adopt at 300 mg/kg.
BRILLIANT BLACK (BLACK PN)	151	500		7	Colour	Adopt at 500 mg/kg.
BROWN HT	155	500		7	Colour	Adopt at 50 mg/kg.
CARAMEL II - SULFITE CARAMEL	150b	50000	183		Colour	Adopt at 50,000 mg/kg with removal of Note 183.
CURCUMIN	100(i)	500		7	Colour	Adopt at 500 mg/kg.
LUTEIN FROM TAGETES ERECTA	161b(i)	500		4	Colour	Hold provision until additive has been considered for inclusion in Table 3.
PAPRIKA EXTRACT	160c(ii)	300	39	2	Colour	Adopt at 100 mg/kg.
QUINOLINE YELLOW	104	500		7	Colour	Adopt at 50 mg/kg.
TARTRAZINE	102	500		7	Colour	Adopt at 500 mg/kg.

Appendix 2: Provision for trisodium citrate in FC 01.1.1

1. Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to discuss:¹
 - Provision for trisodium citrate in FC 01.1.1 (comments on technological need for the use of the food additive in milk from bovine species)

Background

2. The EWG on the GSFA to CCFA49 compiled comments on the appropriateness of the food additive provisions both adopted and in the step process in the revised food category 01.1 (Fluid milk and milk products) and its subcategories 01.1.1 (Fluid milk (plain)), 01.1.3 (Fluid buttermilk (plain)) and 01.1.4 (Flavoured fluid milk drinks).² The physical working group (PWG) on the GSFA to CCFA49 discussed the proposals and information compiled by the EWG.³

3. CCFA49 discussed the general use of trisodium citrate (INS 331(iii)) in UHT and sterilized products conforming to food category 01.1.1. The discussion focused on whether the provision for trisodium citrate should have a numeric use level or a maximum use level of GMP. CCFA49 agreed to 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 in food category 01.1.1.⁴

4. The PWG on the GSFA to CCFA50 discussed the report of the EWG to CCFA50, including the technological need for a numeric or GMP level for the provision for trisodium citrate in food category 01.1.1.⁵ The PWG subsequently recommended that the provision be adopted with a GMP use level in food category 01.1.1 with Note A17 that reads “For UHT milk from non-bovine species only.”⁶

5. CCFA50 endorsed the PWG recommendation to adopt the provision at GMP after replacing Note A17 with a new note which reads “For use in sterilized and UHT treated milks from non-bovine species only.”⁷ However, after the Committee endorsed the recommendation for adoption, a member country requested that the provision for trisodium citrate in FC 01.1.1 be held at Step 7 and recirculated for comment to confirm whether there was any technological justification to support the use of the additive in milk from bovine species. The Committee agreed to hold the provision and to task the EWG on the GSFA to recirculate the provision for comment.¹

Working Document

6. The EWG issued three circulars for comment. The first and second circular contained EWG comments on the technological justification for the use of trisodium citrate (INS 331(iii)) in fluid milk (plain) from bovine species. The third circular contained EWG comments on the proposal for the use of trisodium citrate (INS 331(iii)) in food category 0.1.1.1 (fluid milk (plain)) at GMP and with Note 438 “Only for use as emulsifier or stabilizer”, Note 227 “for use in sterilized and UHT treated milks only” and remove Note 439 “For use in sterilized and UHT treated milks from non-bovine species only”. The document presents a compilation of comments provided by EWG members to the first, second and third circulars.

Conventions

7. The current document presents a recommendation for the provision for trisodium citrate in FC 01.1.1. This document presents a proposal (adopt, adopt with revision) for the draft provision under discussion based upon a consensus approach taking into account comments on the first, second and third 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

¹ REP 18/FA, para. 71.

² CX/FA 17/49/7, Appendix 5.

³ FA/49 CRD2.

⁴ REP17/FA paras 77, 78, and 109.

⁵ CX/FA 18/50/7, Appendix 4.

⁶ FA/50 CRD2.

⁷ REP18/FA para 70.

Current provision under discussion:

Trisodium citrate INS 331(iii)		Functional Class:	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer	
Food Cat No.	Food Category	ML (mg/kg)	Notes	Step
01.1.1	Fluid milk (plain)	GMP	438, 439	7

438: Only for use as emulsifier or stabilizer

439: For use in sterilized and UHT treated milks from non-bovine species only

I. General Summary of comments provided in response to the First Circular

The first circular requested comment on the provision for INS 331(iii) in food category 01.1.1. Specifically, The first circular asked those not in favour of the use of INS 331(iii) in milk from bovine species to provide discussion as to why INS 331(iii) would not be technologically justified in milk from bovine species including discussion on what physical properties differ between bovine milk and milk from non-bovine species that would cause INS 331(iii) to be technologically justified in non-bovine sterilized and UHT treated milk but not justified in sterilized and UHT treated milk from bovine species. The first circular also asked those in favour of the use of INS 331(iii) in milk from bovine species to provide justification and supporting information based on the criteria in Section 3.2 of the Preamble of the GSFA and to discuss if there are physical property similarities between milk from bovine species and milk from non-bovine species that would support the general use of INS 331(iii) in all sterilized and UHT treated milks.

Comments submitted in response to the first circular that were not in favour of the use of trisodium citrate in UHT treated milks from bovine species focused on whether the use has an advantage or would mislead the consumer. Several Members noted that only phosphates were allowed for use as stabilizers in bovine milks in their countries, and that no other stabilizers are necessary. These comments noted that milk from bovine species is less sensitive to protein coagulation than other milks and therefore trisodium citrate is not necessary in bovine milks. One commented that the use of citrates can mislead the consumer by buffering a low pH (which is an indicator of spoilage) while another noted that the use of stabilizers could be used to mask bad handling practices. Another expressed concern that the use of trisodium citrate may change the organoleptic properties of milk and affect milk fermentation.

However, comments from Members in favour of the use of trisodium citrate in UHT milk from bovine species addressed the advantage of the use and whether the use would mislead the consumer. These members noted that trisodium citrate is allowed in bovine milks in their countries. These members noted that all UHT bovine milks utilize stabilizers, and that trisodium citrate has advantages that other stabilizers (*i.e.*, phosphates) do not. One member provided information that trisodium citrate is required for pastured cattle as feeding cattle forage results in production of milk with a lower natural sodium citrate content, which results in greater tendency for gelation of these milks under UHT processes. Sodium citrate is a natural component of milk. The use of trisodium citrate corrects the natural citrate deficiency in milk from pastured cattle, which the use of phosphates cannot do. The use would not mislead the consumer as stabilizers are already allowed for use in bovine milks. One Member noted that restricting the use of trisodium citrates to non-bovine species is contrary to the principles of Codex as the restriction would not benefit public health but would have an adverse trade impact on developing countries.

II. General Summary of comments provided in response to the Second Circular

Based on comments submitted to the first circular, and in order to determine an approach to consensus, the second circular requested comment from EWG members on the following:

- a) Those not in favour of the use of INS 331(iii) in UHT treated milk from bovine species were requested to provide discussion on how the information provided in response to the first circular does not demonstrate that the use meets the criteria listed in Section 3.2 of the preamble of the GSFA. Those who assert that the use of trisodium citrate can mislead the consumer by masking spoiled milk or bad handling practices were requested to discuss why there is a concern for the use of trisodium citrate in bovine milks but not for phosphates, which would have the same effect.

Two comments were received in response to this request. One comment noted that the reported need for INS 331(iii) in UHT treated milk from bovine species is limited to certain Codex Members as a result of bovine feeding systems utilized by those Members. This comment observes that this appears to result in the need to compensate for a lower content of natural citrate in milk produced in Countries utilizing such feeding

systems, but that this justification is not applicable to all Codex Members. The second comment asserted that INS 331(iii) is only justified in goats milk but not other non-bovine species. This comment also noted that there is no data on how the use of INS 331(iii) will affect the processes of milk fermentation and other processes of milk, but provided no information explaining why INS 331(iii) would be expected to affect milk fermentation or processing. Neither comment discussed the technological information provided in response to the first circular or how the use of trisodium citrate INS 331(iii) would differ from the currently allowed use of phosphates.

- b) Those in favour of the use of INS 331(iii) in UHT treated milk from bovine species were requested to provide further discussion on how the use will not mislead the consumer (i.e., is not used to lower pH to cover spoilage, is not used to mask bad handling practice, etc)

Comments in favour of the use of INS 331(iii) in UHT treated milk from bovine species noted that extensive information had been provided to demonstrate that the use complies with all criteria in section 3.2 of the preamble to the GSFA: it is technologically justified, has an advantage, is safe, does not mask bad handling practices and that stabilizers are required in all bovine milks therefore the use does not mislead the consumer. These comments provided information on the need for INS 331(iii) in milks with lower citrate content, that INS 331(iii) is a table three additive and is allowed in infant formula so there is no safety issue, and all bovine milk requires stabilizers to limit the deposition of calcium and protein salts so the use cannot mislead the consumer.

Other comments

One EWG member proposed establishing a numeric use level in bovine milk to address the concerns of some members that the use of INS 331(iii) can be used to mask bad handling practices. However, other comments noted that the use cannot be used to mask bad handling practices as excessive use would likely spoil the milk. Other EWG members observed that Note 438 “Only for use as an emulsifier or stabilizer” is already attached to this provision and should address concern expressed in comments to the first circular that INS 331(iii) can mask bad handling practices by buffering pH levels.

One EWG member noted that an allowance for the use of INS 331(iii) in bovine milk should not impact countries where trisodium citrate is not allowed, due to the limited self-life and need for uninterrupted cold-storage chain for milk which limits its international trade to within specific geographical regions.

III. General Summary of comments provided in response to the Third Circular

The EWG was invited to comment on the adoption of a provision for INS 331(iii) in food category 01.1.1 at a level of GMP with the Note 438 “Only for use as an emulsifier or stabilizer” and Note 227 “for use in sterilized and UHT treated milks only” and to remove Note 439 “For use in sterilized and UHT treated milks from non-bovine species only”. The comments received from the EWG indicated some EWG members were in favor of the proposal, while some members were not in favor of the proposal. One EWG member not in favor of the proposal restated their position that there is no technological justification to support the use of INS 331(iii) in the production of Mare's, camel's and other types milk obtained from non-bovine species (mare, camel, sheep and other species of milk) and there is no data on how the use of INS 331(iii) will affect the processes of milk fermentation and other processes of milk processing non-bovine species.

IV. Final EWG Proposal:

Trisodium citrate		Functional Class:			
INS 331(iii)		Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer			
Food Cat No.	Food Category	ML (mg/kg)	Notes	Step	EWG Final Proposal
01.1.1	Fluid milk (plain)	GMP	438, 439	7	Adopt with Note 438 “Only for use as emulsifier or stabilizer” and Note 227 “for use in sterilized and UHT treated milks only”. Remove Note 439 “For use in sterilized and UHT treated milks from non-bovine species only”
<u>Overall summary of all comments by EWG Members:</u>					
a. <u>Those in favour of the use of INS 331(iii) in UHT treated milk from bovine species:</u> Brazil, Colombia, Guatemala, Indonesia, Paraguay, USA, FoodDrinkEurope, IDF					
b. <u>Those not in favour of the use of INS 331(iii) in UHT treated milk from bovine species:</u>					

EU, Russian Federation, Spain, Uganda

c. Other Comments

Switzerland, USA

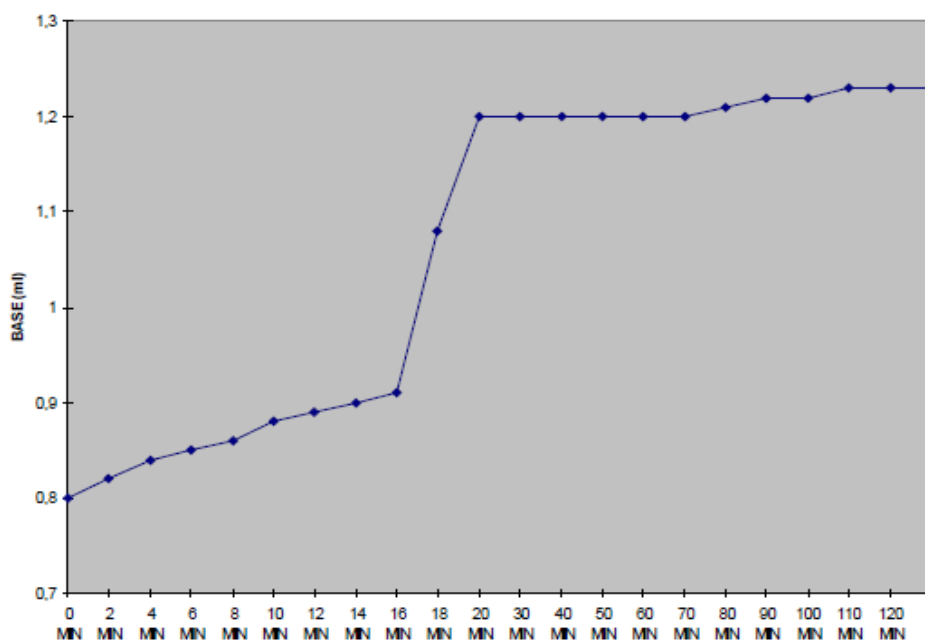
Overall summary of comments on the technological purpose for the use of INS 331(iii) in UHT treated milk from bovine species:

Brazil: The use of trisodium citrate in bovine milk is technologically justified, safe to human health and is not used to mask bad handling practices. Therefore, its use in bovine milk complies with the Codex Alimentarius principles for food additives.

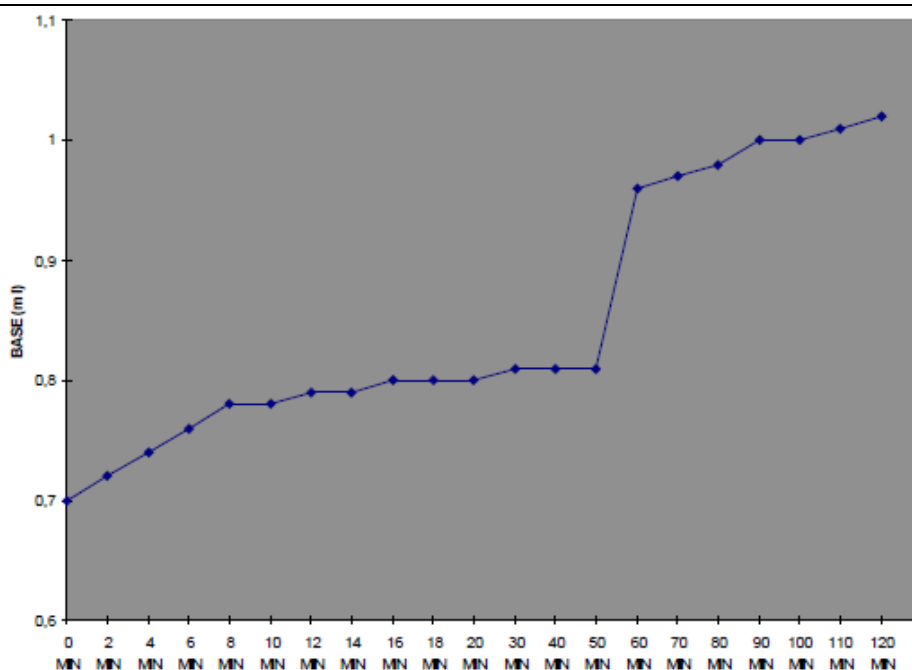
Milk is a colloidal suspension consisting mainly of water, fat, carbohydrates, proteins, mineral substances and organic acids. Milk fat is to a greater extent made up of triacylglycerides, however phospholipids, cholesterol, free fatty acids and diglycerides can also be found. The major carbohydrate found in milk is lactose. Milk consists of different kinds of proteins of which caseins make up about 80% of the total protein content. The serum proteins, also called whey proteins, make up the remaining part of the total protein content and consist of β -lactoglobulin (β -LG), α -lactalbumin, serum albumin, immunoglobulins and peptides. The most commonly found minerals in milk are K, Na, Ca, Mg, Cl and P and the most common organic acid is citrate (Walstra et al., 1999). It means that citrate naturally occurs in milk.

Brazilian bovine cattle milk has a lower content of natural citrate, most probably by the influence of the extensive and semi-extensive breeding system, with the whole herd to the pasture. Feeding of Brazilian cattle based on low nutrient forage results in the production of a milk with saline imbalance (lower sodium citrate content). Thus, the addition of sodium citrate as a stabilizing additive promotes the reduction of the calcium content available for the formation of salt bridges between the protein complexes, thus preventing milk sedimentation, and favoring the stability of this product, as can be observed in the charts:

Graph 1. Induction time of amorphous calcium phosphate formation **without citrate**.



Graph 2. Induction time of amorphous calcium phosphate formation **with citrate**.



Bovine milk produced in Brazil shows average levels of citrate below international limits, as showed bellow:

Reference	Country	Citrate average (as citric acid)
FOX, P.F, 1991	Ireland	176 mg/100 mL
JENNES AND PATTON, 1999	Maryland, EUA	175 mg/100 mL
WALSTRA P. AND JENNES, 1978	New York, EUA	175 mg/100 mL
WHITE & DAVIES, 1958	EUA	179 mg/100 mL
SILVA, P.H.F, 2004	Brasil	158,5 mg/100 mL

Citrate is present in milk distributed in two phases: soluble and colloidal. In the soluble phase, 94% of the milk citrate is present, being bound to calcium and magnesium (85%), as trivalent citrate (14%) and divalent citrate (1%). The casein-bound colloidal citrate represents 6% of the total citrate (Fox, 1991). According to Fox (1991), the additions of citrate and phosphate to milk promote an increase in the thermal stability of the milk, by the sequestering effect on ionic calcium and, especially in the case of citrate, by the conversion to soluble citrate. Phosphates and citrates are recognized in increasing the thermal stability of milk (Fox, 1991).

Despite the favorable effect of citrate addition, excess of citrate may unbalance milk. Addition of sodium phosphates to milk generally increases stability by sequestering calcium 2+, but citrate is more effective. If the milk is stabilized with phosphates, the initial Ca/P ratio is around 1: 1, which can contribute to the deposition of calcium and protein salts in the bottom of the UHT milk package if compared to the product which was added with citrate.

Finally, Brazil believes that this is the reality of most developing countries that keep their bovine cattle exclusively on pasture. Therefore, the restriction of sodium citrate use only for non-bovine species would generate a commercial barrier, excluding these countries from international trade, especially MERCOSUR countries, where the use of citrate in UHT cow's milk is widely used and regulated. Brazil understands that the restriction of the use of citrates only for milks from non-bovine species violates the principle of CODEX, which is to promote equal market conditions among its member countries, while observing food security. Sodium citrate is a natural component of bovine milk and it is a food additive whose IDA is not limited and therefore, does not pose a risk to public health.

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Wiley-Interscience Publ. John Wiley & Sons, Inc. New York.

IDF: Supports the use of INS 331(iii) in milk from bovine species UHT treated in order to prevent Coagulation and sedimentation. The heat treatment to which UHT milk is subjected can destabilize milk proteins by altering its original form, altering its electrical charge, so that protein sedimentation and gelation occur throughout its shelf life. The use of sodium citrate in bovine UHT milk is carried out in order to maintain the stability of the casein micelles by binding sodium citrate with free calcium present in the milk.

About 10% of the total calcium present in the milk is in the ionic phase. Calcium and phosphorus ions act as adjuvants, making the connection between casein micelles. The equilibrium of the ionic phase of calcium with its colloidal phase (associated with phosphorus in casein micelles) and soluble (calcium salts) is decisive for the stability of the milk. The charges of casein micelles are controlled by the amount of calcium bound and, therefore, by the free calcium content present in the milk. With the increase of total calcium in milk, the amount of bound calcium increases and reduces the negative charges of the micelles, which decreases the energy barrier for coagulation. When the calcium content is reduced, there is an increase in the negative charges of the micelles and, as a result, the repulsion between them increases, which makes the coagulation difficult. It is important to note that sodium citrate is a natural stabilizer, but insufficient to immobilize all free calcium in milk.

Appendix 3: Proposed draft provisions related to FC 01.1.2 (Other fluid milks (plain)) with the technological function of emulsifier and stabilizer

1. Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to discuss:¹
 - Draft provisions for food additives related to FC 01.1.2 with the technological function of emulsifier and stabilizer

Background

2. CCFA48 revised the structure, title and descriptor of food category 01.1 (Fluid milk and milk products) and its subcategories. CCFA48 noted that the scope of the new food category 01.1.2 (Other fluid milks (plain)) did not correspond to the scope of a historical food category and therefore there were no provisions for the use of food additives in this food category. CCFA48 subsequently 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.²

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 01.1.2.³ Responses to the circular letter were compiled for CCFA49 and discussed by the physical working group (PWG) on the GSFA to CCFA49.^{4,5} The PWG recommended that specific provisions proposed for food category 01.1.2 be included in the GSFA at Step 2.⁶ CCFA49 agreed to the recommendation of the PWG and requested that the electronic working group (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 and sweetener) and prepare recommendations for those provisions.⁷

4. The PWG on the GSFA to CCFA50 considered the report of the EWG on the GSFA, including proposals for the draft provisions in the GSFA in food category 01.1.2.⁸ However, the PWG was unable to reach consensus on the draft provisions for the use of additives with functional classes that include “thickener”. Several member countries expressed concerns that the use of these food additives had the potential to increase the viscosity of the products under food category 01.1.2 and potentially mislead consumers into mistaking these products for plain fluid milks under food category 01.1.1 (*Fluid milk (plain)*). However, other members in support of the use of these additives noted that these additives were primarily used for their emulsifier and stabilizer functions, which are required for many products under food category 01.1.2 to keep all ingredients in suspension.

5. During the PWG discussion, several Observers provided a description on the range and diversity of products that fall into food category 01.1.2. These products generally contain blends of milk proteins, milk fats and fortification ingredients which had been separated then recombined or reconstituted. It was explained that when all ingredients have been blended together, the natural milk solids and fortification ingredients separate or oxidize, making the food product less desired by consumers. The use of emulsifiers, stabilizers and antioxidants can reduce oxidation and the separation of milk components. The Observer organization noted that clear product labelling should show the use of food additives in products of food category 01.1.2 and not mislead the consumer. Furthermore, the Observer noted that products covered under food category 01.1.2 are specialized milk products that are not intended to replace milk. It was also noted that CCFA had worked for several years to revise food category 01.1 to create a subcategory specifically for various fluid milk products that utilize additives – this work had resulted in the development of food category 01.1.2. It was also noted that the majority of the products under food category 01.1.2 could not exist without the use of emulsifiers and stabilizers, and that, simply due to physical properties, almost all emulsifiers and stabilizers also exhibit thickener function.⁹

6. The discussion of the PWG was continued in the plenary session at CCFA50. The Committee agreed to hold and circulate for comment specific food additive provisions in food category 01.1.2 with the technological function of emulsifier and stabilizer for further discussion on the use level and the specific products within food category 01.1.2 in which the additives are used.¹

¹ REP18/FA para 75(iii).

² Rep 16/FA, para. 86.

³ CL 2016/8-FA

⁴ CX/FA 17/49/9; FA49 CRD12; FA49 CRD19.

⁵ FA/49 CRD2

⁶ FA/49 CRD2 Annex 5.

⁷ REP 17/FA paras 88 and 109.

⁸ CX/FA 18/50/7, Appendix 6.

⁹ FA/50 CRD2

Working Document

7. The EWG issued three circulars for comment. The first circular contained EWG comments on the differences between products which fall under food category (FC) 01.1.2 ((Other fluid milks (plain)) and FC 01.1.1 (Fluid milk (plain)) and on specific draft provisions for food additives in food category 01.1.2, including the use levels needed in order to achieve the intended technological function of emulsifier and stabilizer in specific products formulated with the food additive. Additionally, the first circular requested discussion on concerns pertaining to misleading the consumer in the context of the use of emulsifiers and stabilizers with incidental thickening properties in food category 01.1.2. The second circular contained EWG comments on three different general approach options for the provisions for food additives in food category 01.1.2. The third circular contained EWG comments on a general numeric use level for each additive in modified milk products based on the level at which the additive mainly exhibits stabilizer/emulsifier function and the thickener function is not exhibited to the extent that it would significantly affect the organoleptic properties of the product. Each provision (with the exception of propylene glycol alginate (INS 405)) would also include a note "For use at GMP in milk-based beverages only". The document presents a compilation of comments provided by EWG members to the first, second and third circulars.

Conventions

8. The current document presents recommendations for the draft provisions for food additives related to FC 01.1.2 with the technological function of emulsifier and stabilizer under discussion in the format of the food categories listed in Table 2 of the GSFA. This document presents proposals (adopt, adopt with revision) for the draft provisions under discussion based upon a consensus approach taking into account comments on the first, second and third 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

I. General Summary of comments provided in response to the First Circular

The first circular requested information on the differences between products which fall under food category (FC) 01.1.2 ((Other fluid milks (plain)) and FC 01.1.1 (Fluid milk (plain)). In this context the first circular also requested discussion on concerns pertaining to misleading the consumer in the context of the use of emulsifiers and stabilizers with incidental thickening properties in food category 01.1.2. This circular also requested comment on specific draft provisions for food additives in food category 01.1.2, including the use levels needed in order to achieve the intended technological function of emulsifier and stabilizer in specific products formulated with the food additive.¹⁰

Information submitted in response to the first circular pertaining to the differences between products which fall under food category (FC) 01.1.2 and FC 01.1.1 are summarized below:

- FC 01.1.1 applies to a very limited number of “natural” products that are defined by the processing of milk – FC 01.1.1 is limited to milk processed through pasteurization, UHT treatment, sterilization, homogenization and fat adjustment. The first four of these processes generally do not involve addition or removal of any components of the product, whereas fat adjustment is typically achieved through the addition/removal of milk components.
- FC 01.1.2 covers a wider range of products and processing methods – the processing methods and other factors (for example, fortification) pertaining to these products require the use of additives in these products. EWG members appeared to take two different approaches to subcategorizing these products:
 - 1) “advantage” based subcategorization – these comments focused on the technological justification for additives in the product (a “need” for the additive either due to the processing method, fortification of the product, etc), rather than the “nature” of the product.
 - These comments tended to be in favor of adopting provisions for Table 3 additives at GMP throughout the food category, as all products within the food category may require a function, but the use level may vary even in a particular subcategorization.
 - These comments noted that labeling requirements would inform the consumer of the presence of additives. Many comments also observed that several countries had specific labeling requirements for these products to differentiate them from products in FC 01.1.1.
 - Many of these comments noted that many countries have compositional requirements for milk products. These comments assert that the use of these additives cannot mislead the consumer as to the nature of the product as any product would have to meet these milk component specifications. For example, an additive with thickening properties cannot be used to cover up the use of too much water in a reconstituted milk product, because the reconstituted product must meet the national requirements for milk component content.
 - 2) “nature of product” based subcategorization – these comments asserted that the properties of the products in FC 01.1.2 should be related to the properties of the milk components. Emulsifiers and stabilizers maintain the organoleptic properties of the milk components while thickeners change those organoleptic properties. However, several of these comments also recognized that this food category covers a wide variety of products, and in their view the “nature” of these products varies between subcategorizations:
 - “Modified milks” subcategorization (all products listed in descriptor with exception of milk-based beverages – These products are processed differently than those in FC 01.1.1 but the composition and use patterns of some products in this subcategory (some plain recombined fluid milks, plain reconstituted fluid milks, plain composite milks) are similar to products in FC 01.1.1. Emulsifiers and stabilizers directly related to processing or fortification are justified but other justified technological functions may be limited – some EWG Members do not agree that additives with thickener function should be allowed in these products
 - “Milk-based beverages” subcategorization - composition is significantly different than products in FC 01.1.1, products are marketed/used differently than FC 01.1.1. These products are processed differently, need for additives with a wider range of technological function. Thickeners may be appropriate in these products as the products are more removed from “milk”.

¹⁰ Comments provided in response to the first circular request for information on specific draft provisions for food additives in food category 01.1.2 are summarized in Annex 2 – Third Circular Working Document.

II. General Summary of comments provided in response to the Second Circular

Based on comments submitted to the first circular pertaining to the types of products which fall under food category (FC) 01.1.2, the second circular did not request further information on the specific draft food additive provisions under discussion. Rather, the second circular requested comment on three different general approach options for the provisions under discussion in FC 01.1.2. The intent of the second circular was to reach consensus on one of these approaches, and then to apply the consensus approach to the provisions under consideration during the third circular. The three options, and a general summary of comments on those options submitted in reply to the second circular, are provided below:

1. Apply a note to each provision limiting use to a specific subset of products covered under FC 01.1.2 (for example, “For use in milk-based beverages only”). This approach would limit the use to those foods in the food category that are less “milk like”. EWG members could suggest wording for the appropriate note in response to the Second Circular.

Several EWG members submitted comments in favor of Option 1 as in their opinion “modified milk” products have similar processing to milks and therefore only have the same need for additives as milks in FC 01.1.1, and the use patterns of “modified milk” products are similar to milk, and that any change in the organoleptic properties in “milk like” products misleads the consumer. Other EWG members were opposed to this approach as many of the “modified milk” products in FC 01.1.2 (such as reconstituted, recombined and composite fluid milks) are processed differently than milks under FC 01.1.1 and therefore require different additives. Many of these comments stated that the additives under discussion can be used in those products at appropriate levels that would not have significant thickening effect or appreciably change the organoleptic properties of the product from that inherent to the organoleptic properties of the milk components of the product.

Some EWG members proposed that this approach be revised to exclude only lactose modified or vitamin/mineral fortified milks, but other members noted that the additives under discussion are necessary in those products and cited page 132 of the WHO *Guidelines on food fortification with micronutrients* which stated that calcium fortified milks require gums (such as carrageenan and guar gum) to prevent sedimentation of the calcium salt.

2. Assign a numeric use level to the Table 3 additives based on the level necessary to achieve emulsifier/stabilizer function. Also apply a note to each provision “For use at GMP in milk-based beverages only”. This approach would limit the use of the additives under discussion to the level necessary to achieve emulsifier/stabilizer function in “milk-like” products. Any incidental thickening as a result of use at these levels would be minimal and should not change the organoleptic properties of the product to the extent that the consumer would be misled (for example, milk reconstituted from skim milk powder could not be thickened to appear as whole milk). However, for “milk-based beverages” the additives could be used at levels that may result in appreciable thickening.

Many EWG members did not support this option as food category 01.1.2 covers a wide variety of products and it would be difficult to set a numeric use level as the use level varies widely between these products. Several of these comments also noted that the additives under discussion are Table 3 additives and there is no safety-based reason to set a numeric use level (with the exception of INS 405). However, other EWG members observed that this approach may be the only means to achieve consensus within the committee as it accommodates the technological need for these additives in all products within FC 01.1.2 while addressing concerns of some Members that thickening of modified milks misleads the consumer. Several members noted that “milk-based beverages” should be more clearly defined.

3. Allow use of Table 3 additives at GMP without restriction to specific products. This approach recognizes that FC 01.1.2 covers a wide range of product and one numeric use level may not address the need across all products.

Several EWG members supported this option as these additives are Table 3 additives (with the exception of INS 405), allowing these additives at GMP will not result in a change in the level of milk components in these products so consumers will not be misled. Several of these comments asserted that consumer perception concerns related to the milk component content of modified milk products should be addressed through composition standards and labeling requirements rather than restricting additive use. However, other EWG members did not support this option as they asserted it does not adequately address consumer perception that the organoleptic properties of plain modified milk products are the result of the milk components of the product and not additives.

III. General approach for comments in response to the Third Circular

There was no consensus within the EWG for any of the approaches proposed in the second circular. In reviewing the comments provided to the second circular the EWG Chair observes that there does not appear to be an opportunity for consensus on Approaches 1 or 3: information provided indicates that these additives

are required in modified milk products, therefore there is no opportunity for consensus on Approach 1; several Members are fundamentally opposed to the use of additives to change the organoleptic properties of modified milk, and maximum use levels of GMP do not appear to address those Member's concerns, therefore consensus on Approach 3 is unlikely. However, the EWG Chair also observes that the objections to Approach 2 are technical in nature (*i.e.*, that these additives are used at different levels in different products and therefore it may be difficult to designate a numerical use level that is adequate for all products) and therefore consensus may be achievable on this approach.

The EWG Chair observes that the general objection to GMP is the opportunity for the additives under discussion to thicken modified milk products and therefore change the inherent organoleptic properties that result from the milk components. The general objection to numeric use levels is that it would be difficult to set a numeric level as the actual use level varies widely between modified milk products. However, the EWG Chair notes that the thickening function of these additives is inherent to the additive itself, and therefore should not be milk-product product dependent. Rather than attempting to set a numeric use level for each additive based upon actual use level in specific products, it may be possible to reach consensus on a general use level for each additive in modified milk products based on the level at which the additive mainly exhibits stabilizer/emulsifier function and the thickener function is not exhibited to the extent that it would significantly affect the organoleptic properties of the product.

The third circular working document requested proposals for a general numeric use level for each additive in modified milk products based on the level at which the additive mainly exhibits stabilizer/emulsifier function and the thickener function is not exhibited to the extent that it would significantly affect the organoleptic properties of the product (see Annex 2). The EWG members were asked to provide supporting information and/or discussion as to why the proposed use level would not have significant thickening effect or appreciably change the organoleptic properties of the product from that inherent to the organoleptic properties of the milk components of the product.

Under the approach undertaken in the third circular, each provision (with the exception of INS 405) would also include a note "For use at GMP in milk-based beverages only". For the purposes of defining "milk-based beverages", this term would encompass all products within the scope of FC 01.1.2 not otherwise provided for in the descriptor of the food category (*i.e.*, "milk-based beverages" would include all products with the exception of plain recombined fluid milks, plain reconstituted fluid milks, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks, and lactose reduced milk).

IV. Final EWG Proposal**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)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
CAROB BEAN GUM	410	GMP		2	Emulsifier, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 800 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 410 in FC 01.1.2:**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 to CCFA50:

Brazil: See General Comment below

EU: concerned with the use of thickeners which have impact on the nature of milk.

EU Specialty Food Ingredients: 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.

ICGMA, IFAC: Carob bean gum is used in UHT treated or sterilized, recombined and reconstituted milk as a stabilizer. Gelation of UHT milk during storage is a major factor limiting 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 stabilizes these protein complexes so that the matrix formation is delayed and consequently, the shelf life is extended.

EU Specialty Foods, ICGMA, IFAC: 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: 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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "For Milk Based Beverages only".

India: Doesn't support the proposal to allow use of food additives with thickener function.

NZ: This additive should be permitted at GMP because technological justification has already been provided in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, we disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FC 01.1.1 and FC 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: For use in food in general at GMP

EU Specialty Food Ingredients: Carob bean gum is often used in combination with other emulsifiers, stabilizers & thickeners in this food category. We thus propose up to 800 mg/kg in modified milk products. At the proposed use level stabilizing effect is obtained and thickening is insignificant.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

IFAC: Proposed use level: Up to 800 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
CARRAGEENAN	407	GMP		2	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 1700 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 407 in FC 01.1.2:**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.

Comments to EWG to CCFA50:

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: 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

ICGMA: 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.

Japan: Carrageenan is used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.

NZ: Carrageenan is added to suspend particles in fluid milk to prevent sedimentation. Carrageenan interacts with the milk proteins and thus form a network that keeps the particles suspended. 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 mouthfeel

EU Specialty Foods, ICGMA, IFAC: 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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "For Milk Based Beverages only".

China: The Actual use level in fortified milk and lactose reduced milk is 1000mg/kg. INS 407 is to stabilize the fluid milk products, creating a thixotropic network together with dairy proteins, which can keep solids suspended. It would not have significant thickening effect to final milk product, the viscosity of the modified milk is no difference with the pure milk defined in FC 1.1.1.

Guatemala: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP

India: does not support the proposal to allow the use of additives with thickener function in this food category

Japan: Carrageenan is used at 800 mg/kg as stabilizer to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.

NZ: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. This additive should be permitted at GMP because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by

compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC

Spain: This food additive is authorized in European Union for FC. Dehydrated milk as defined by Directive 2001/114/EC with a use level of Quantum Satis. This category covers partly dehydrated preserved milk and totally dehydrated preserved milk.

Thailand: Products which FA is used: - Pasteurized & UHT recombined/reconstituted milk (whole, partly skimmed ,skimmed); - Pasteurized & UHT recombined/reconstituted milk which are fortified with vitamin, mineral, fiber, protein or DHA; - Lactose reduce recombined milk; Actual use level: Ranged from 150-1,700 mg/kg; Technological justification: - To be used as stabilizer and emulsifier; - To prevent water-fat separation; - To aid the suspension and prevent the sedimentation of solid particles in milk products (e.g., protein and insoluble nutrients) during storage period; - Carrageenan has the property of reacting with proteins which can increase the stability of products.

US: For use in food in general at GMP

EU Specialty Food Ingredients: Carrageenan is often used in combination with other emulsifiers, stabilizers & thickeners in this food category. We thus propose up to 500 mg/kg in modified milk products. At the proposed use level stabilizing effect is obtained and thickening is insignificant.

IFAC: Proposed use level: Up to 500 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See attached general response.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
GELLAN GUM	418	GMP		2	Thickener, Stabilizer	Discuss further the proposal options: i. Adopt at 1500 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 418 in FC 01.1.2:

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.

Comments to EWG to CCFA 50:

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 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

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.

Japan: Gellan gum is used to prevent sedimentation in non-flavoured mineral fortified fluid milks.

NZ: 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.

EU Specialty Foods, ICGMA, IFAC: 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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: The Actual use level in fortified milk and lactose reduced milk is 1500mg/kg, INS418 is 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. It would not have significant thickening effect to modified milk product, the viscosity of the modified milk is no difference with the pure milk defined in FC 1.1.1.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "For Milk Based Beverages only".

Guatemala: As a stabilizer for use in milk based drinks by GMP

India: does not support the proposal to allow the use of additives with thickener function in this food category

Japan: Gellan gum is used at 120 mg/kg as stabilizer to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.

NZ: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, and composite milk products. This additive should be permitted at GMP because technological justification has already been provided in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more

water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FC FC 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: For use in food in general at GMP

EU Specialty Food Ingredients: 500 mg/kg. Only a slight increase in viscosity is measurable when gellan gum is used. However, this increase is well below the threshold, starting from which the product would no longer be perceived as a fluid milk, be it visually (upon pouring product into a glass seeing it flow just “like water”) and per mouth feeling experience. It is understood that the “fluidity” aspect is part of this category “definition”, and this use of gellan gum does not compromise on the aspect of “fluidity” of the products. Onset of a real thickening effect is undesirable technically and unintentional. The stabilization functionality – which is to maintain a uniform dispersion- is the technical purpose of gellan gum addition. Data acquired in 2018 in a rheology lab for the purpose to support this CCFA gellan gum work, conclude on a strong shear-thinning effect of gellan gum and measurements with a Bostwick Consistometer using products of this food category (1.1.2) confirm that products remain as fluid as milk despite addition of gellan gum. These properties render gellan gum in this food category a very suitable candidate for stabilization but not thickening.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

IFAC: Proposed use level: Up to 600 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
GUAR GUM	412	GMP		2	Emulsifier, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 6000 mg/kg with New Note, “Except for use at GMP in milk-based beverages only” ii. GMP in these products

Background information on provision for INS 412 in FC 01.1.2:

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.

Comments to EWG to CCFA 50:

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

ICGMA, IFAC: 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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: The Actual use level in fortified milk is 1000mg/kg. INS 412 is used to stabilize colloidal suspension and prevent sedimentation of solid particles in milk. It would not have significant thickening effect to modified milk. The viscosity of the modified milk is no difference with the pure milk defined in FC 1.1.1.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "*For Milk Based Beverages only*".

Guatemala: As a stabilizer for use in milk based drinks by GMP

India: does not support the proposal to allow the use of additives with thickener function in this food category

Japan: page 132 of the WHO *Guidelines on food fortification with micronutrients* which stated that calcium fortified milks require gums (such as carrageenan and guar gum) to prevent sedimentation of the calcium salt.

NZ: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. This additive should be permitted at GMP because technological justification has already been provided in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FC FC 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: Allowed in milk products as stabilizer at 0.6% (6,000 mg/kg)

EU Specialty Food Ingredients: Guar gum is often used in combination with other emulsifiers, stabilizers & thickeners in this food category. We thus propose up to 800 mg/kg in modified milk products. At the proposed use level stabilizing effect is obtained and thickening is insignificant.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

IFAC: Proposed use level: Up to 800 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
GUM ARABIC	414	GMP	Use in non-flavoured vitamin and mineral fortified fluid milks only	2	Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer,	Discuss further the proposal options: i. Adopt at 500 mg/kg with New Note, "Except for use at GMP in milk-based beverages only"

					Thickener	ii. GMP in these products
Background information on provision for INS 414 in FC 01.1.2:						
Initial Country Comment:						
Japan: Used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.						
Comments to EWG to CCFA 50:						
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, 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						
Overall summary of all comments by EWG Members:						
Brazil, IDF: See general comments.						
Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note " <i>For Milk Based Beverages only</i> ".						
Guatemala: As a stabilizer for use in milk based drinks by GMP						
India: Doesn't support the proposal to allow use of food additives with thickener function.						
Japan: Gum Arabic is used at 500 mg/kg as stabilizer to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.						
NZ: This additive should be permitted at GMP because technological justification has already been provided in Annex 1 and in previous comments and there are no safety concerns for its use at GMP. Furthermore, we disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product.						
Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.						
US: For use in food in general at ML 10,000						
IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.						
IFAC: Proposed use level: GMP in modified milk products. At GMP, there would be no significant thickening effect.						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
HYDROXYPROPYL STARCH	1440	GMP		2	Emulsifier, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 4500 mg/kg with New Note, "Except for use at GMP in milk-based beverages only"

						ii. GMP in these products
Background information on provision for INS 1440 in FC 01.1.2:						
<p>Initial Country Comment:</p> <p>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.</p>						
Comments to EWG to CCFA 50:						
<p>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.</p>						
Overall summary of all comments by EWG Members:						
<p>Brazil: See general comments.</p> <p>Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note <i>"For Milk Based Beverages only"</i>.</p> <p>Guatemala: As a stabilizer for use in milk based drinks by GMP</p> <p>India: Doesn't support the proposal to allow use of food additives with thickener function.</p> <p>NZ: This additive should be permitted at GMP because technological justification has already been provided in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, we disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.</p> <p>Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.</p> <p>Thailand: Products which FA is used: - Pasteurized & UHT recombined/reconstituted milk (whole, partly skimmed ,skimmed); - Pasteurized & UHT recombined/reconstituted milk which are fortified with vitamin, mineral, fiber, protein or DHA; Actual use level: 4,500 mg/kg; Technological justification: - To be used as stabilizer; - To aid the suspension and prevent the sedimentation of solid particles in milk products (e.g., protein and insoluble nutrients) during storage period.</p> <p>US: For use in food in general at GMP</p> <p>IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
MICROCRYSTALLINE CELLULOSE (CELLULOSE GEL)	460(i)	GMP		2	Anticaking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 4500 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 460(i) in FC 01.1.2:

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.

Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milk

Comments to EWG to CCFA 50:

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

Japan: Microcrystalline cellulose is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. This additive is also used in non-flavoured vitamin fortified fluid milks for the same purpose.

NZ: 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: Cellulose gel 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 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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: The Actual use level in fortified milk and lactose reduced milk is 1000mg/kg~3000mg/kg, INS 460(i) could 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. Would not have significant thickening effect to

modified milk, the viscosity of the modified milk is no difference with the pure milk defined in FC 1.1.1.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note *"For Milk Based Beverages only"*.

Guatemala: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML

India: Doesn't support the proposal to allow use of food additives with thickener function.

Japan: Corrects the actual use level of Microcrystalline cellulose (cellulose gel) from 1,600 mg/kg to 2,000 mg/kg. It is used as stabilizer to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milk.

NZ: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. This additive should be permitted at GMP because technological justification has already been provided in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

Thailand: Products which FA is used: - Pasteurized & UHT recombined/reconstituted milk (whole, partly skimmed ,skimmed); - Pasteurized & UHT recombined/reconstituted milk which are fortified with vitamin, mineral, fiber, protein or DHA; - Lactose reduce recombined milk; Actual use level: Ranged from 1,200 - 4,500 mg/kg; Technological justification: - To be used as stabilizer and emulsifier; - To prevent water-fat separation; - To aid the suspension and prevent the sedimentation of solid particles in milk products (e.g., protein and insoluble nutrients) during storage period.

EU Specialty Food Ingredients: Microcrystalline Cellulose is often used in combination with other emulsifiers, stabilizers & thickeners in this food category. We thus propose up to 800 mg/kg in modified milk products. At the proposed use level stabilizing effect is obtained and thickening is insignificant.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

IFAC: Proposed use level: Up to 800 mg/kg in modified milk products. At the proposed use level stabilizing effect is obtained and thickening is insignificant.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
PECTINS	440	GMP		2	Emulsifier, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 3000 mg/kg with New Note, "Except for use at GMP in milk-based beverages only"

						ii. GMP in these products
Background information on provision for INS 440 in FC 01.1.2:						
<p>Initial Country Comment:</p> <p>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.</p>						
Overall summary of all comments by EWG Members:						
<p>Brazil: See general comments.</p> <p>Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note <i>"For Milk Based Beverages only"</i>.</p> <p>Guatemala: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML</p> <p>India: Doesn't support the proposal to allow use of food additives with thickener function.</p> <p>NZ: Widely used as a stabilizer in FC 01.1.2 products, including in fortified, reconstituted, and composite milk products. This additive should be permitted at GMP because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.</p> <p>Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.</p> <p>US: For use in food in general at GMP.</p> <p>EU Specialty Food Ingredients: Added as a stabilizer. Recommended use level is 3000 mg/kg in plain recombined and reconstituted milks. The uses confirmed by EU SFI for a limited number of sub-categories within FC 1.1.2 is not intended to imply that there were no other uses among any of the other sub-categories in FC 1.1.2. Data provided only mean that a member of EU SFI had specific information about that specific use without implying that this use excludes use in any of the other sub-categories of FC 1.1.2. More application/use information will likely be provided during the second circulation of the document.</p> <p>IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.</p> <p>IFAC: Proposed use level: Up to 3,000 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
POLYDEXTROSES	1200	GMP		2	Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 5000 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 1200 in FC 01.1.2:

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.

Comments to EWG to CCFA 50:

ICGMA, IFAC: 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

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: The Actual use level in fortified milk and lactose reduced milk is 1000mg/kg~50000mg/kg, INS1200 is added to contributing to mouthfeel and the perception of creaminess, it would not have significant thickening effect to modified milk product, the viscosity of the modified milk is no difference with the pure milk defined in FC 1.1.1.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "*For Milk Based Beverages only*".

Guatemala: Supports the use by GMP

India: Doesn't support the proposal to allow use of food additives with thickener function.

NZ: This additive should be permitted at GMP because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, we disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2.

There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: For use in food in general at GMP.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
POTASSIUM CARBONATE	501(i)	GMP	Use in non-flavored vitamin and mineral fortified milks only	2	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener Acidity regulator, Stabilizer	According to CXG 36-1989, Potassium Carbonate INS 501(i) only has the technological functions of Acidity regulator, Stabilizer. Therefore, the food additive will not have a technological function of Thickener on the milk product. Adopt as listed.

Background information on provision for INS 501(i) in FC 01.1.2:

Initial Country Comment:

Japan: Used in non-flavoured mineral fortified milk to prevent denaturation of protein during pasteurization.

Comments to EWG to CCFA 50:

Japan: 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.

Overall summary of all comments by EWG Members:

Brazil: Supports the adoption of a numerical use level, considering that it is an additive with numerical ADI (6 mg/kg bw/day). See general comments

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note *"For Milk Based Beverages only"*.

Guatemala: supports the adoption at GMP and the new note

India: does not support the proposal to allow the use of additives with thickener function in this food category

Japan: Proposes adoption at GMP. Several members expressed concern that the use of food additives with the technological function of thickener would mislead the consumer (see FA50 CRD2 p. 7). However, only acidity regulator and stabilizer are listed in potassium carbonate (INS 501(i)) according to the CXG 36-1989. Potassium carbonate is used as acidity regulator to prevent denaturation of protein during pasteurization in non-flavoured vitamin and mineral fortified fluid milks.

NZ: This additive should be permitted at GMP because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, we disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid

milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: For use in food in general at GMP.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
PROPYLENE GLYCOL ALGINATE	405	4000		2	Emulsifier, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 4000 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 405 in FC 01.1.2:

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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: allows at 4000 mg/kg in this FC, but there was no reported use for this circular

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "*For Milk Based Beverages only*".

Guatemala: This additive should be permitted because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at ML proposed

India: Doesn't support the proposal to allow use of food additives with thickener function.

NZ: This additive should be permitted because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at ML proposed. We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should

there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: For use in food in general at ML 3000.

IDF: Support use level of 4000 mg/kg for all products of category 1.1.2.

IFAC: Proposed use level: GMP in modified milk products. At GMP, there would be no significant thickening effect.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	GMP		2	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 3000 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 466 in FC 01.1.2:

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 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.

China: 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.

Japan: Used to prevent sedimentation in non-flavoured mineral fortified fluid milks.

Comments to EWG to CCFA 50:

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.

Japan: 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.

NZ: 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.

EU Specialty Foods, ICGMA, IFAC: 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

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: The Actual use level in fortified milk and lactose reduced milk is 1500mg/kg~2500mg/kg, INS466 is used to stabilize milk by increasing viscosity of the continuous water phase and thereby reducing creaming or sediment rates in fortified milk products. It would not have significant thickening effect to modified milk, the viscosity of the modified milk is actually no difference with the pure milk defined in FC 1.1.1.

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "*For Milk Based Beverages only*".

Guatemala: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML

India: Doesn't support the proposal to allow use of food additives with thickener function.

Japan: Corrects the actual use level of Sodium carboxymethyl cellulose (cellulose gum) from 180 mg/kg to 150 mg/kg. It is used as stabilizer to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milk.

NZ: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products.

This additive should be permitted at GMP because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FC FC 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

Thailand: Products which FA is used: - Pasteurized & UHT recombined/reconstituted milk (whole, partly skimmed, skimmed); - Pasteurized & UHT recombined/reconstituted milk which are fortified with vitamin, mineral, fiber, protein or DHA; - Lactose reduce recombined milk; Actual use level: Ranged from 150-1,700 mg/kg; Technological justification: - To be used as stabilizer and emulsifier; - To prevent water-fat separation; - To aid the suspension and prevent the sedimentation of solid particles in milk products (e.g., protein and insoluble nutrients) during storage period.

US: For use in food in general at GMP.

EU Specialty Food Ingredients: Added as a stabilizer. Recommended use level is 2000 mg/kg in plain recombined and reconstituted milks. The uses confirmed by EU SFI for a limited number of sub-categories within FC 1.1.2 is not intended to imply that there were no other uses among any of the other sub-categories in FC 1.1.2. Data provided only mean that a member of EU SFI had specific information about that specific use without implying that this use excludes use in any of the other sub-categories of FC 1.1.2. More application/use information will likely be provided during the second circulation of the document.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See attached general response

IFAC: Proposed use level: Up to 3000 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	EWG Final Proposal
XANTHAN GUM	415	GMP		2	Emulsifier, Foaming agent, Stabilizer, Thickener	Discuss further the proposal options: i. Adopt at 800 mg/kg with New Note, "Except for use at GMP in milk-based beverages only" ii. GMP in these products

Background information on provision for INS 415 in FC 01.1.2:

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 fluid milks.

Comments to EWG to CCFA 50:

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 Fermented milk (natural / simple) without heat treatment after fermentation and 01.2. 1.2 Fermented milk (natural / simple) heat-treated after fermentation

Japan: 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: 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.

Overall summary of all comments by EWG Members:

Brazil: See general comments.

China: Allows at GMP in this FC, but there was no reported use for this circular

Colombia: Supports the adoption of the proposed additive in FC 01.1.2. However, taking into account that this category includes plain recombined fluid milks, plain reconstituted fluid milk, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks and lactose reduced milk, which are considered in Colombia similar to Fluid milks (plain), with the same needs as those of FC 01.1.1, Colombia proposes to include a note "For Milk Based Beverages only".

Guatemala: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML

India: Doesn't support the proposal to allow use of food additives with thickener function.

Japan: Xanthan gum is used at 140 mg/kg as stabilizer to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks

NZ: Widely used as a stabilizer in FC 01.1.2 products, including in fortified, reconstituted and composite milk products. This additive should be permitted at GMP because technological justification has already been provided, in Annex 1 and in previous comments, and there are no safety concerns for its use at GMP. Furthermore, this additive is often used in combination with other stabilizers and emulsifiers and so there will be varied use levels depending on how additives are combined in a particular product. Therefore, the most appropriate ML would be "GMP". We disagree that the use of this additive has the potential to mislead consumers to believe that the product is a FC 01.1.1 product because taken as a whole, the label will indicate to the consumer that it is a FC 01.1.2 product. The amount of any thickening effect is self-limiting beyond which products would be no longer be fluid milks. Should there be concerns that thickening is accompanied with the addition of extra water, our comment is that the addition of water would normally be limited by compositional requirements set for the milk product concerned under national legislation. Too much water will dilute other milk components below what is stipulated in the compositional requirements. Consumers are further protected by the need to declare water as an ingredient when added at eg 5% or more water. This would include reconstituted milk where more water is added than needed to reconstitute the product.

Russian Federation: The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FCs 01.1.1 and 01.1.2. There is not technological justification for to use of this FA in all species of fluid milks included in this FC.

US: For use in food in general at GMP.

EU Specialty Food Ingredients: Xanthan gum is often used in combination with other emulsifiers, stabilizers & thickeners in this food category. We thus propose up to 800 mg/kg in modified milk products. At the proposed use level stabilizing effect is obtained and thickening is insignificant.

IDF: Widely used as a stabilizer in FC 01.1.2 products globally, including in fortified, reconstituted, recombined and composite milk products. Use levels are varied as the additive is often used in combination with other stabilizers and emulsifiers. This additive should be permitted at GMP rather than be limited to a specific ML. See IDF general comment.

IFAC: Proposed use level: Up to 800 mg/kg in modified milk products. At this proposed use level, the stabilizing effect is obtained and thickening is insignificant.

Appendix 4: Draft and proposed draft provisions in Table 1 and 2 of the GSFA in food categories 01.0 through 16.0, with the exception of those additives with technological functions of colour (excluding those provisions discussed in point (i)) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from CCSCH, CCPFV or CCFO

1. Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to:¹
 - Request information on actual use levels and technological justification on the proposed food additive provisions held at the current step in Table 1 and 2 of the GSFA in food categories 01.0 through 16.0, with the exception of those additives with technological functions of colour (excluding those provisions discussed in the Step process in food categories 05.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 05.3 (Chewing gum), 05.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces)) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 aligned its subcategories, and provisions awaiting a reply from CCSCH, CCPFV or CCFO.

Introduction

2. CCFA50 agreed that the EWG on the GSFA to CCFA51 should prepare proposals for the remaining draft and proposed draft provisions for food additives in food categories 01.0 through 16.0, with the exception of provisions for food additives with technological functions of colour (excluding those provisions discussed in point (i)) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from CCSCH, CCPFV or CCFO.

Working document

3. The EWG issued three circulars for comment. The current document contains the remaining draft and proposed draft provisions in Tables 1 and 2 of the GSFA in food categories 01.0 through 16.0. However, within food categories 01.0 through 16.0 this Appendix does not include draft and proposed draft provisions for:

- The provision for trisodium citrate (INS 331(iii)) in FC 01.1.1, which is discussed in Appendix 2 of this circular;
- Proposed draft provisions in food category 01.1.2 for food additives with emulsifier or stabilizer function, which are discussed in Appendix 3 of this circular;
- Food additives with “sweetener” or “colour” function (provisions for additives with “colour” function in food categories 05.2, 05.3, and 05.4 are discussed in Appendix 1 of this circular);
- 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/or CCFA50 and therefore are not appropriate subjects for the EWG on the GSFA.²;
- Provision related to FC 14.2.3 and its subcategories; and
- Provisions awaiting a reply from CCSCH, CCPFV or CCFO.

4. The current document presents proposals 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, the decision of the physical working groups (PWGs) to the 45th and 46th CCFA as to the justification of emulsifiers, stabilizer, thickeners, or acidity regulators in that food category and comments on the first, second and third circular 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.

5. The third circular presents the provisions under discussion in the format of the food categories listed in Table 2 of the GSFA. The following conventions were used to prepare the second circular:

- When the recommendation 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.

¹ REP 18/FA, para. 112.

² REP 17/FA paras 86 and 87, 106.

Draft and proposed draft provisions in the GSFA in FC 01.0 to FC 16.0, except for those additives with technological functions of colour (excluding those provisions discussed in point (i)) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from CCSC, CCPFV or CCFO

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

Corresponding commodity standards: None

General Note: Information provided by New Zealand in CX/FA 18/50/8:

- **New provision.** Submitted by New Zealand at CCFA50 (CX/FA 18/50/8)
- Chair note: several acidity regulators were adopted into this FC by CCFA50 with the note “excluding lactose reduced milks”
- **Justification:** See CX/FA 18/50/8 for full information: Sodium hydroxide is widely used as an acidity regulator (alkali agent). It is used to adjust the pH of milk, enhancing protein stability of sterilized and UHT treated milk. The new request is consistent with several adopted provisions in the GSFA including: FC 01.2.1.2, FC 13.1.1, FC 13.1.3, and FC 13.1.2 follow-up.
- **Safety:** Table 3 Additive.
- **Mislead Consumer:** The use of sodium hydroxide at GMP is technically justified and safe. Its use as a food additive does not change the nature of products or disguise the effects of the use of faulty raw materials which could mislead consumer.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
SODIUM HYDROXIDE	524	GMP	AAA ³	2	Acidity regulator	Adopt with note “excluding lactose reduced milks” – no information provided why use would mask spoiled milk when other approved acidity regulators were found to be technologically justified at GMP by 50 th CCFA.	<p>Saudi Arabia, IDF, USA, Indonesia, Guatemala, Paraguay, Costa Rica, FoodDrinkEurope: Supports proposal</p> <p>New Zealand, Australia: supports the proposal. It is a widely used acidity regulator to adjust the pH of milk, enhancing protein stability of sterilized and UHT treated milk. The new request is consistent with several adopted provisions in the GSFA including: FC 01.2.1.2, FC 13.1.1, FC 13.1.3, and FC 13.1.2 follow-up.</p> <p>RU: Strongly opposite proposal. The proposal cannot be considered before the introduction of classification and definition for the different types of milk included in the FC 01.1.1 and FC 01.1.2.</p> <p>Brazil: does not support. Promotes acidity correction on milk, it can be used to disguise undesirable (including unhygienic) practices, thus hampering the progression of milk improvement programs underway in a number of developing countries. It helps to mask low quality milk, being used in milk fraud. Therefore, its use would represent a</p>

³ New Note AAA - Excluding lactose reduce milks

							<p>“regularization” of fraud and a considerable loss in programs to improve milk quality, especially in Brazil, where it is underway and achieving excellent results. The permission of these additives could imply a regression to the advances already obtained. Asks technological need and discussion on how the use will not mislead the consumer (i.e., is not used to lower pH to cover spoilage, is not used to mask bad handling practice, etc).</p> <p>EU: is concerned about the information provided by Brazil related to fraudulent practices in milk production. If this was correct the use of INS 524 would indeed NOT fulfill the requirements of the GSFA Preamble section 3.2.</p>
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Food Category No. 01.6.4 (Processed cheese)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	5000		7	Emulsifier	Adopt at 500 mg/kg	<p>Japan: supports the adoption 500 mg/kg. Used in processed cheese at 500 mg/kg to prevent separation of oil and fat while processing and provide stable emulsification in final product.</p> <p>IDF: Supports proposal, has reports of use at 500 mg/kg</p> <p>Australia: no Australian permission for cheese and cheese products which is the relevant food category</p> <p>Brazil: Considering an ADI of 7.5 mg/kg bw/d, and the proposed level of 5000 mg/kg, a child of 15 kg could consume only 22.5 g of processed cheese not to exceed ADI. So, the ML should be reduced</p> <p>Guatemala, Costa Rica, FoodDrinkEurope, Paraguay: Supports adoption</p> <p>RU, Indonesia: Does not support; Low ADI</p>
Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
TARTRATES	334, 335(ii),	34900	45 - “as tartaric	7	All: Acidity regulator ,	Adopt at 30,000 with note 45 “as	<p>Saudi Arabia: Needs more technological justification</p> <p>IDF: supports level of 30,000 mg/kg with reports by members</p>

	337		acid"		<p>Sequestrant</p> <p><u>INS 334:</u> Antioxidant, Flavour enhancer</p> <p><u>INS 335(ii) and 337:</u> Emulsifying salt, Stabilizer</p>	<p>tartaric acid"".</p>	<p>of use at these levels. Processed cheese requires the emulsification of the high level of milkfat in the product and this is accomplished traditionally through the use of citrates, tartrates or phosphates with a long history of use of these emulsifying food additives in many parts of the world. Tartrates emulsify the milk fat so that upon heating or melting (main processes to make processed cheese), the globules of milkfat/cheesefat do not separate out and create a product that becomes watery and does generally hold its shape. The use of tartrates is also important to meet consumer expectations related to product texture and product consistency.</p> <p>Australia: Permitted at GMP for the relevant food category, being cheese and cheese products in Australia.</p> <p>Brazil: Supports reduction of proposed ML Considering the ML of the additive of 30,000 mg/kg and an ADI of 30 mg/kg bw/d, and the proposed level of 34,900 mg/kg, a child of 15 kg could consume only 12 g of processed cheese not to extrapolate ADI. This consumption would represent approximately 125% of the ADI for children with 15kg. So, the ML should be reduced. Not allowed in processed cheese according to Brazilian legislation, no info on use level;</p> <p>Indonesia, Guatemala, Costa Rica, FoodDrinkEurope, Paraguay: Supports adoption</p> <p>RU: Does not support proposal; no technological justification. ADI=7,5 mg/kg bm. So on ML is high. At ML 34,900 child ≤ 20 kg reaches ADI with 17 g processed cheese. ML is high established ADI for adult consumers with bm=60 kg more than in 19 times.</p> <p>USA: INS 335(ii) and 337 allowed in processed cheese at 3% (30,000 mg/kg) of the finished product when used singly or in combination with other emulsifying agents. INS 334- Allowed in foods in general at GMP</p> <p>EU: Supports seeking further information and restricting the use and ML</p>
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Food Category No. 01.7 (Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt))

Corresponding commodity standards: 243-2003: allows various additives in various foods

General Note: Information provided by Japan in CX/FA 17/49/9:

- **Revision of existing provision**
- **Justification:** Codex standard for fermented milks (CODEX STAN 243-2003) permits the use of INS 491 - 495 as an emulsifier in flavoured products. However, the GSFA currently permits the use of these additives in this FC but excludes all products conforming to CODEX STAN 243-2003. To align the GSFA provision with CODEX STAN 243-2003, proposes that Note XS 243 be replaced with Note 362 “Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)”.
- **Safety:**
 - INS 491-495: Notes 26th JECFA evaluation. As this proposal is for alignment with existing Codex Standard, proposal does not affect total dietary exposure to sorbitan esters of fatty acids. If the CCFA needs further information on exposure of this additive from Food category 01.7, the CCFA should collect information from relevant commodity committee.
 - INS 473, 473(a), 474: Notes 73rd JECFA evaluation (p.256 – 268) <http://www.inchem.org/documents/jecfa/jecmono/v62je01.pdf> which estimates dietary exposure based on poundage data and national intake survey data from USA and Japan which found levels are well below the upper bound of the JECFA ADI (see CX/FA 17/49/9 for details).
 - INS 334, 335(ii), 337: Notes 17th and 21st JECFA evaluation. State: As this proposal is for alignment with existing Codex Standard, proposal does not affect total dietary exposure to tartrates. According to the Total Diet Study (market basket method) conducted by Ministry of Health of Japan in in 1998, 199, daily intake of L(+) tartaric acid is 65.1 mg/person (1.18 mg/kg bw), which is far below the upper bound of the JECFA ADI.
- **Mislead Consumer:** The use does not affect nature and quality of the food that would be expected by consumers.

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	5000	362	2	Emulsifier, Stabilizer	Revise the adopted provisions in the FC to remove note XS243 and add Note 362 “excluding plain products conforming to CODEX STAN 243”	Australia, EU, Indonesia, Japan, Malaysia, Guatemala, Costa Rica, IDF, FoodDrinkEurope, Saudi Arabia, IDF: supports the proposal to align with CXS 243-2003. Brazil: supports the proposal. Allowed as emulsifier and stabilizer in “other desserts” with ML of 5000 mg/kg.
SUCROGLYCERIDES	474	5000	348 & 362	2	Emulsifier	Revise the adopted provisions in the FC to remove note XS243 and add Note 362 “excluding plain products conforming to CODEX STAN 243”	RU: Does not support proposal; no technological justification. ML is high established ADI for adult consumers with bm=60kg more than in 3 times. At ML 5000 child ≤ 20 kg reaches ADI with 100 g processed cheese. USA: CODEX STAN 243-2003 limits the use of emulsifiers to flavoured products but permits the use of stabilizers in reconstituted and recombined plain fermented milks and in all plain and flavoured fermented milk heat treated after fermentation.
SUCROSE ESTERS OF FATTY ACIDS	473	5000	348 & 362	2	Emulsifier, Glazing agent, Stabilizer	Revise the adopted provisions in the FC to remove note XS243 and add Note	

						362 “excluding plain products conforming to CODEX STAN 243”	
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473(a)	5000	348 & 362	2	Emulsifier, Glazing agent, Stabilizer	Revise the adopted provisions in the FC to remove note XS243 and add Note 362 “excluding plain products conforming to CODEX STAN 243”	
TARTRATES	334, 335(ii), 337	2000	45 & 362	2	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	Revise the adopted provision to remove note XS243 and add new note “excluding plain fermented milks and drinks based on fermented milks not heat treated after fermentation conforming to CXS-243-2003.”	<p>Australia, EU, Brazil, US, Indonesia, Malaysia, IDF, Guatemala, Costa Rica, IDF, FoodDrinkEurope: Supports proposal</p> <p>RU: Does not support</p> <p>Japan: proposes removing Note 403 and adding new note “excluding plain fermented milks and drinks based on fermented milk not heat treated after fermentation conforming to CXS 243-2003”.</p> <p>CXS 243-2003 permits the use of tartrates as acidity regulator in flavoured fermented milks and drinks based on fermented milk not heat treated after fermentation, and flavoured/plain fermented milks and drinks based on fermented milk heat treated after fermentation by CXS 243-2003.</p>
Background information on provisions in FC 01.7							
Chair’s Note: These proposals are to revise the adopted provisions in this FC to align provision with CODEX STAN 243.							

Food Category No. 04.1.1.2 (Surface treated fresh fruit)

Descriptor: The surfaces of certain fresh fruit are coated with glazes or waxes or are treated with other food additives that act as protective coatings and/or help to preserve the freshness and quality of the fruit. Examples include apples, oranges, dates, and longans.

Horizontal approach (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): acidity regulators not horizontally justified - ES&T on hold until secondary additives discussion

Corresponding commodity standards: 143-1985: Standard does not address coatings

General Note: CCFA45 discussed the horizontal approach to Table 3 ES&T and initially proposed that ES&T are horizontally justified in this FC with a note “for use in glaze, coating, and decoration only”. However, during discussion on FC 04.2.1.2 the Committee noted that the use of additives in coatings may be a secondary additive use and held the provisions for discussion at CCFA46 (REP13/FA paras 82-85). The PWG on the GSFA to CCFA46 held these provisions for further discussion on secondary additives (CCFA46 CRD2). CCFA49 discussed that secondary additives could be addressed by using notes within the current GSFA food category system (REP 16/FA).

General Summary of comments submitted to First and Second Circular and Third Circular Proposal pertaining to horizontal approach (FC 04.1.1.2)

General Summary of comments to horizontal approach

For Food Category (FC) 04.1.1.2 the first and second circulars focused on a horizontal approach to the use of Table 3 emulsifiers, stabilizers and thickeners (ES&T) in coatings (*i.e.*, glazes or waxes) applied to the outside of fresh fruit.

The first circular requested comment on a horizontal approach where provisions for Table 3 ES&T were adopted at GMP with a note limiting use to glaze coatings or decorations only. The first circular also requested further information on how coatings are used in this FC (*i.e.*, range of foods that use coatings, if ES&T are used in all coatings, and advantage of ES&T use). Most comments submitted to 1st Circular were in favor of developing a horizontal approach for the use of Table 3 emulsifiers and stabilizers in coatings/waxes/glazes applied to the surface of fresh fruit. The main subject of disagreement was whether this use is appropriate for fruits with edible peels.

The second circular requested information from EWG members on how coatings on fresh fruit are used in their region - specifically whether they allow coatings on fresh fruit with edible peels. The second circular also asked for comment on how consumer expectations on the use of coatings on fresh fruit is addressed by EWG members. The majority of comments submitted in response to the second circular stated that wax and coatings are used on fruits with both edible and non-edible peels and members have relied on the combination of both labeling and historical use to inform consumers of use. Comments also refer to the importance of these products in regions that lack access to refrigerated or modified atmosphere storage and transportation equipment, as well as areas that lack a well-connected shipping and transportation infrastructure. Comments noted that there were no safety concerns for these additives as the provisions under discussion are all for Table 3 additives. The only comments which opposed to these provisions generally were for those food additives with the technological function of firming agent, which some EWG members stated could be used to mislead the consumer if their application had an effect on the fruit itself.

The third circular sought comment on the proposal to apply a horizontal approach to FC 04.1.1.2 that all Table 3 additives with ES&T function (with the exception of those with the technological function of firming agent) are justified at GMP with the note “For use in waxes, coatings, or glazes applied to the surface of fresh fruit only.” Adopt those provisions for Table 3 ES&T that do not have the technological function of firming agent and discontinue all provisions with the technological function of firming agent (INS 511 and 466). All comments supported the proposal to discontinue the provisions with the technological function of firming agent. Most comments supported the adoption of the provisions with the proposed note. One comment suggested that the note be revised to read “for use as a secondary food additive in waxes, coating, or glazed applied to the surface of fresh fruit only.”

Final EWG Proposal:

Apply a horizontal approach to FC 04.1.1.2 that all Table 3 additives with ES&T function (with the exception of those with the technological function of firming agent) are justified at GMP with the note “For use in waxes, coatings, or glazes applied to the surface of fresh fruit only.” Adopt those provisions for Table 3 ES&T that do not have the technological function of firming agent and discontinue all provisions with the technological function of firming agent (INS 511 and 466).

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
ACETIC AND FATTY ACID ESTERS OF GLYCEROL	472a	GMP	16	7	Emulsifier, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
ACETYLATED DISTARCH PHOSPHATE	1414	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
AGAR	406	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
ALGINIC ACID	400	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
AMMONIUM ALGINATE	403	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
CALCIUM ALGINATE	404	GMP		7	Antifoaming agent, Bulking agent, Carrier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
CAROB BEAN GUM	410	GMP		7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
CARRAGEENAN	407	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
CITRIC AND FATTY ACID ESTERS OF GLYCEROL	472c	GMP	16	7	Antioxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
GELLAN GUM	418	GMP		7	Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
GUAR GUM	412	GMP		7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
GUM ARABIC (ACACIA GUM)	414	GMP	16	7	Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
HYDROXYPROPYL CELLULOSE	463	GMP	16	7	Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
HYDROXYPROPYL METHYL CELLULOSE	464	GMP	16	7	Bulking agent, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
HYDROXYPROPYL STARCH	1440	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
KARAYA GUM	416	GMP		7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
KONJAC FLOUR	425	GMP		7	Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
LACTIC AND FATTY ACID ESTERS OF GLYCEROL	472b	GMP	16	7	Emulsifier, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
LECITHIN	322(i)	GMP	16	7	Antioxidant, Emulsifier	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
MAGNESIUM CHLORIDE	511	GMP	16	7	Colour retention agent, Firming agent, Stabilizer	Discontinue as per horizontal approach
METHYL CELLULOSE	461	GMP	16	7	Bulking agent, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
METHYL ETHYL CELLULOSE	465	GMP	16	7	Emulsifier, Foaming agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
MICROCRYSTALLINE CELLULOSE (CELLULOSE GEL)	460(i)	GMP	16	7	Anticaking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
MONO- AND DI-GLYCERIDES OF FATTY ACIDS	471	GMP	16	7	Antifoaming agent, Emulsifier, Glazing agent, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
OXIDIZED STARCH	1404	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
PECTINS	440	GMP		7	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
POTASSIUM ALGINATE	402	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
POWDERED CELLULOSE	460(ii)	GMP	16	7	Anticaking agent, Bulking agent, Emulsifier, Glazing agent, Humectant,	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
					Stabilizer, Thickener	
PROCESSED EUCHEUMA SEAWEED (PES)	407a	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
SALTS OF MYRISTIC, PALMITIC AND STEARIC ACIDS WITH AMMONIA, CALCIUM, POTASSIUM AND SODIUM	470(i)	GMP	16 & 71 – "calcium, potassium and sodium salts only"	7	Anticaking agent, Emulsifier, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
SALTS OF OLEIC ACID WITH CALCIUM, POTASSIUM AND SODIUM	470(ii)	GMP	16	7	Anticaking agent, Emulsifier, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
SODIUM ALGINATE	401	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	GMP	16	7	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Discontinue as per horizontal approach
TARA GUM	417	GMP		7	Gelling agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
TRAGACANTH GUM	413	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"
XANTHAN GUM	415	GMP		7	Emulsifier, Foaming agent, Stabilizer,	Adopt with New Note "For use in waxes, coatings, or glazes applied to the surface of fresh fruit only"

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
					Thickener	surface of fresh fruit only"

Food Category No. 04.2.1.2 (Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes (including soybeans), and aloe vera), seaweeds and nuts and seeds)

Descriptor: The surfaces of certain fresh vegetables are coated with glazes or waxes or are treated with other food additives that act as protective coatings and/or help to preserve the freshness and quality of the vegetable. Examples include: avocados, cucumbers, green peppers and pistachio nuts.

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

Corresponding commodity standards: None

General Note: CCFA45 discussed the horizontal approach to Table 3 ES&T. However, the Committee could not come to agreement on use of ES&T in FC 04.2.1.2. Several delegations recommended to limit application to a number of product (e.g. nuts). Other noted these additives are used in a broader range of product, for example waxed cucumbers. The Committee noted that the use of additives in coatings may be a secondary additive use and held the provisions for discussion at CCFA46 (REP13/FA paras 82-85). The PWG on the GSFA to CCFA46 held these provisions for further discussion on secondary additives (CCFA46 CRD2). CCFA49 discussed that secondary additives could be addressed by using notes within the current GSFA food category system (REP 16/FA).

General Summary of comments submitted to First and Second Circular and Third Circular Proposal pertaining to horizontal approach (FC 04.2.1.2)

General Summary of comments to 1st and 2nd circulars:

For Food Category (FC) 04.2.1.2 the first and second circulars focused on a horizontal approach to the use of Table 3 emulsifiers, stabilizers and thickeners (ES&T) in coatings (*i.e.*, glazes or waxes) applied to the outside of fresh vegetables.

The first circular requested comment on a horizontal approach where provisions for Table 3 ES&T were adopted at GMP with a note limiting use to glaze coatings or decorations only. The first circular also requested further information on how coatings are used in this FC (*i.e.*, range of foods that use coatings, if ES&T are used in all coatings, and advantage of ES&T use). Most comments submitted to 1st Circular were in favor of developing a horizontal approach for the use of Table 3 emulsifiers and stabilizers in coatings/waxes/glazes applied to the surface of fresh vegetables. The main subject of disagreement was whether this use is appropriate for vegetables with edible peels.

The second circular requested information from EWG members on how coatings on fresh vegetables are used in their region - specifically whether they allow coatings on fresh vegetables with edible peels. The second circular also asked for comment on how consumer expectations on the use of coatings on fresh vegetables is addressed by EWG members. Comments submitted in response to the second circular indicate a difference in use of coatings on fresh vegetables, where some EWG members allow coatings on fresh vegetables with both edible and inedible peels, and others only allow coatings on nuts. Those in favour of the use of coatings on vegetables, including vegetables with edible peels, noted that the descriptor of FC 04.2.1.2 lists vegetables with edible peels, e.g. peppers, and non-edible peels e.g. avocado. These members stated they have relied on the combination of both labeling and historical use to inform consumers of use. These members also observed that the technological justification for the use of coatings (*i.e.*, to prolong the shelf life) is applicable to vegetables with or without edible peels, and that using coatings to achieve this benefit does not change the "unprocessed" nature of the vegetable. Those opposed to the use of coatings on vegetables assert that consumers expect that fresh unprocessed vegetables do not contain food additives so the use of additives would mislead consumers. Comments to the second circular also contend that additives with firming agent function should not be used with fresh vegetables.

The third circular requested information from the EWG members on whether or not waxes/ coatings/ glazed are applied to fresh vegetables in specific regions. The third circular also requested comment from the EWG members on the application of a horizontal approach to FC 04.2.1.2 that all Table 3 additives with ES&T function (with the exception of those with

the technological function of firming agent) are justified at GMP with the note “For use in waxes, coatings, or glazes applied to the surface of fresh vegetables only.” Discontinue all provisions with the technological function of firming agent (INS 466, 509, 511 and 516). Pertaining to the criteria for the use of food additives as outlined in Section 3.2 of the preamble to the GSFA, information provided to the working group demonstrates that coatings applied to fresh vegetables and the use of additives in those coatings, are technologically justified, have an advantage, and are safe. Comments submitted in response to the third circular indicate a difference in use of coatings on fresh vegetables, where some EWG members allow coatings on fresh vegetables with both edible and inedible peels, and others oppose the use other than on nuts. Those in favor of the horizontal approach, note that the use of waxes, coatings and glazes do not change the nature, substance, or quality of the food in such a way so as to deceive the consumer. Those who oppose the horizontal approach assert that waxes/coatings/glazes are not applied to fresh vegetables in their region and that consumers expect that fresh vegetables would not include additives.

EWG final proposal for horizontal approach: Apply a horizontal approach to FC 04.2.1.2 that all Table 3 additives with ES&T function (with the exception of those with the technological function of firming agent) are justified at GMP with the note “For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds.” Discontinue all provisions with the technological function of firming agent (INS 466, 509, 511 and 516).

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
ACETIC AND FATTY ACID ESTERS OF GLYCEROL	472a	GMP	16	7	Emulsifier, Sequestrant, Stabilizer	Adopt with New Note “For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds.”
ACETYLATED DISTARCH PHOSPHATE	1414	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note “For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds.”
AGAR	406	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note “For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds.”
ALGINIC ACID	400	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note “For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds.”
AMMONIUM ALGINATE	403	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note “For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds.”

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
CALCIUM ALGINATE	404	GMP		7	Antifoaming agent, Bulking agent, Carrier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
CALCIUM CHLORIDE	509	800	58	7	Firming agent, Stabilizer, Thickener	Discontinue as per horizontal approach
CALCIUM SULFATE	516	800	58 – as calcium	7	Acidity regulator, Firming agent, Flour treatment agent, Sequestrant, Stabilizer	Discontinue as per horizontal approach
CAROB BEAN GUM	410	GMP		7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
CARRAGEENAN	407	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
CITRIC AND FATTY ACID ESTERS OF GLYCEROL	472c	GMP	16	7	Antioxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
GELLAN GUM	418	GMP		7	Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
GUAR GUM	412	GMP		7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
HYDROXYPROPYL CELLULOSE	463	GMP	16	7	Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
HYDROXYPROPYL METHYL CELLULOSE	464	GMP	16	7	Bulking agent, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
HYDROXYPROPYL STARCH	1440	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
KARAYA GUM	416	GMP		7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
KONJAC FLOUR	425	GMP		7	Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
LACTIC AND FATTY ACID ESTERS OF GLYCEROL	472b	GMP	16	7	Emulsifier, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
LECITHIN	322(i)	GMP	16	7	Antioxidant, Emulsifier	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
MAGNESIUM CHLORIDE	511	GMP	16	7	Colour retention agent, Firming agent, Stabilizer	Discontinue as per horizontal approach
METHYL CELLULOSE	461	GMP	16	7	Bulking agent, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
METHYL ETHYL CELLULOSE	465	GMP	16	7	Emulsifier, Foaming agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
MICROCRYSTALLINE CELLULOSE (CELLULOSE GEL)	460(i)	GMP	16	7	Anticaking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
MONO- AND DI-GLYCERIDES OF FATTY ACIDS	471	GMP	16	7	Antifoaming agent, Emulsifier, Glazing agent, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
OXIDIZED STARCH	1404	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
PECTINS	440	GMP		7	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
POTASSIUM ALGINATE	402	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
POTASSIUM DIHYDROGEN CITRATE	332(i)	GMP	16	7	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
POWDERED CELLULOSE	460(ii)	GMP	16	7	Anticaking agent, Bulking agent, Emulsifier, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
PROCESSED EUCHEUMA SEAWEED (PES)	407a	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal
SALTS OF MYRISTIC, PALMITIC AND STEARIC ACIDS WITH AMMONIA, CALCIUM, POTASSIUM AND SODIUM	470(i)	GMP	16 & 71	7	Anticaking agent, Emulsifier, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
SALTS OF OLEIC ACID WITH CALCIUM, POTASSIUM AND SODIUM	470(ii)	GMP	16	7	Anticaking agent, Emulsifier, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
SODIUM ALGINATE	401	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	GMP	16	7	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Discontinue as per horizontal approach
TARA GUM	417	GMP		7	Gelling agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
TRAGACANTH GUM	413	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
TRIPOTASSIUM CITRATE	332(ii)	GMP	16	7	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."
XANTHAN GUM	415	GMP		7	Emulsifier, Foaming agent, Stabilizer, Thickener	Adopt with New Note "For use in waxes, coatings, or glazes where these surface treatments are allowed for application to the surface of fresh vegetables, seaweeds, and nuts and seeds."

Food Category No. 05.1.4 (Cocoa and chocolate products)

Corresponding commodity standards: 87-1981: refers to acidity regulators, antioxidants, bulking agents, colours, emulsifiers, glazing agents, and sweeteners listed in GSFA FC 05.1.4. Also specific Table 3 additives.

General Note: CCFA49 discussed the use of INS 473 in this FC but it was noted that this additive was not listed in CODEX STAN 87-1981. It was decided that proposals to list INS 473, 473a, and 474 in FC 05.1.4 and CODEX STAN 87-1981 should be submitted in response to the CL for new or revised adopted provisions (REP 17/FA para 61)

Information provided by Japan in CX/FA 18/50/8:

- **Justification:** CXS 87-1981, amended in 2016, permits to use emulsifiers in general in accordance with Tables 1 and 2 of the General Standard for Food Additives (CXS 192-1995) in FC 05.1.4 and its parent food categories
- **Exposure:** Japan provided dietary exposure data based on poundage and national nutrition survey.
- **Mislead Consumer:** CODEX STAN 87-1981 already allows emulsifiers. The proposed use of the food additives in food category 05.1.4 “Cocoa and chocolate products” does not change the nature of the food in any way to mislead the consumer.

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by the EWG on the Proposal
SUCROGLYCE RIDES	474	6000	348	2	Emulsifier , Stabilizer	Adopt at 3000 with new note “except for use in chocolate containing not less than 70% total cocoa solids at 6000 mg/kg”.	Japan: 474- not permitted in country. 473 and 473 a- The maximum use level of sucrose esters of fatty acids is 6,000 mg/kg. Sucrose esters of fatty acids are used at 3,000 mg/kg in general to prevent fat bloom during shelf-life.
SUCROSE ESTERS OF FATTY ACIDS	473	6000	348	2	Emulsifier, Foaming agent, Glazing agent, Stabilizer	Adopt at 3000 with new note “except for use in chocolate containing not less than 70% total cocoa solids at 6000 mg/kg”.	Sucrose esters of fatty acids are used at 6,000 mg/kg in chocolate containing not less than 70 % of total cocoa solids. Sucrose esters of fatty acids are needed at higher use level in chocolate containing higher percentage of total cocoa solids to prevent fat bloom by blocking transformation of the crystal structure of cocoa butter. Crystal transformation tend to occur easily in chocolate containing high percentage of total cocoa solids.
SUCROSE OLIGOESTER S, TYPE I AND TYPE II	473a	6000	348	2	Emulsifier, Glazing agent, Stabilizer	Adopt at 3000 with new note “except for use at 6000 mg/kg in chocolate containing not less than 70% total cocoa solids”	Sucrose esters of fatty acids are more appropriate than other emulsifiers because of the following reasons: <ul style="list-style-type: none"> • They effectively reduce the plastic viscosity of the chocolate, and enable easy handling during manufacturing process. • They maintain moderate yield value so that they are favorable for molding and coating process, while other emulsifiers remarkably reduce or increase the value. For example, excessive

						<p>amount of lecithin increases the yield value.</p> <ul style="list-style-type: none"> • They prevent the generation and growth of rough fat crystals in the chocolate (it means prevent fat bloom) more effectively than lecithin and sorbitan tristearate do. • They do not affect the taste. <p>It is difficult to replace cocoa butter with emulsifiers because emulsifiers are used to prevent fat bloom and lower the viscosity to provide aids in the processing. The technological function cannot be achieved by cocoa butter. In addition, according to the descriptor of GSFA, FC 05.1.4 is for chocolate as defined in “the Standard for Chocolate and Chocolate Products” (CXS 87-1981) and for confectionery that uses chocolate that meets the standard, and it also defines the amount of cocoa butter, so chocolate within FC 05.1.4 must contain the required amount of cocoa butter.</p> <p>Australia: 473, 473a- allowed at GMP, 474- Not used in country.</p> <p>Costa Rica, Indonesia, USA: Supports proposal. Functional class already found to be justified</p> <p>EU: Not permitted in CS 87-1981. why those additives are needed? What specific functionality of those emulsifiers that cannot be achieved, e.g. by using ADI not specified emulsifiers? Not permitted in cocoa and chocolate products in the EU and the most recent exposure estimates indicate the EFSA ADI (40 mg/kg bw/d; JECFA ADI is 30 mg/kg bw/d) being potentially exceeded for many population groups especially toddlers and children.</p> <p>EU does not support. INS 473, 473a, 474 were not listed in CXS 87-1981. EU questions the technological need as it was not explained why the permitted emulsifiers in CXS 87-1981 are not sufficient and what the specific characteristics of INS 473, 473a, 474 which cannot be achieved by other emulsifiers are. This is especially important in view of the exposure concerns the EU has for INS 473, 473a, 474.</p> <p>In January 2018 EFSA published the “Refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive”</p>
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						<p>(http://www.efsa.europa.eu/en/efsajournal/pub/5087) in which the refined brand loyal scenario was considered as the most relevant for the safety evaluation. The highest mean and 95th percentile refined exposure estimates in the brand-loyal scenario were 54 and 124 mg/kg bw per day, respectively, in toddlers (12–35 months) and children (3–9 years) thus highly exceeding the JECFA ADI (30 mg/kg bw/d). The EU therefore opposes further extension of use of INS 473, 473a, 474 in this food category.</p> <p>As for CX/FA 18/50/8 the document refers to WHO Food Additives Series No. 62, 2010. Toxicological Monographs of the 71st meeting. The relevance of the mentioned publication to the provisions under discussion is limited by the following factors:</p> <ul style="list-style-type: none">- Limitations of the poundage data method - the estimated exposure is based neither on observed consumption patterns nor on data on the actual concentration in foods; a very large year-to-year variability in poundage data may occur; gives calculations per capita (not related to consumers); there is a very large uncertainty in a mean dietary exposure derived, as typically no information is available that allows the user to identify the precise foods in which the substance is consumed, who is consuming the food or how much of the substance is discarded; highly exposed consumers are not captured and the method is not sufficient to determine if their dietary exposure is within health based guidance values (see FAO&WHO publication "Principles and methods for the risk assessment of chemicals in food", chapter 6 Dietary Exposure Assessment of Chemicals in Food, p. 46-47, available at http://apps.who.int/iris/bitstream/handle/10665/44065/WHO_EHC_240_9_eng_Chapter6.pdf;jsessionid=0B4756B33AE86439E5553E3C14732F86?sequence=9)- Dietary exposure estimates based on national nutrition survey data are based on a very limited uses reported by the industry in 2010 (see table 2 on p. 256 of WHO Food Additives Series No. 62) which do not correspond to much longer list of permissions for INS 473, 473a, 474 in the GSFA. It should be noted that even for the uses reported in WHO No. 62 the ML reported by the industry are very often lower than ML
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						<p>adopted in the GSFA.</p> <p>- The exposure of (young) children, adolescents does not seem to be covered by WHO Food Additives Series No. 62 (Table 4 on p. 258 of WHO Food Additives Series No. 62 seems to relate to adults only)</p> <p>ICA: sucrose esters of fatty acids with a low HLB-value (high multi-ester content) are very strong oil-in-water emulsifiers t would not replace the use of cocoa butter in cocoa and chocolate products, but instead these would be used with cocoa butter as an emulsifier. More fatty sucrose oligo-esters at a low HLB level are needed to act as an emulsifier for cocoa, therefore the proposal states for use at the 1,500 mg/kg level.</p> <p>Advantages of sucrose esters of fatty acids: Accelerated sugar (or polyol) crystallisation, thus more rapid processing; Formation of small sized, stable, crystals; Dry, non-sticking, surface of the candy; Improved shelf life; and a Smooth and soft structure. t Sucrose esters in the shell formulate the best results with a minimum of 500 mg/kg and maximum of 1,500 mg/kg. T.</p> <p>Proposal is for use in sugar-shelled chocolate products and for use within products that use cocoa butter. No other limitations are known at this time.</p> <ul style="list-style-type: none"> •Sucrose esters would be used for the sugar shell to enhance whiteness. •Sucrose oligoesters would be for use within the chocolate and would not replace cocoa butter. <p>FoodDrinkEurope: 473a- This has to be used for water-based fillings in chocolate products and in particular, when there is a 'bubble' structure. This is the only type of emulsifier that will hold the structure successfully. Lecithins can only be used in fat-based products such as chocolate.</p> <p>RU: Does not support</p>
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Corresponding commodity standards: 309R-2011 corresponds to subcategory 05.2.2 - only allows acidity regulators and emulsifiers listed in Table 3.

General Note: Information provided by China in CX/FA 17/49/9:

- **Submitted by China at CCFA49 (CX/FA 17/49/9):** Proposal is to revise adopted provision with current ML of 2,000 mg/kg (2016) to a ML of 20,000 mg/kg.
- **Justification:** Tartrates are used as acidity (i.e. pH) control agents to provide the initial impact of sourness to confectionery. It contributes to a strong tart taste and has the ability to increase and enhance the flavors of fruits where they are naturally present. The sweetness of sucrose is also increased by acid such tartaric acid, thus allowing some reduced use of sucrose. Tartrates are important ingredients for fruit flavored candy playing a role in the stability of the acidity of these candies, which in return play a synergist role in stabilizing the flavor profile of the added flavorings. Tartaric acid itself is the most water-soluble of the solids acidic substances, followed by, in decreasing order, malic acid, citric acid, adipic acid, fumaric acid and succinic acid. Tartaric acid provides the highest level of upfront tartness from the variety of commonly available food acids. In fruit flavored candies, the upfront tartness which enhances the natural flavor is of most important interest to the consumer. Thus, tartrates (INS 334, 335(ii), and 337) satisfy a consumer need that none of the other permitted acids can meet. Based on literature data, each individual consumer also differ radically in their physical and psychological ability to detect differences in acidic taste and in identifying acids. Hence, tartrates may also be found in combination with two or more acids (e.g. citric acid) to enhance the flavor of fruits. Overall, **tartrates (INS 334, 335(ii), and 337) are technologically needed at 20,000 mg/kg specifically in 05.2 confectionery.**
- **Exposure:** JECFA allocated a group ADI of 0-30 mg/kg b.w./day for tartrates. Consumption of a 5 grams' piece of candy containing the future maximum permitted use level of **20,000 mg/kg** of tartrates by a 60 kg adult would result in the possible ingestion of only 100 mg of tartrates, i.e. **5.6% of the ADI.**
- **Mislead Consumer:** this level is technically justified and safe, based on the technical needs and related safety calculations mentioned above.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal	Comments by EWG member Proposal
TARTRATES	334, 335(ii), 337	20,000	45 & XS309R	2	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant	Adopt at 5000 with note "at 20,000 in fruity confection products".	<p>Japan: proposes revising note "at 3,000 mg/kg in fruity confection products".</p> <p>Tartrates are used in fruity hard candy at 3,000 mg/kg as acidity regulator to adjust acidity and provide preferable taste.</p> <p>India: Supports adoption at 2000 mg/kg</p> <p>FIA: The proposal has a typo error. It should be replaced: Adopt at 5000 mg/kg with note "at 20,000 mg/kg in fruity confection products". Tartrates (INS 334, 335(ii), and 337) are technologically needed at 20,000 mg/kg to perform the desired technical effect in FC No. 05.2 confectionery.</p> <p>ICA: technologically needed at 20,000 ppm specifically in 05.2 confectionery. This level allows manufacturers to provide stability to the various ingredients in this Confectionary food category as well as provide a more repeatable and consistent texture and mouth-feel to</p>

						<p>meet consumer taste preferences and expectations. consumer acceptance. The level of 20,000 ppm is justified and there is no toxicology data to suggest otherwise. Lowering the use to 5,000mg would be very limiting and decrease consumer likeability and acceptance of foods in this category. Our members do not support that the use of tartrates would be limited to the use of fruit-flavored Confectionary products, as there is no justification for such a limitation.</p> <p>Australia: Supports proposa</p> <p>EU: Supports proposal as listed in 3rd circular (Note: Proposal contained a typo so that note read “at 2000 in fruity confection products”)</p> <p>Brazil: In Brazilian legislation, allowed as acidity regulator in confectionary, with ML of 5000 mg/kg. Considering an ADI of 30 mg/kg bw/d, and the proposed level of 20,000 mg/kg, a child of 15 kg could consume only 22.5g of confectionary not to extrapolate ADI. So, the ML should be reduced.</p> <p>China, India, Indonesia, Malaysia: supports proposal</p> <p>Guatemala: Supports proposal. Use at up to 5000mg / kgt.</p> <p>RU: Does not support proposal. According to the preamble of the CAC 192-1995, if the food additive does not perform a technological function in the established ADI, such additive is not used in this FC. The reference to the fact that the ADI cannot be exceeded by the use of one candy looks very convincing. Quite a simultaneously wide range of people (sweethearts) can eat 100-1000 g of confectionery.</p> <p>The use of this FA could lead to adulteration of food included in this FC. ML is highly inflated, which could lead to negative consequences for public health.</p> <p>USA: Supports proposal. INS 334 is GRAS for use in Foods in General at GMP</p>
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Food Category No. 06.2.1 (Flours)

Chair's Note: STAN 152-1985 (wheat flour) allows specific flour treatment agents, including benzoyl peroxide. Note 57 "GMP is 1 part benzoyl peroxide and not more than 6 parts of the subject additive by weight." Ties use to benzoyl peroxide.

Horizontal approach (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): acidity regulators not horizontally justified, ES&T justified with Note 25: "For use at GMP in full fat soy flour only"

Corresponding commodity standards: 301R-2011: references FC 06.2.1 Tables 1 & 2; 176-1989, 154-1985, 173-1989, 170-1989, 178-1991, 155-1985: do not discuss food additives; 152-1985: lists specific enzymes and flour treatment agents

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
CALCIUM SULFATE	516	GMP	57	7	Acidity regulator, Firming agent, Flour treatment agent, Sequestrant, Stabilizer	Adopt in GSFA, forward to alignment WG to discuss revising CODEX STAN 152-1985 to add INS 516 to list of allowed flour treatment agents.	<p>Malaysia, Guatemala, Costa Rica, Paraguay, FoodDrinkEurope, Indonesia: Supports proposal</p> <p>Australia: Not permitted but can support. Also, supports passing to alignment WG</p> <p>Brazil: In Brazilian legislation (RDC n. 60/2007 and RDC n. 45/2010), allowed as flour treatment in wheat flour, as GMP.</p> <p>RU: supports requesting further info. questions the technological need.</p> <p>EU: From info received, is not clear if used as acidity regulator or flour treatment agent. Can technological need and function be clarified?</p> <p>USA: Authorized for use in USA as a bleaching agent at 6x benzoyl peroxide in multiple flour products (enriched, bromated, self-rising, enriched self-rising, enriched bromated and regular). Bleaching agent is a technological purpose under flour treatment agent in CAC/GL 36-1989. INS 516 is in Table 3, however FC 06.2 is in the annex to Table 3. INS 516 is used in conjunction with benzoyl peroxide, which is allowed in CODEX STAN 152-1985 as a flour treatment agent. Supports adoption and revision of CXS 152-1985</p>
Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
MAGNESIUM	504(i)	1500		4	Acidity regulator,	Adopt in GSFA,	Australia: Not permitted

CARBONATE					Anticaking agent, Colour retention agent	forward to alignment WG to discuss revising CODEX STAN 152-1985 to add INS 516 to list of allowed flour treatment agents. .	<p>Malaysia, Guatemala, Costa Rica, Paraguay, FoodDrinkEurope: Support adoption as anticaking agent</p> <p>RU: requests further info. Questions technological need.</p> <p>EU: Anticaking agents not listed in CXS 152-1985</p> <p>USA: Authorized for use as a bleaching agent at 6x benzoyl peroxide in multiple flour products (enriched, bromated, self-rising, phosphated, enriched self-rising, and regular). Bleaching agent is a technological purpose under flour treatment agent in CAC/GL 36-1989. INS 504(i) is used in conjunction with benzoyl peroxide, which is allowed in CODEX STAN 152-1985 as a flour treatment agent. INS 504(i) is in Table 3, however FC 06.2 is in the annex to Table 3.</p>
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Food Category No. 07.2.3 (Mixes for fine bakery wares (e.g. cakes, pancakes))

Corresponding commodity standards: None

General Note: Information provided by EFEMA in CX/FA 17/49/9:

- **Justification:** At the 48th meeting of the Codex Committee on Food Additives several provisions for polyglycerol esters of fatty acids (INS 475) were adopted. Among these were the following:

07.2.1 Cakes, cookies and pies (e.g., fruit-filled or custard types) with a maximum level of 10000 mg/kg; 07.2.2 Other fine bakery products (e.g. doughnuts, sweet rolls, scones, and muffins) with a max level of 10000 mg/kg and 07.2.3 Mixes for fine bakery wares (e.g. cakes, pancakes) with a max level of 15000 mg/kg on the flour basis (Note 11). In the stated food categories polyglycerol esters of fatty acids (INS 475) is used as part of a 'whipping emulsifier' compound. This compound helps to aerates the batter during the whipping step of the batter production and stabilizes the incorporated air. Furthermore, the compound helps to ensure the stability of the batter during the baking.

The maximum level is given on the finished product basis for food categories 07.2.1 and 07.2.2, while the maximum level is stated on the flour basis for food category 07.2.3.

Products in the food categories 07.2.1, 07.2.2 and 07.2.3 all contain considerable amounts of ingredients besides flour. These are typically sugar, fat (butter, margarine, oil or the like), eggs, liquid and a number of minor ingredients. This means that when the amount of polyglycerol esters of fatty acids (INS 475) is calculated on the flour basis as opposed to calculated on the basis of the total product, then the permitted amount is reduced with the same fraction as the weight of the flour has to the weight of the final product. The percentage of flour in this type of baking products may be as low as 30-35% hereby reducing the permitted amount polyglycerol esters of fatty acids (INS 475) to a level where it no longer has any technological function, when it is calculated on the flour basis.

Furthermore, some pre-mixes for fine bakery wares do not contain any flour at all, instead they are made with starch. In this type of mixes polyglycerol esters of fatty acids INS 475 is not permitted, since they contain no flour. These products included mixes for gluten-free products.

- **Exposure:** See CX/FA 17/49/9 for full information: As mixes for fine bakery wares are not consumed as such, but always prepared into a final product before consumption, this change would not lead to any increased level of consumption of polyglycerol esters of fatty acids (INS 475) compared to the products being purchased as baked goods.

- **Mislead Consumer:** Polyglycerol esters of fatty acids (INS 475) is permitted for the use as an emulsifier and stabilizer in food category 07.2.3 Mixes for fine bakery wares. The proposed change only affects the maximum permitted level in this category.

In accordance with CODEX STAN 1-1985 on the Labelling of Prepackaged Foods, food additives like Polyglycerol esters of fatty acids (INS 475) must be declared on the label of the product in the list of ingredients by indicating either: (i) the functional class together with the specific name or (ii) the functional class together with the recognized numerical identification such as the Codex International Numbering System (CAC/GL 36-1989).

All ingredients shall be listed in descending order of ingoing weight (m/m).

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	16000		2	Emulsifier, Stabilizer	Revise adopted provision to ML of 16,000 mg/kg, remove Note 11, and add new note "On the dry mixture basis".	<p>EU, Japan, EFEMA, USA, Guatemala, China: supports the adoption at 16,000 mg/kg with new note "On the dry mixture basis".</p> <p>Indonesia: permits the use of this food additive up to 10000 mg/kg.</p> <p>Australia: Supports. Permitted for the food category biscuits, cakes and pastries, with MPL of 15,000 mg/kg, but with a condition for cakes only. The MPL is on the final product for sale</p> <p>Brazil: Allowed as emulsifier and stabilizer on mixes for bakery products with ML of 10,000 mg/kg. The ML refers to the amount of the additive on the mix for bakery product (not on flour basis).</p> <p>RU: Does not support proposal. According to the preamble of the CAC 192-1995, if the food additive does not perform a technological function in the established ADI, such additive is not used in this FC. The reference to the fact that the ADI cannot be exceeded by the use of "baking products may be as low as 30-35% hereby reducing the permitted amount polyglycerol esters of fatty acids (INS 475)" looks very convincing. So on proposed ML is high established ADI for adult consumers with bm=60kg more than in 10 times: For child ≤ 20 kg - in 26,6 time</p>
Background information on provision for INS 475 in FC 07.2.3							
Submitted by EFEMA at CCFA49 (CX/FA 17/49/9): Proposal is to revise adopted provision with current ML of 15,000 mg/kg and Note 11 "on the flour basis" to a ML of 16,000 mg/kg and removal of Note 11.							

Food Category No. 08.2.2 (Heat-treated processed meat, poultry, and game products in whole pieces or cuts)

Corresponding commodity standards: 96-1981, 97-1981: Preservatives and humectants used in accordance with Tables 1 and 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in food category 08.2.2 "Heat-treated processed meat, poultry, and game products in whole pieces or cuts" and its parent food categories are acceptable for use in foods conforming to this Standard. Only certain Table 3 food additives (as indicated in Table 3) are acceptable for use in foods conforming to this Standard.

General Note: Information provided by Australia in CX/FA 18/50/8:

- **Revision an existing provision:** Remove Notes XS96 and XS97 and Insert new note, which reads "For products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981), use is limited to ready-to-eat products which require refrigeration."
- **Justification:** See CX/FA 18/50/8 for full information: Provisions were adopted at Step 8 in 2016 for lauric arginate ethyl ester (INS 243) in food categories 08.2.2 and 08.3.2 at a level of 200 mg/kg in each category. Each of these provisions was adopted with footnotes that restricted the use of the additive in products conforming to corresponding commodity standards associated with the respective categories. The footnotes adopted FC 08.2.2 for are as follows:

XS96 Excluding products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981).

XS97 Excluding products conforming to the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981).

The adopted provisions in the GSFA for lauric arginate ethyl ester are such that its use is excluded from products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981) by way of the inclusion of notes XS96 and XS97 respectively. As with products conforming to the standards associated with FC 08.3.2, a number of products falling within the scope of the standards associated with FC 08.2.2 are available as ready-to-eat products that require refrigeration to ensure their safety during their shelf life. Lauric arginate ethyl ester provides additional protection for such products against the growth of pathogenic organisms and this can be of particular benefit in developing countries where access to stable refrigeration may be limited and in developed countries where consumers may not follow appropriate (refrigerated) storage conditions.

- **Safety:** The use of lauric acid ethyl ester (INS 243) in meat products that fall under Codex food categories 08.2.2 and 08.3.2 (and without restriction of its use in standardised products), as well as its use in a broad range of other foods, was considered as part of the review of its safety in use as a food additive, and no concerns over dietary intake were identified for Australian and New Zealand consumers.

In addition, consumption of meat products falling within these food categories was taken into consideration as part of the JECFA assessment of the safety of the additive in 2007.

- **Mislead Consumer:** The use of lauric arginate ethyl ester (INS 243) would be indicated on the label of cured meat products falling within FC 08.2.2 and 08.3.2 that are ready-to-eat and that require refrigeration. These products are cured and by their very nature contain additives, and the presence of additives in these products is expected by consumers.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
LAURIC ARGINATE ETHYL ESTER	243	200	BBB ⁴	2	Preservative	Adopt	<p>Australia: Supports proposal</p> <p>Brazil: The additive (INS 243) is required to provide stability of the product in case of instability in the cold chain and in case of non-compliance by the consumer with the storage conditions. Additive is being used to mask the failures of good manufacturing practices, where it is not possible to guarantee the stability of the cold chain, thus harming the food quality. May lead to the sale of low quality foods, and that there is no technological justification for its use, since refrigeration can achieve the objective of conservation proposed by this additive.</p> <p>Indonesia: does not allow the use of INS 243 as preservative. There are other alternative preservatives for this food category that are already permitted</p> <p>RU: Agrees with proposal in ML=160 mg/kg, because low level ADI=4 mg/kg</p> <p>USA: Supports the proposal. Functional class has been found to be warranted for the food category. Would not mislead the consumer as preservatives are already used in the food category. LAEE is GRAS in the USA for use in ready to eat meat at levels up to 200 ppm.</p>

Food Category No. 08.3.2 (Heat-treated processed comminuted meat, poultry, and game products)

Corresponding commodity standards: 88-1981, 89-1981, 98-1981: List specific preservatives, antioxidants, flavour enhancers, acidity regulators, humectants, colours

General Note: Information provided by Australia in CX/FA 18/50/8:

- **Revision an existing provision:** Remove Notes XS88, XS89 and XS98 and Insert Note 377, which reads “For products conforming to the Standard for Luncheon Meat (CODEX STAN 89-1981), Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981), and Standard for Corned Beef (CODEX STAN 88-1981) use is limited to ready-to-eat products which require refrigeration.”

⁴ New Note BBB - For products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981), use is limited to ready-to-eat products which require refrigeration

- **Justification:** See CX/FA 18/50/8 for full information: Provisions were adopted at Step 8 in 2016 for lauric arginate ethyl ester (INS 243) in food categories 08.2.2 and 08.3.2 at a level of 200 mg/kg in each category. Each of these provisions was adopted with footnotes that restricted the use of the additive in products conforming to corresponding commodity standards associated with the respective categories. The footnotes adopted FC 08.3.2 for are as follows:

XS88 Excluding products conforming to the Standard for Corned Beef (CODEX STAN 88-1981).

XS89 Excluding products conforming to Standard for Luncheon Meat (CODEX STAN 89-1981).

XS98 Excluding products conforming to the Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981).

At the 49th Session of CCFA (2017), the Committee considered the use of the preservative nisin (INS 234) in food category 08.3.2 in general, and specifically in products conforming to the corresponding commodity standards associated with this category. The committee agreed that the use of nisin was acceptable in products conforming to the corresponding commodity standards in cases where the products are ready-to-eat and require refrigeration. Lauric arginate ethyl ester (INS 243) is also a preservative that is used in products that conform to the same corresponding commodity standards associated with FC 08.3.2. The additive is effective in controlling the growth of potentially pathogenic organisms in products falling under both food categories 08.2.2 and 08.3.2 and this is particularly the case for products that are ready-to-eat and which require refrigeration. This provides an advantage in developing countries where access to stable refrigeration may be limited or in developed countries where the final consumer may not adhere to storage instructions. Given the use of nisin as a preservative in these ready-to-eat refrigerated products is now permitted under the GSFA, this proposal for new work requests that consideration is given to modification of the adopted provisions for lauric arginate ethyl ester (INS 243) to bring them in line with the provisions applied to nisin for FC 08.3.2.

- **Safety:** The use of lauric acid ethyl ester (INS 243) in meat products that fall under Codex food categories 08.2.2 and 08.3.2 (and without restriction of its use in standardised products), as well as its use in a broad range of other foods, was considered as part of the review of its safety in use as a food additive, and no concerns over dietary intake were identified for Australian and New Zealand consumers.

In addition, consumption of meat products falling within these food categories was taken into consideration as part of the JECFA assessment of the safety of the additive in 2007.

- **Mislead Consumer:** The use of lauric arginate ethyl ester (INS 243) would be indicated on the label of cured meat products falling within FC 08.2.2 and 08.3.2 that are ready-to-eat and that require refrigeration. These products are cured and by their very nature contain additives, and the presence of additives in these products is expected by consumers.

Additive	INS	Max Level (mg/kg)	Notes	Step Adopted /	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
LAURIC ARGINATE ETHYL ESTER	243	200	377 ⁵	2	Preservative	Adopt	<p>Australia: Supports proposal</p> <p>Brazil: The additive (INS 243) is required to provide stability of the product in case of instability in the cold chain and in case of non-compliance by the consumer with the storage conditions. If additive is being used to mask the failures of good manufacturing practices, where it is not possible to guarantee the stability of the cold chain, thus harming the food quality. Use of this</p>

⁵ New Note BBB - For products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981), use is limited to ready-to-eat products which require refrigeration

							<p>additive in this food category may lead to the sale of low quality foods, and that there is no technological justification for its use, since refrigeration can achieve the objective of conservation proposed by this additive.</p> <p>Indonesia: does not allow the use of INS 243 as preservative. There are other alternative preservatives for this food category that are already permitted</p> <p>RU: Agrees with proposal in ML=160 mg/kg, because low level ADI=4 mg/kg</p> <p>USA: Supports the proposal. Functional class has been found to be warranted for the food category. Use of this food additive would not mislead the consumer as preservatives are already used in the food category. LAEE is GRAS in the USA for use in ready to eat meat at levels up to 200 ppm.</p>
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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	Final EWG Proposal	Comments by EWG members on Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	500	-	7	Emulsifier, Stabilizer	Information provided that is used in each subcategory but use level not provided in each subcategory. Discuss use level in each subcategories	<p>Australia: Supports proposal. Permitted at GMP for egg products, being liquid egg products, frozen egg product and dried or heat coagulated egg products.</p> <p>It seems appropriate to keep provisions in the higher category 10.2, rather than adding to each of the subcategories, 10.2.1, 10.2.2 and 10.2.3.</p> <p>EU: What is advantage of this additive with numerical ADI over Table 3 additives. Are use levels related to the product "as consumed"</p> <p>Japan: Supports 2nd Circular proposal. This additive is used in products fallen within FC 10.2.3 in Japan and higher use level is necessary to achieve desired effect in dried products.</p>

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal	Comments by EWG members on Proposal
							<p>Sorbitan esters of fatty acids are used in dried egg white as emulsifier to improve solubility when used in further processing.</p> <p>The maximum use level is 5,000 mg/kg in dried egg white.</p> <p>RU: Agrees with 2nd Circular proposal. Discuss in subcategories</p> <p>There are not technological justification for dried products.ADI 0-25 mg/kg bw. Proposed by Japan ML=5 000 mg/kg so higher</p>

Food Category No. 10.2.1 Liquid egg products

Horizontal approach: 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	2 nd Circular Proposal and EWG comments	Final EWG Proposal	Comments by EWG member on Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	500			Emulsifier, Stabilizer	<p>Do not move from parent category 10.2</p> <p>Australia: Supports proposal</p> <p>Indonesia: only allow the use of INS 491 and 492 as emulsifiers. Indonesia does not allow the use of this food additives in food category 10.2.1</p>	Adopt	<p>Australia: Supports proposal not to move from parent category. Permitted at GMP for egg products, being liquid egg products, frozen egg product and dried or heat coagulated egg products.</p> <p>Indonesia: only allow the use of INS 491 and 492 as emulsifiers. Indonesia does not allow the use of this food additives in food category 10.2.1</p> <p>EU: What is advantage of this additive with numerical ADI over Table 3 additives. Are use levels related to the</p>

								product "as consumed"
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Food Category No. 10.2.2 Frozen 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	2 nd Circular Proposal and EWG comments	Final EWG Proposal	Comments by EWG member on Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	500			Emulsifier, Stabilizer	Do not move from parent category 10.2 Australia: Supports proposal Indonesia: does not allow the use of this food additives in food category 10.2.1	Adopt	Australia: Supports proposal not to move from parent category. Permitted at GMP for egg products, being liquid egg products, frozen egg product and dried or heat coagulated egg products. Indonesia: does not allow the use of this food additives in food category 10.2.1 EU: What is advantage of this additive with numerical ADI over Table 3 additives. Are use levels related to the product "as consumed"

Food Category No. 10.2.3 Dried and/or heat coagulated 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	2 nd Circular Proposal and EWG Comments	Final EWG Proposal	Comments by EWG member on Proposal
SORBITAN ESTERS OF FATTY ACIDS	491-495	500			Emulsifier, Stabilizer	Adopt at 5,000 mg/kg with new note "for use in dried egg"	Adopt at 500 with note, "except for use at 5,000 mg/kg"	Japan: Sorbitan esters of fatty acids are used in dried egg white as emulsifier to improve solubility when soaking in water. This product is used for further processing, such as used as an

					<p>whites only” Proposal based on comments from Japan in parent category 10.2</p> <p>Australia: Supports proposal</p> <p>EU: for eggs for further processing (cf JPN comments in FC 10.2) – does it relate to specific products (for which the reverse carry over might apply?). Is the ML expressed on a dried product or as consumed?</p> <p>Indonesia: only allow the use of INS 491 and 492 as emulsifiers. Indonesia does not allow the use of this food additives in food category 10.2.1</p> <p>Japan: Supports proposal, used in dried egg white as emulsifier at 5,000 mg/kg</p> <p>RU: There are not technological justification for dried products</p>	<p>in dried egg whites used for further processing only”.</p>	<p>ingredient for cured processed meat. The maximum use level is 5,000 mg/kg on a dried product basis.</p> <p>Australia: Supports proposal. Permitted at GMP for egg products, being liquid egg products, frozen egg product and dried or heat coagulated egg products. Cannot comment on note</p> <p>Indonesia: only allow the use of INS 491 and 492 as emulsifiers. Indonesia does not allow the use of this food additives in food category 10.2.1</p> <p>EU: What is advantage of this additive with numerical ADI over Table 3 additives. Are use levels related to the product “as consumed”</p> <p>RU: There are not technological justification for dried products. ADI 0-25 mg/kg bw. Proposed ML=5 000 mg/kg so higher</p>
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						ADI 0-25 mg/kg bw. Proposed ML=5 000 mg/kg so higher		
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Food Category No. 10.4 Egg-based desserts (e.g. custard)

Descriptor: Includes ready-to-eat products and products to be prepared from a dry mix. Examples include: flan and egg custard. Also includes custard fillings for fine bakery wares (e.g. pies).

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
TOCOPHEROLS	307a, b, c	150		7	Antioxidant	Adopt at 500 with Note 72 "on the ready to eat basis"	<p>Japan: notes that 100 mg/kg is sufficient in ready-to-eat products. Requests the actual use level and technological justification if higher ML is needed in ready-to-eat or dry mix products. used in flan to prevent oxidation and flavour deterioration</p> <p>Australia: Not permitted but could support proposal</p> <p>Brazil: Allowed as antioxidant in "other desserts" (ready-to-eat products and also applies to egg-based desserts) with ML of 500 mg/kg.</p> <p>EU: supports asking for technological justification</p> <p>EU Specialty Food Ingredients: Permitted at quantum satis (GMP) level in the EU food category 16 (<i>Desserts excluding products covered in category 1, 3 and 4</i>). This category seems to cover Codex Food Category 10.4 being at the same time broader and covering more products than those falling within the scope of Codex FC 10.4. A product check on the internet shows that some producers use antioxidants in products under FC 10.4. This might be technically justified based on the following reasons: the products are sold prepacked and their shelf life may range from weeks (products cooled in multideck cabinet) to several months (dry mixes). As they contain egg added as such or added as egg/egg yolk powder, they are prone to oxidation. Compositional data show that egg yolk lipids contain high amounts of poly-unsaturated fatty acids, in particular the omega-3 fatty</p>

							<p>acid DHA. Due to the rather long shelf life and the fact that dry mixes contain powdered ingredients (large surface area!), the use of tocopherols can be indicated to protect products from rancidity and off-flavour. Thus, the use of tocopherols preserves the nutritional and organoleptic quality and enhances the keeping quality and stability. The use of this additive is not misleading to consumers as the packaging informs the consumer about both, shelf life ("use-by-date") and the presence of the antioxidant in the ingredient list.</p> <p>Indonesia: does not allow the use in this food category</p> <p>RU: Agrees with proposal</p> <p>USA: INS 307c is GRAS for use in Foods in General at GMP as a nutrient</p>
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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	Final EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Hold until issue of benzoates in FC 14.1.4 is resolved

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	Final EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Hold until issue of benzoates in FC 14.1.4 is resolved

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	Final EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Hold until issue of benzoates in FC 14.1.4 is resolved

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	Final EWG Proposal
BENZOATES	210-213	1000	13	3	Preservative	Hold until issue of benzoates in FC 14.1.4 is resolved

Food Category No. 14.1.4.1 Carbonated water-based flavoured drinks

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	Final EWG Proposal	Comments by EWG member on Proposal
PROPYLENE GLYCOL	1520	3000		7	Emulsifier, Carrier, Glazing agent, Humectant	Adopt with new note "for use as carrier only"	<p>Australia, Colombia, Brazil, China, Malaysia, Japan, New Zealand, Saudi Arabia, Paraguay, Costa Rica, India, RU, ICGMA, IOFI, ICBA, FIA: support discontinuation.</p> <p>Propylene glycol is contained in products of FC 14.1.4.1 because of carry-over from flavourings and does not serve a technological function in the final products. It does not meet the definitions of food additive defined in GSFA (see Preamble of GSFA), so it is inappropriate to adopt the provision. Non-flavouring ingredients in flavourings are appropriately covered under the Codex Guidelines for the Use of Flavourings (Section 3.5 in CAC/GL 66-2008).</p> <p>Additionally, the Joint (FAO/WHO) Expert Committee on</p>

						<p>Food Additives (JECFA) reviewed the use of propylene glycol as a flavouring adjuvant in 2001 (<u>2002 JECFA</u>). No safety concerns were raised for daily dietary exposures of 2,400 mg <i>per capita</i>.</p> <p>EU: does not support the ML higher than 1000ppm due to exposure concerns. EFSA (2018) indicated that the exposure is very close to the ADI and flavoured drinks was the main contributing food category (together with fine bakery wares). In addition, the maximum reported level by the industry (which was used in the EFSA intake calculations) was 300ppm, i.e. one order of magnitude lower than requested now. This questions the need for ML of 3000ppm.</p> <p>Guatemala: notes the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) evaluated propylene glycol as a flavoring adjuvant in <u>2002 JECFA</u>, suggesting propylene glycol levels up to 2,400,000 µg/day (or 2,400 mg/day) accounted for 96% of the total annual daily per U.S. capita intake. Propylene glycol is known to be transformed into lactic acid in mammals and would not be expected to be a safety concern. (Lactic acid is endogenous to humans.)</p> <p>In the <u>2018 EFSA Opinion</u>, no adverse reproductive or developmental effects in rodents were noted following exposures up to 10,000 mg/kg bw/day. At high concentrations, free propylene glycol was suggested to be excreted in the urine as its elimination from the body is saturated at dose levels higher than 20,000 mg/day in humans (i.e., more than 300 mg/kg bw/day).</p> <p>Indonesia: permits the use up to 600 mg/kg. Indonesia considers the ML of 600 mg/kg has already gives the technological function</p> <p>USA: If a provision is adopted it should contain an ML that reflects the safe use and use level needed to meet the technological need</p> <p>Canada: Received info by a member of beverages industry that expected levels of use would be about 1000 mg/kg as a carrier for flavours (notably citrus-based flavours) in beverages. No product-specific levels of use available, wonder if product-specific information would be helpful in setting the ML. Would support the proposal of 1000 mg/kg with the note 131 “for use as a flavor carrier only”.</p> <p>India: Industry has shared their feedback that the proposed</p>
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							levels will significantly impact their ability to use current flavour formulations. Hence the provisions being considered should re-evaluated in the light of difficulties shared by industries.
Additive	INS	Max Level (mg/kg)	Notes	Step	INS Functional Class	3 rd Circular Proposal	Comments by EWG member on 3 rd Circular Proposal
SUCROSE ESTERS OF FATTY ACIDS	473	1000		7	Emulsifier, Glazing agent, Stabilizer	Discontinue	India, Australia, Canada, Costa Rica, EU, Indonesia, ICBA, USA, RU: Supports Discontinuation
Background information on provision for INS 473 in FC 14.1.4.1:							
Chair's Note: CCFA50 discussed provisions for INC 473 in all subcategories of FC 14.1.4. The result is CCFA50 adopted a provision for INS 473 in FC 14.1.4 with a ML of 200 mg/kg and Notes 219 & 348. REP 18/FA Appendix VIII recorded that provisions for INS 473 were discontinued in subcategories 14.1.4.2 and 14.1.4.3, but omitted 14.1.4.1.							

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

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	Comments by EWG member on 3 rd Circular Proposal
PROPYLENE GLYCOL	1520	3000		7	Emulsifier, Carrier, Glazing agent, Humectant	Adopt with new note "for use as carrier only"	Australia, Colombia, Japan, New Zealand, Saudi Arabia, India, Malaysia, RU, Paraguay, Costa Rica, India, IOFI, ICBA, ICGMA, FIA: support discontinuation Propylene glycol is contained in products of FC 14.1.4.2 because of carry-over from flavourings and does not serve a technological function in the final products. It does not meet the definitions of food additive defined in GSFA (see Preamble of GSFA), so it is inappropriate to adopt the provision. Non-flavouring ingredients in flavourings are appropriately covered under the Codex Guidelines for the Use of Flavourings (Section 3.5 in CAC/GL 66-2008). Additionally, the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) reviewed the use of propylene

						<p>glycol as a flavouring adjuvant in 2001 (<u>2002 JECFA</u>). No safety concerns were raised for daily dietary exposures of 2,400 mg per capita.</p> <p>Guatemala: notes the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) evaluated propylene glycol as a flavoring adjuvant in <u>2002 JECFA</u>, suggesting propylene glycol levels up to 2,400,000 µg/day (or 2,400 mg/day) accounted for 96% of the total annual daily per U.S. capita intake. Propylene glycol is known to be transformed into lactic acid in mammals and would not be expected to be a safety concern. (Lactic acid is endogenous to humans.)</p> <p>In the <u>2018 EFSA Opinion</u>, no adverse reproductive or developmental effects in rodents were noted following exposures up to 10,000 mg/kg bw/day. At high concentrations, free propylene glycol was suggested to be excreted in the urine as its elimination from the body is saturated at dose levels higher than 20,000 mg/day in humans (i.e., more than 300 mg/kg bw/day).</p> <p>EU: Does not support the ML higher than 1000ppm due to exposure concerns. EFSA (2018) indicated that the exposure is very close to the ADI and flavoured drinks was the main contributing food category (together with fine bakery wares). In addition, the maximum reported level by the industry (which was used in the EFSA intake calculations) was 300ppm, i.e. one order of magnitude lower than requested now. This questions the need for ML of 3000ppm.</p> <p>USA: If a provision is adopted it should contain an ML that reflects the safe use and use level needed to meet the technological need</p> <p>Indonesia: permits the use up to 600 mg/kg. Indonesia considers the ML of 600 mg/kg has already gives the technological function</p> <p>Canada: Would support the proposal of 1000 mg/kg with the note 131 “for use as a flavor carrier only” See comments under 14.1.4.1</p>
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Food Category No. 14.1.4.3 Concentrates (liquid or solid) for water-based flavoured drinks

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	Comments by EWG member on 3 rd Circular Proposal
PROPYLENE GLYCOL	1520	200000		7	Emulsifier, Carrier, Glazing agent, Humectant	Adopt with new note "for use as carrier only" and note 2 "On the dry ingredient, dry weight, dry weight, dry mix or concentrate basis"	<p>Australia, Colombia, Malaysia, RU, Japan, New Zealand, Saudi Arabia, Paraguay, Costa Rica, India, IOFI, ICBA, ICGMA, FIA: support discontinuation</p> <p>Propylene glycol is contained in products of FC 14.1.4.2 because of carry-over from flavourings and does not serve a technological function in the final products. It does not meet the definitions of food additive defined in GSFA (see Preamble of GSFA), so it is inappropriate to adopt the provision. Non-flavouring ingredients in flavourings are appropriately covered under the Codex Guidelines for the Use of Flavourings (Section 3.5 in CAC/GL 66-2008).</p> <p>Additionally, the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) reviewed the use of propylene glycol as a flavouring adjuvant in 2001 (<u>2002 JECFA</u>). No safety concerns were raised for daily dietary exposures of 2,400 mg <i>per capita</i>.</p> <p>Guatemala: notes the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) evaluated propylene glycol as a flavoring adjuvant in <u>2002 JECFA</u>, suggesting propylene glycol levels up to 2,400,000 µg/day (or 2,400 mg/day) accounted for 96% of the total annual daily per U.S. capita intake. Propylene glycol is known to be transformed into lactic acid in mammals and would not be expected to be a safety concern. (Lactic acid is endogenous to humans.)</p> <p>In the <u>2018 EFSA Opinion</u>, no adverse reproductive or developmental effects in rodents were noted following exposures up to 10,000 mg/kg bw/day. At high concentrations, free propylene glycol was suggested to be excreted in the urine as its elimination from the body is saturated at dose levels higher than 20,000 mg/day in humans (i.e., more than 300 mg/kg bw/day).</p> <p>EU: Does not support the ML higher than 1000ppm due to exposure concerns. EFSA (2018) indicated that the exposure is very close to the ADI and flavoured drinks</p>

						<p>was the main contributing food category (together with fine bakery wares). In addition, the maximum reported level by the industry (which was used in the EFSA intake calculations) was 300ppm, i.e. one order of magnitude lower than requested now. This questions the need for ML of 3000ppm.</p> <p>Indonesia: permits the use up to 600 mg/kg. Indonesia considers the ML of 600 mg/kg has already gives the technological function</p> <p>USA: If a provision is adopted it should contain an ML that reflects the safe use and use level needed to meet the technological need</p> <p>Canada: Assuming the ML is confirmed to be 200,000 mg/kg on the basis of the concentrate, then we recommend adding Note 2: "On the dry ingredient, dry weight, dry weight, dry mix or concentrate basis". See comments on use level under 14.1.4.1</p>
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Appendix 5 - Proposed draft provisions for tamarind seed polysaccharide (INS 437) and gum ghatti (INS 419) in Table 3

1. Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to consider:¹
 - Proposed draft provisions for tamarind seed polysaccharide (INS 437) and gum ghatti (INS 419) in Table 3.

Introduction

2. The 84th Joint Expert Committee on Food Additives (JECFA) meeting evaluated the safety of gum ghatti (INS 419) and tamarind seed polysaccharide (INS 437). This review resulted in an acceptable daily intake of “not specified” for both food additives. As a result, the 84th JECFA recommended that CCFA51 include provisions for both food additives in Table 3 of the GSFA and circulate the provisions for comment at Step 3.²

3. CCFA50 agreed to include provisions for tamarind seed polysaccharide (INS 437) and gum ghatti (INS 419) in Table 3 of the GSFA and request that the EWG on the GSFA to CCFA51 circulate these Table 3 provisions for comment at step 3.³

Working document

4. The EWG issued three circulars for comments. The current document presents proposals for proposed draft provisions in Table 3 for tamarind seed polysaccharide (INS 437) and gum ghatti (INS 419). The provisions under discussion are presented in the format of Table 3 of the GSFA. These proposals are based upon a consensus approach taking into account comments on the first circular 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.

5. Please note that proposals for new provisions for tamarind seed polysaccharide (INS 437) and gum ghatti (INS 419) for inclusion in Tables 1 and 2 of the GSFA (i.e., proposals for the use of these additives in food categories listed in the Annex to Table 3) should be submitted in response to the circular letter requesting proposals for new and/or revision of adopted food additive provisions.

The EWG members to CCFA51 are invited to comment comments on the following proposed provisions on Table 3 of the GSFA.

¹ REP 18/FA, paras. 23 & 112(iii).

² CX/FA 18/50/3, Table 1.

³ REP18/FA paras. 23 & 112(iii), and Appendix II.

INS	Additive	INS Functional Class	Step	Year	Acceptable, including foods conforming to the following commodity standards	Final EWG Proposal	Comments by EWG members on Proposal
419	Gum ghatti	Thickener, Stabilizer, Emulsifier, Carrier	3			Adopt as listed	<p>USA: in principle, the USA supports the adoption of this provision into Table 3 of the GSFA. The additive has a JECFA ADI of “not specified” - there is no safety concern for its use. The additive has an INS number and functional class, and meets a technological need. In the USA gum ghatti is GRAS for foods in general.</p> <p>Indonesia: Supports proposal, additive allowed in food category 14.1.4.1 and 14.1.4.2 at ML of 2000 ppm as thickener and stabilizer</p> <p>Canada: Not currently permitted for use as a food additive</p> <p>ICA, IDF: Supports proposal</p>

INS	Additive	INS Functional Class	Step	Year	Acceptable, including foods conforming to the following commodity standards	Final EWG Proposal	Comments by EWG members on Proposal
437	Tamarind seed polysaccharide	Thickener, Stabilizer, Emulsifier, Gelling agent	3				<p>Chair's Note: The 1st circular requested proposals for the use of INS 437 in commodity standards and the 2nd circular requested comment on proposals submitted in response to the 1st circular. In preparing the third circular the EWG Chair observed that the proposed commodity standards can be categorized into 4 groups based on the following criteria: 1) does the commodity standard have a general reference or list specific additives, 2) is the corresponding commodity committee active or adjourned, and 3) has the commodity standard been aligned with the GSFA. The third circular groups the proposals for inclusion of INS 437 in commodity standards based upon the above criteria, and puts forward proposals or requests for information for each group</p> <p>Comments are requested on <u>each proposal below</u>.</p>

					<p>Group 1. CODEX STAN contains a general reference to Table 3 for specific functional classes (commodity committee adjourned <i>sine die</i>):</p> <p><u>CXS 243-2003, 296-2009 and 256-2007.</u> (Listing of these CODEX STANs is warranted until such time as technology allows on-line Table 3 to be revised per decision at CCFA50)</p> <p>Proposal: Adopt and include CXS 243-2003, 296-2009 and 256-2007 in column "Acceptable including foods conforming to commodity standard column"</p>	<p>EU, USA, Indonesia, ICA, IDF: Supports proposal</p>
					<p>Group 2. CODEX STAN with active commodity committee</p> <p><u>CXS 115-1981</u></p> <p>Proposal: Refer to CCPFV to determine technological justification of the use of INS 437 in mustard type pickled cucumbers (CXS 115-1981).</p>	<p>EU, USA, Indonesia: Supports proposal</p>
					<p>Group 3. CODEX STAN are aligned and list specific Table 3 additives of applicable functional class (commodity committee adjourned <i>sine die</i>)</p> <p><u>CXS 94-1981 and 119-1981</u></p> <p>Proposal: Adopt and include CXS 94-1981 and 119-1981 in column "Acceptable</p>	<p>Japan: Tamarind seed polysaccharide is suitable for processing canned products conforming to CXS 94-1981 and CXS 119-1981 because of the following reasons:</p> <p>Tamarind seed polysaccharide is soluble in cold water.</p> <p>Tamarind seed polysaccharide provides good mouthfeel without pastiness and spinnability.</p> <p>Compared to other thickeners, such as Guar gum, Tamarind seed polysaccharide shows excellent resistance to heat and acid. The viscosity thickened by Tamarind seed polysaccharide maintains well after heat</p>

					<p>including foods conforming to commodity standard column”</p>	<p>treatment and under acidic condition. It is also stable under high concentration of salts and sugars.</p> <p>USA: Supports proposal</p> <p>EU: Supports proposal for technological justification for use in CXS 94-1981 and 119-1981</p>
					<p>Group 4. CODEX STAN not aligned, do not contain a general reference to Table 3 (commodity committee adjourned <i>sine die</i>)</p> <p><u>CXS 249-2006, 273-1968, 275-1973, 288-1976.</u></p> <p>Proposal: Adopt in GSFA, and add to the column “Acceptable including foods conforming to commodity standard column” CXS 249-2006, 273-1968 (as a stabilizer in cheese mass only), 275-1973 (as a stabilizer, thickener and emulsifier in cheese mass only), 288-1976.</p> <p>Forward to alignment WG to discuss revising CXS 249-2006, 273-1968, 275-1973, 288-1976.</p>	<p>EU, USA, Indonesia, IDF: Supports proposal</p> <p>Japan: CXS 249-2006, 273-2968 and 275-1973 and 288-1976 do not contain general reference to Table 3. For ensuring consistency with Group 3, CCFA should request technological justification on the use of INS 437 in these 4 commodity standards.</p> <p>Tamarind seed polysaccharide has advantages over other thickeners listed in CXS 249-2006 because of the following reasons:</p> <p>Tamarind seed polysaccharide confers heat stability and mechanical strength upon starch for protection.</p> <p>Compared to other thickeners, such as Guar gum, Pectins and Xanthan gum, Tamarind seed polysaccharide improves elasticity of noodles without providing hardness.</p>

Appendix 6: Standard for Mozzarella (CXS 262-2006)

1. Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to discuss:¹
 - The technological justification for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content covered by the *Standard for Mozzarella* (CXS 262-2006)

Background

2. At CAC38 the Codex Secretariat noted that in the table listing the technological functions of food additives in CXS 262-2006, entries for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content had been left blank. However, it had not been possible to find a clear record of the CCMMP decision on how these entries should be completed (i.e., whether these two functional classes of food additives were technologically justified). CAC39 did not address this issue due to time constraints. CAC40 did discuss this issue, and determined that this issue was not sufficient to keep the Codex Committee on Milk and Milk Products (CCMMP) active and therefore requested CCFA to address only the technological justification of the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content in the framework of the alignment work of food additive provisions of CCMMP standards and those of the GSFA. CCFA50 considered this request and determined that this task should be undertaken by the EWG on the GSFA to CCFA51.

CODEX STAN 262-2006

3. The Standard for Mozzarella (CODEX STAN 262-2006) differentiates two types of mozzarella: high moisture and low moisture. Mozzarella with a high moisture content is a soft cheese with overlying layers that may form pockets containing liquid of milky appearance. It may be packed with or without the liquid and has a near white colour. Mozzarella with a low moisture content is a firm/semi-hard homogeneous cheese without holes and is suitable for shredding. These types of mozzarella have different minimum milkfat in dry matter requirements, with high moisture having a minimum of 20%, and low moisture a minimum of 18%.

4. Section 4 of CODEX STAN 262-2006 has a table on “Justified Use” of various functional classes of additives in mozzarella. In addition to the Table on “justified use”, CODEX STAN 262-2006 also has a separate table which lists specific food additives for each technologically justified functional class.

5. The table on “Justified Use” in CODEX STAN 262-2006 differentiates between the food additives allowed in low versus high moisture mozzarella. It also further differentiates between additives allowed in the cheese mass versus those allowed for surface treatment for both types of mozzarella. This table has an “X” if additives of a certain functional class is technologically justified, and a “-“ if additives of that class are not technologically justified. However, the table provides no indication on the technological justification of preservatives or anti-caking agents for surface treatment of mozzarella with high moisture content: the entries for these uses in the Table are blank. It is also noted that the Table lists preservatives as justified for cheese mass and surface treatment of low moisture content, as well as for cheese mass for high moisture content mozzarella. The table also lists anti-caking agents as being justified for surface treatment of low moisture content but only for sliced, cut, shredded, or grated cheese. This table has been reproduced below:

¹ REP 17/FA, para. 109.

Additive functional class	JUSTIFIED USE			
	Mozzarella with low moisture content		Mozzarella with high moisture content	
	Cheese mass	Surface treatment	Cheese mass	Surface treatment
Colours:	X ^(a)	–	X ^(a)	–
Bleaching agents:	–	–	–	–
Acidity regulators:	X	–	X	–
Stabilizers:	X	–	X	–
Thickeners:	X	–	X	–
Emulsifiers:	–	–	–	–
Antioxidants:	–	–	–	–
Preservatives:	X	X	X	–
Foaming agents:	–	–	–	–
Anti-caking agents:	–	X ^(b)	–	–

^(a) Only to obtain the colour characteristics, as described in Section 2.

^(b) For the surface of sliced, cut, shredded or grated cheese, only.

X The use of additives belonging to the class is technologically justified.

– The use of additives belonging to the class is not technologically justified.

Corresponding Food Category of the GSFA

6. In the GSFA food category 01.6.1 (Unripened cheese) corresponds to CODE STAN 262-2006. As per Annex C of the GSFA, food category 01.6.1 also corresponds to CODEX STANS 221-2001, 273-1968, 175-1973, and 283-1978. It should be noted that CCFA has yet not done the work of aligning food category 01.6.1 with the corresponding commodity standards. Currently, food category 01.6.1 has several adopted provisions for preservatives (Natamycin (INS 235)) with note 3 “surface treatment only” and Note 82; Lauric arginate ethyl ester (INS 243) with no note; and Nisin (INS 234) with note 233; and one provision in the step process for nitrates (INS 251, 252) with note 30. There are no provisions for anticaking agents either adopted or in the step process. Food category 01.6.1 is not listed in the Annex to Table 3, however, since CODEX STAN 221-2001 lists specific additives, Table 3 additives cannot be used in the standardized food unless specifically listed in the commodity standard.

Working Document

7. The EWG issued three circulars for comment. The current document presents recommendations for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content covered by the *Standard for Mozzarella* (CODEX STAN 262-2006). The document also presents a compilation of comments provided by EWG members to the first, second and third circulars.

Conventions

8. These recommendations are based upon a consensus approach taking into comments on the first, second and third circulars by members of the EWG and information on the *Standard for Mozzarella* (CODEX STAN 262-2006). These recommendations are based on the “weight of evidence”; that is, comments containing justifications were given more weight than comments with no supporting justification.

I. General Summary of comments provided in response to the First Circular:

The first circular requested comment on the technological justification for the use of preservatives and anti-caking agents for surface treatment of mozzarella with high moisture content corresponding to CODEX STAN 262-2006. Specific to anti-caking agents the first circular observed that CODEX STAN 262-2006 states that low moisture content mozzarella “is suitable for shredding” and that anti-caking agents are suitable only for the surface treatment of “sliced cut, shredded, or grated” low moisture content mozzarella, but is silent on the suitability of high moisture content mozzarella for shredding. Therefore, the first circular requested comment on the suitability (or lack therefore) of high moisture content mozzarella for shredding

A. Preservatives:

Of the comments submitted to the first circular on preservatives, most comments asserted that preservatives are justified for use on for surface treatment of high moisture content mozzarella. These comments noted that the surface treatment of low-moisture mozzarella is listed as justified in in CODEX STAN 262-2006, and that the same justification for low-moisture mozzarella applies to high-moisture mozzarella to an even greater extent (e.g., that the higher moisture content of these cheeses will encourage microbial growth to an even higher extent than low-moisture cheeses). Several of these comments noted that the brine used to pack high-moisture mozzarella should not contain preservatives, but it was unclear from the comments provided if there was consensus that preservatives are applied to the surface of high-moisture mozzarella prior to being packed in brine.

The second circular proposed that CCFA inform CAC that the use of preservatives in the surface treatment of high-moisture mozzarella is justified, but requested comment from the EWG as to whether such use is justified only when the product is not packaged in liquid. The second circular put forward two proposals to revise the “Justified Use” table in CODEX STAN 262-2006 dependent upon the EWG reply to this question.

B. Anti-caking agents:

All comments submitted to the first circular on anti-caking agents agreed that these additives are only justified for use in the surface treatment of shredded cheese. Several comments noted that high-moisture mozzarella in the lower end of the moisture range can be shredded, and that surface treatment of anticaking agents are justified in those applications only. However, comments also noted that the compositional distinction between high-moisture and low-moisture mozzarella should be maintained, and therefore requested that CCFA recommend to CAC that CCMMP be tasked to address a new type of mozzarella that can be shredded at higher moisture content and different compositional specifications than what is currently differentiated in CODEX STAN 262-2006.

The second circular proposed that the use of anti-caking agents in the surface treatment of high-moisture mozzarella is justified for shredded mozzarella cheese regardless of moisture content. The second circular put forward a proposal to revise both the “Justified Use” table and Section 2 “Description” in CODEX STAN 262-2006 to reflect that certain high-moisture mozzarella in the low moisture range is suitable for shredding and that anti-caking agents are justified in shredded high-moisture mozzarella.

II. General Summary of comments provided in response to the Second Circular

The comments to the second circular supported the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content. Specific to preservatives, comments to the second circular indicated that their use is justified only when the product is not packaged in liquid. Specific to anticaking agents, all comments were in support of revising the “Justified Use” table in CODEX STAN 262-2006 to reflect that anti-caking agents are justified in shredded mozzarella with high moisture content. However, there were differing opinions on the revision of Section 2 “Description” in CODEX STAN 262-2006 to reflect that certain high-moisture mozzarella in the low moisture range is suitable for shredding. Several comments suggested such revision was redundant, while one comment suggested that this issue should be forwarded to CCMMP for consideration.

III. General Summary of comments provided in response to the Third Circular

The EWG provided comment on the third circular proposal for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content covered by the *Standard for Mozzarella* (CODEX STAN 262-2006). The EWG members support the third circular proposals in 1, 2, and 3. Several EWG members commented that it was not necessary to amend Section 2. “Description” of CODEX STAN 262-2006. One observer organization recommended additional editorial reorganization of the table on “Justified Use” in CODEX STAN 262-2006.

IV. Final EWG Proposal

Taking the comments from the third circular proposal, the final EWG proposal will include 1, 2 and 3. Proposal 4 from the 3rd circular will not be considered. Additionally, the requests from the Observer

organization for amendments to the table on “Justified Use” in CODEX STAN 262-2006 will not be included; there was not sufficient time for the EWG to discuss and does not clearly fall within the mandate of the work proposed.

Thus, CCFA to inform CAC that:

- 1) The use of anti-caking agents in the surface treatment of high-moisture mozzarella is technologically justified only when that mozzarella is in a shredded or diced format.
- 2) The use of preservatives in the surface treatment of high-moisture mozzarella is technologically justified when that mozzarella is not packaged in liquid
- 3) Recommend that the table on “Justified Use” in CODEX STAN 262-2006 be revised as shown in **bolded text** below to reflect the technologically justified use of these additives in high-moisture mozzarella:

Additive functional class	JUSTIFIED USE			
	Mozzarella with low moisture content		Mozzarella with high moisture content	
	Cheese mass	Surface treatment	Cheese mass	Surface treatment
Colours:	X ^(a)	–	X ^(a)	–
Bleaching agents:	–	–	–	–
Acidity regulators:	X	–	X	–
Stabilizers:	X	–	X	–
Thickeners:	X	–	X	–
Emulsifiers:	–	–	–	–
Antioxidants:	–	–	–	–
Preservatives:	X	X	X	X^(c)
Foaming agents:	–	–	–	–
Anti-caking agents:	–	X ^(b)	–	X^(d)

^(a) Only to obtain the colour characteristics, as described in Section 2.

^(b) For the surface of sliced, cut, shredded or grated cheese, only.

^(c) **Only for high-moisture mozzarella not packaged in liquid.**

^(d) **For the surface treatment of shredded and/or diced cheese, only.**

X The use of additives belonging to the class is technologically justified.

– The use of additives belonging to the class is not technologically justified

Appendix 7: Provisions in Table 1 and 2 of the GSFA in food categories 14.1.4 and 14.1.5

1. Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to:¹
 - Request information on the actual use levels, technological justifications and available relevant dietary exposure data on specific food additive provisions in food categories 14.1.4 and 14.1.5.

Background

2. The electronic working group (EWG) on the GSFA to CCFA50 considered proposals for the remaining draft and proposed draft provisions for food additives in food categories 14.1.4 (Water-based flavoured drink, including “sport”, “energy”, or “electrolyte” drinks and particulated drinks), its subcategories, and 14.1.5 (Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa), with the exception of provisions for food additives with “colour” or “sweetener” function, adipates, and nitrites and nitrates.

3. During the discussion on specific draft and proposed draft provisions for food additives in food categories 14.1.4, its subcategories, and 14.1.5, one Member Organization made comments that the use of several food additives in products of these food categories at the proposed maximum levels may exceed their JECFA Acceptable Daily Intake (ADI) if even limited amount of the products was consumed by a small child. Several Members noted that such a calculation did not demonstrate that the proposed maximum use level of a specific food additive was unsafe. The Committee noted the differing opinions and also that the discussion indicated the need for further data on exposure to the food additives.² As a result, CCFA50 agreed to circulate the provisions through the EWG on the GSFA to CCFA51. The EWG was mandated to collect data and information on the actual use levels, technological justifications and available relevant dietary exposure data to be used to develop proposals for consideration by CCFA51.³

Working Document

4. The EWG issued three circulars for comment. The first circular contained EWG comments on the available dietary exposure data for the additives under discussion, as relevant to the draft provisions for the use of these additives in food categories 14.1.4 and 14.1.5, as well as exposure for young children from products in these food categories that contain the additive. The second and third circulars contained EWG comments on the request for information on the actual use level and types of fruit-flavoured beverages. The document presents a compilation of comments provided by EWG members to the first, second and third circulars.

Conventions

5. The current document presents recommendations for the draft and proposed draft provisions in food categories (FCs) 14.1.4, its subcategories and 14.1.5 under discussion in the format of the food categories listed in Table 2 of the GSFA. This document presents proposals (adopt, adopt with revision) for the draft provisions under discussion based upon a consensus approach taking into account comments on the first, second and third 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.

¹ REP 18/FA, para. 92(iii) and (iv).

² REP 18/FA, para. 91.

³ REP18/FA para 92 (iii) and (iv).

Provision for INS 480 in FC 14.1.4**Food Category No. 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	3rd Circular Proposal	EWG Final Proposal
DIOCTYL SODIUM SULFOSUCCINATE	480	10		7	Emulsifier, Humectant	Adopt in FC 14.1.4 with a new note "For use in fruit-flavoured beverages only" and Note 127 "On the served to the consumer basis" Request additional information on actual use level and types of fruit-flavoured beverages	Discuss 3 rd Circular proposal further Request additional information on types of fruit-flavoured beverages

DIOCTYL SODIUM SULFOSUCCINATE JECFA ADI: 0-0.1 mg/kg bw**Summary of information provided to 1st Circular on available exposure assessments for INS 480**

One Comment cited a recent US FDA evaluation of INS 480 which gave Generally Recognized As Safe status to the use in beverages at 10 ppm. The comment also cited a the 1977 JECFA exposure assessment which utilized a survey of use levels for the additive with food intake surveys to derive additive intakes for high-percentile consumers of those foods. This assessment assumed additive use in all beverages (conservative). To put the JECFA exposure assessment into an updated context the comment noted more recent poundage data and per captia intake for all emulsifiers, and contrasted that to more recent poundage data for INS 480. The comment states "The maximum estimated intake level for current uses of DSS in food is 130 µg/day, or 0.13 mg/day. Cumulative intake of DSS from all food uses, therefore, will not exceed the total of this value and the 5.6 mg/day intake conservatively calculated above for soft drink use, or about 5.7 mg/day. This is below the ADI set by JECFA for DSS."

A separate comment noted that one region is considering removing INS 480 from their list of permitted food additives.

Chair's Note: In the 1995 JECFA report, it was noted the "current estimates of the dietary intake of dioctyl sodium sulfosuccinate from food additive uses may reach 2 µg/p/d (equivalent to 0.03 µg/kg-bw/d)". Though because of the limited toxicological data currently available, the Committee withdrew its request for a long-term study and determined it appropriate to increase the previous safety factor of 200 (from the 1977 exposure assessment) to 500. Thus, the Committee established an ADI of 0-0.1 mg/kg-bw/d for the food additive use of dioctyl sodium sulfosuccinate.

Overall summary of all comments by EWG Members:

Australia: This food additive is permitted in Australia for water based flavoured drinks, at the same MPL, with no additional conditions. Industry information indicated that for all

relevant beverages it is only used as an emulsifier in flavour preparations added to the beverages, not added directly.

Brazil: In Brazilian legislation (RDC n. 5/2007), this additive (INS 480) is allowed as stabilizer in ready-t-drink non-alcoholic beverages (carbonated or not) with ML of 10 mg/L.

Canada: permits INS 480 at 10 mg/kg as a wetting agent in fumaric acid-acidulated dry beverage bases. INS 480 is a dibasic anionic surfactant used to solubilize emulsifiers, particularly those that carry flavourings. Its use is limited (mostly to carbonated and non-carbonated beverages with fruit-flavoured emulsions), but the types of beverages span all sub-categories of FC 14.1.4.

Colombia: Supports to Adopt in FC 14.1.4 at 10 mg/Kg, with a new note "For use in fruit-flavoured beverages only" and Note 127 "On the served to the consumer basis"

Costa Rica: Use level 10 ppm (primarily fruit flavored beverages); Is a dibasic anionic surfactant providing unique wetting agent properties for flavoring emulsions specifically in fruit flavored beverages; Has uses limited in beverages and an ML should be in specific subcategories.

EU: Does not support. The ADI is very low. It is not clear why this emulsifier is needed and why other emulsifiers with higher ADIs or ADIs not specified are not suitable. The reference to the JECFA assessment of 1977 (41 years old!) does not seem to be very convincing as well as per capita intake calculations based on poundage data from 1987.

"Fruit-flavoured beverages" still cover a broad group of products. If it is used for niche products such products need to be better described.

By using Annex A to the GSFA and the least conservative scenario (i.e. Guideline 14) the ML shall not exceed 4 mg/kg (0.5 x 0.1 x 80). Levels above this value should only be accepted for products where calculation of potential intake will show that exceeding the ADI is unlikely (e.g. strong alcoholic beverages). The other scenarios, which may be valid for brand loyal consumers, lead even to lower ML acceptable from the exposure point of view (e.g. Guideline 11, ML = 1 mg/kg).

Indonesia: Does not allow the use of INS 480 as food additive. The reason is this additive has a very low ADI value, 0 – 0.1 mg/kg bw/day.

Paraguay: does not oppose on adoption of provisions for FC 14.1.4

Russian Federation: Does not support proposal; no technological justification ML is high. ADI 0, 1 mg/kg. ML could not be higher 6 mg/kg

Spain: There are others additives which are already authorized for this FC with the same function.

ICBA: Use level 10 ppm (primarily fruit flavored beverages); DSS is a dibasic anionic surfactant providing unique wetting agent properties for flavoring emulsions specifically in fruit flavored beverages, carbonated and non-carbonated; DSS has limited uses in beverages, yet is applicable across all subcategories.

Provision for INS 475 in FC 14.1.4

Food Category No. 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	3rd Circular Proposal	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	9000		7	Emulsifier, Stabilizer	Adopt in FC 14.1.4 at 5,000 mg/kg with Note 127 "On the served to the consumer basis" Request additional information in products at 10,000 mg/kg	Adopt in FC 14.1.4 at 5,000 mg/kg with Note 127 "On the served to the consumer basis"
POLYGLYCEROL ESTERS OF FATTY ACIDS JECFA ADI: 0-25 mg/kg bw							
Summary of information provided to 1st Circular on available exposure assessments for INS 475							
<p>One Comment cited a dietary intake assessment conducted by Japan where dietary intake was calculated based on 2013 poundage data. The assessment considered the total amount of all glycerol esters of fatty acids in all food products, but did not specify the amount within FC14.1.4 and 14.1.5. The calculated intake was 214 mg/person/day (equivalent to 3.6 mg/kg bw/day), based on a body weight of 60 kg. The JECFA ADI is 0- 25 mg/kg bw.</p> <p>Several other comments cited a 2017 assessment by EFSA that noted that exposure to INS 475 most likely would not exceed JECFA's ADI, but this assessment did not include FC 14.1.4 or 14.1.5. However, the comments also cite that EFSA's review stated that there is no need for a numerical ADI for INS 475 as no adverse effects have been identified for the additive.</p>							
Overall summary of all comments by EWG Members:							
<p>Australia: There is no permission and no use for this food additive in this food category in Australia.</p> <p>Canada: permits INS 475 as an emulsifier/stabilizer in unstandardized foods in general, at GMP. Information provided by industry suggests that a ML is sufficient for emulsification of flavours, with most notable uses in emulsifying fruit-flavours, nutrient premixes, whiteners, and preventing separation of milk constituents in coffee, tea, or cocoa liquid. INS 475 therefore has use in all sub-categories of FC 14.1.4.</p> <p>China: Actual use levels in specific products within the food category: In China the maximum use level of polyglycerol fatty acid esters in beverages is 10000mg/kg. It is reported from industries that the effective dose of polyglycerol fatty acid esters is generally 0.05%~1%. Technological justification for the use at the specified ML in those products: The emulsifying property of polyglycerol fatty acid ester in neutral pH is equal to that of high HLB sucrose fatty acid ester, but with increase in acidity, the water solution of sucrose fatty acid ester will be agglomerated, while the emulsifying property of polyglycerol fatty acid ester is good, even if the pH value is very low. In addition, Polyglycerol fatty acid ester has good antibacterial effect on bacteria, mould, yeast and spores. It can improve the stability and dispersity of the beverage, improve the quality of canned beverage and prolong shelf life with good taste, stable performance and good heat resistance. Whether a general ML across the parent category is appropriate or use should be discussed in the subcategories: China supports to have a general ML across the parent category.</p> <p>Colombia: Supports to adopt in FC 14.1.4 at 5,000 mg/kg with Note 127 "On the served to the consumer basis"</p> <p>Costa Rica: Use level 5000 ppm (primarily fruit flavored beverages and cold and hot coffee and tea); Provide emulsification for certain fruit flavoring emulsions, nutrient premixes, and whiteners in beverages. Additionally, EFSA recently re-reviewed PEFAs, 2017 December. EFSA did not have any concerns for safety at the reported uses and use levels and that</p>							

there was no need for a numerical ADI. <https://doi.org/10.2903/j.efsa.2017.5089>; Are used in a range of beverage types, an ML in the parent category is appropriate

EU: the ML of 10.000 does not seem to be compatible with the current JECFA ADI.

Indonesia: does not allow the use of INS 475 in food category 14.1.4, but allowed in food category 14.1.4.2 with note “only for ready-to-drink coffee” with ML 100 mg/kg. The use at the ML already gives the technological function.

Japan: This additive is used in non-carbonated water-based flavoured drinks at 2000 mg/kg. It is used in concentrates for non-carbonated water-based flavoured drinks at 6000 mg/kg. This use level is converted to 1200 mg/kg as served to consumer basis. This additive is used to prevent separation of oil ingredients of non-carbonated water-based flavoured drinks.

Paraguay: does not oppose on adoption of provisions for FC 14.1.4

Russian Federation: agrees with need of request JECFA EWG to place INS 475 on JECFA priority list for re-evaluation

ICBA: Use level up to 5000 ppm (primarily fruit flavored beverages and cold and hot coffee and tea); PEFA provide emulsification for certain fruit flavoring emulsions, nutrient premixes, and whiteners in beverages. PEFA also provides emulsifier stabilization to prevent separation between milk constituents and coffee, tea or cocoa liquid. Examples of products that require PEFA include: coffee with milk, tea with milk and cocoa with milk; PEFA are used in a range of beverage types, an ML in the parent category is appropriate

Provision for stearoyl lactylates in FC 14.1.4 and subcategories

Food Category No. 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	3rd Circular Proposal	EWG Final Proposal
STEAROYL LACTYLATES	481(i), 482(i)	2000		7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	Discontinue in FC 14.1.4. Consider only in subcategories 14.1.4.2 and 14.1.4.3	Discontinue in FC 14.1.4. Consider only in subcategories 14.1.4.2 and 14.1.4.3
STEAROYL LACTYLATES JECFA ADI: 0-20 mg/kg bw							
Summary of information provided to 1st Circular on available exposure assessments for stearoyl lactylates							
Several comments cited a 2013 assessment by EFSA that included the use in powders for the preparation of hot beverages in FC 14.1.4 and 14.1.5, but that EFSA assumed that this use did not added to exposure. EFSA assessment noted that exposure exceeds ADI for high percentile consumers.							
One comment cited a Eurasian Commission assessment that did not include FC 14.1.4 or 14.1.5.							
Overall summary of all comments by EWG Members:							
Australia, China, Colombia, Costa Rica, EU, India, Russian Federation, ICBA, ICGMA: supports discontinuation in parent category in favor of provisions in subcategories							
Canada: does not permit these additives in beverages. However, industry has advised that there is known use of up to 2,000 mg/kg, primarily in cocoa-containing beverages (FC 14.1.4.2) to emulsify cocoa preparations, and in hot coffee and tea (FC 14.1.5) to emulsify whiteners. These limited uses would suggest sub-category specific provisions are preferable and confirmation of use-levels in products in those sub-categories.							
Indonesia: Does not allow the use of INS 481(i) and 482(i) in food category 14.1.4.2. The reason is the high consumption of the products in the food category (220 grams/person/day). There are other emulsifiers for this food category that are already permitted.							
Paraguay: does not oppose on adoption of provisions for FC 14.1.4: Does not support proposal; no technological justification: ML is high							
Spain: 2000 PPM; only powders for the preparation of hot beverages. (The additives may be added individually or in combination).							

Food Category No. 14.1.4.1 Carbonated water-based flavoured drinks**Corresponding commodity standards: None**

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	EWG Final Proposal
STEAROYL LACTYLATES	481(i), 482(i)	2000			Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	Do not move to FC 14.1.4.1	Do not move to FC 14.1.4.1

Overall summary of all comments by EWG Members:

Australia, Canada, China, Costa Rica, EU, India, Russian Federation, ICBA, ICGMA: Supports the recommendation to not move this provision to 14.1.4.1.

Indonesia: Does not allow the use of INS 481(i) and 482(i) in food category 14.1.4.1. The reason is the high consumption of the products in the food category (220 grams/person/day). There are other alternative emulsifiers for this food category that are already permitted.

Paraguay: does not oppose on adoption of provisions for FC 14.1.4

Spain: This additive is not authorized in EU for this kind of drinks. There are others additives which are already authorized for this FC with the same function

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

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	EWG Final Proposal
STEAROYL LACTYLATES	481(i), 482(i)	2000			Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	Adopt with New note "for use in cocoa containing beverages and coffee and tea products containing milk constituents only"	Discuss 3 rd Circular proposal further Request information on "ready-to-drink products" and "protein containing beverages" Chair's Notes: Cocoa-based beverage does not appear to be covered under FC 14.1.4.2. See FCs 1.1.4 and 5.1.1.

Overall summary of all comments by EWG Members:

Australia: As above, not used

Canada: does not permit these additives in beverages. However, industry has advised that there is known use of up to 2000 mg/kg, primarily in cocoa-containing beverages (FC 14.1.4.2) to emulsify cocoa preparations, and in hot coffee and tea (FC 14.1.5) to emulsify whiteners. Unless other product-specific examples are provided, Canada might not object to use in cocoa-containing beverages, specifically.

China: Supports the proposal, but suggests revising the note to "for use in cocoa and protein containing beverages and coffee and tea products containing milk constituents only".

China permits INS 481(i) and INS 482(i) in “Protein containing beverages” and “Tea, coffee, or plant based beverages” with ML 2000mg/kg.

Colombia: Supports to adopt at 2000 mg/Kg with new note “for use in cocoa containing beverages and coffee and tea products containing milk constituents only”

Costa Rica: Use level 2000 ppm (primarily cocoa containing beverages and cold and hot coffee and tea); Stearoyl lactylate provide emulsification for cocoa preparations and whiteners in beverages; Stearoyl lactylate are used in a limited range of beverage types, an ML in the appropriate categories is appropriate.

EU: the EFSA’s exposure assessment indicates the ADI being exceeded for toddlers, children and adolescents at mean level and for all groups of population at high level. The use in FC 14.1.4 is restricted in the EU legislation to “powders for the preparation of hot beverages” and it was not taken into account in the exposure estimates. The ML 2000 ppm is as marketed – thus related to powders – further limiting the exposure. The EU is not in the position to support broader uses taking into account the exposure concerns.

India: supports the proposal

Indonesia: Does not allow the use of INS 481(i) and 482(i) in food category 14.1.4.2. The reason is the high consumption of the products in the food category (220 grams/person/day). There are other emulsifiers for this food category that are already permitted.

Paraguay: does not oppose on adoption of provisions for FC 14.1.4

Russian Federation: Does not support proposal; no technological justification: ML is high

Spain: This additive is not authorized in EU for this kind of drinks. There are others additives which are already authorized for this FC with the same function.

ICBA, ICGMA: Use level 2000 ppm in the finished beverage as served to the consumer (primarily cocoa containing beverages and cold (14.1.4.2) and hot (14.1.5) coffee and tea); Stearoyl lactylate provide emulsification for cocoa preparations and whiteners in beverages; Stearoyl lactylate are used in a limited range of beverage types.

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

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	EWG Final Proposal
STEAROYL LACTYLATES	481(i), 482(i)	2000			Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	Adopt with New note “for use in cocoa containing beverages and coffee and tea products containing milk constituents only” and Note 127 “On the served to the consumer basis”	Discuss 3 rd Circular proposal further Request information on “ready-to-drink products” and “protein containing beverages” Chair’s Notes: Cocoa-based beverage does not appear to be covered under FC 14.1.4.2. See FCs 1.1.4 and 5.1.1.

Overall summary of all comments by EWG Members:

Australia: As above, not used

Canada: does not permit these additives in beverages. Requests product-specific examples for further consideration, including confirmation of levels of use.

China: Supports the proposal, but suggests revising the note to “for use in cocoa and protein containing beverages and coffee and tea products containing milk constituents only”.

China permits INS 481(i) and INS 482(i) in “Protein containing beverages” and “Tea, coffee, or plant based beverages” with ML 2000mg/kg.

Colombia: Supports to adopt at 2000 mg/Kg with new note “for use in cocoa containing beverages and coffee and tea products containing milk constituents only” and Note 127 “On the served to the consumer basis”

Costa Rica: Use level 2000 ppm (primarily cocoa containing beverages and cold and hot coffee and tea); Stearoyl lactylate provide emulsification for cocoa preparations and whiteners in beverages; Stearoyl lactylate are used in a limited range of beverage types, an ML in the appropriate categories is appropriate. Supports the recommendation to adopt this provision at 2,000 ppm in the specific subcategory 14.1.4.3. with new notes.

EU: EFSA’s exposure assessment indicates the ADI being exceeded for toddlers, children and adolescents at mean level and for all groups of population at high level. The use in FC 14.1.4 is restricted in the EU legislation to “powders for the preparation of hot beverages” and it was not taken into account in the exposure estimates. The ML 2000 ppm is as marketed – thus related to powders – further limiting the exposure. The EU is not in the position to support broader uses taking into account the exposure concerns.

India: supports the proposal

Indonesia: Does not allow the use of INS 481(i) and 482(i) in food category 14.1.4.3. The reason is the high consumption of the products in the food category (220 grams/person/day). There are other emulsifiers for this food category that are already permitted.

Paraguay: does not oppose on adoption of provisions for FC 14.1.4

Russian Federation: Does not support proposal; no technological justification: ML is high

Spain: 2000 PPM; only powders for the preparation of hot beverages. (The additives may be added individually or in combination).

ICBA, ICGMA: Use level 2000 ppm in the finished beverage as served to the consumer (primarily cocoa containing beverages and cold (14.1.4.2) and hot (14.1.5) coffee and tea); Stearoyl lactylate provide emulsification for cocoa preparations and whiteners in beverages; Stearoyl lactylate are used in a limited range of beverage types. ICBA recommends deletion of the suggested note relative to cocoa but supports Note 127.

Provision for INS 475 in FC 14.1.5**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”

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	EWG Final Proposal
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	5000		7	Emulsifier, Stabilizer	Adopt at 5000 mg/kg with Note 160 “For use in ready-to-drink products and pre-mixes for ready-to-drink products only” Request clarification on the use level as served to the consumer basis Request additional information in products at 10,000 mg/kg	Adopt at 5000 mg/kg with Note 127 “On the served to the consumer basis”.

POLYGLYCEROL ESTERS OF FATTY ACIDS JECFA ADI: 0-25 mg/kg bw

Summary of information provided to 1st Circular on available exposure assessments for INS 475

One Comment cited a dietary intake assessment conducted by Japan where dietary intake was calculated based on 2013 poundage data. The assessment considered the total amount of all glycerol esters of fatty acids in all food products, but did not specify the amount within FC14.1.4 and 14.1.5. The calculated intake was 214 mg/person/day (equivalent to 3.6 mg/kg bw/day), based on a body weight of 60 kg. The JECFA ADI is 0- 25 mg/kg bw.

Several other comments cited a 2017 assessment by EFSA that noted that exposure to INS 475 most likely would not exceed JECFA’s ADI, but this assessment did not include FC 14.1.4 or 14.1.5. However, the comments also cite that EFSA’s review stated that there is no need for a numerical ADI for INS 475 as no adverse effects have been identified for the additive.

Overall summary of all comments by EWG Members:

Australia: There is no permission for this food additive in this food category in Australia.

Canada: permits INS 475 as an emulsifier/stabilizer in unstandardized foods in general, at GMP. Information by industry suggests that a ML is sufficient for emulsification of flavours, with most notable uses in emulsifying whiteners, and preventing separation of milk constituents in coffee, or tea.

China: Actual use levels in specific products within the food category: In China the maximum use level of polyglycerol fatty acid esters in beverages is 10000mg/kg. It is reported from industries that the effective dose of polyglycerol fatty acid esters is generally 0.05%~1%. Technological justification for the use at the specified ML in those products: The emulsifying property of polyglycerol fatty acid ester in neutral pH is equal to that of high HLB sucrose fatty acid ester, but with increase in acidity, the water solution of sucrose fatty acid ester will be agglomerated, while the emulsifying property of polyglycerol fatty acid ester is good, even if the pH value is very low. In addition, Polyglycerol fatty acid ester has good antibacterial effect on bacteria, mould, yeast and spores. It can improve the stability and dispersity of the beverage, improve the quality of canned beverage and prolong shelf life with good taste, stable performance and good heat resistance. Whether a general ML across the parent category is appropriate or use should be discussed in the subcategories: China supports to have a general ML across the parent category.

Colombia: Supports to adopt at 5000 mg/kg with Note 160 "For use in ready-to-drink products and pre-mixes for ready-to-drink products only"

Costa Rica: Use level 5000 ppm (primarily fruit flavored beverages and cold and hot coffee and tea); Provide emulsification for certain fruit flavoring emulsions, nutrient premixes, and whiteners in beverages. Additionally, EFSA recently re-reviewed PEFAs, 2017 December. EFSA did not have any concerns for safety at the reported uses and use levels and that there was no need for a numerical ADI. <https://doi.org/10.2903/j.efsa.2017.5089>; Are used in a range of beverage types, an ML in the parent category is appropriate. Supports the recommendation to adopt this provision at 5,000 ppm in 14.1.5. but suggests replacing Note 160 with Note 127 "On the served to the consumer basis".

Indonesia: Does not support the proposed maximum level. At the maximum level of 5000 mg/kg give the high exposure up to 176%ADI for children and 73%ADI for adults.

Japan: Maximum use level: Ready to drink coffee or ready to drink black tea: 2000 mg/kg. Concentrates for milk tea: 6000 mg/kg (200 mg/kg as served to consumer basis); This additive is used as emulsifier to prevent separation of oil ingredients of coffee, black tea or milk tea. It is also used as stabilizer to aid emulsion stability and improve shelf-life. Proposes adopting without Note 160 "For use in ready-to-drink products and pre-mixes for ready-to-drink products only", and adding Note 127 "On the served to the consumer basis". Polyglycerol esters of fatty acids are not only used in ready-to-drink products and pre-mixes, but also in concentrates as emulsifier to prevent oil separation of oil ingredients. According to FC 14.1.5 descriptor of GSFA, mixes and concentrates are defined as different products. However, if the provision is adopted with Note 160, polyglycerol esters of fatty acids cannot used in concentrates. Ready-to-drink products and their mixes and concentrates are fallen within FC 14.1.5. Note 127 should be added to FC 14.1.5 for clarification.

Russian Federation: Does not support proposal; no technological

ICBA: Use level up to 5000 ppm (primarily fruit flavored beverages and cold and hot coffee and tea); PEFAs provide emulsification for certain fruit flavoring emulsions, nutrient premixes, and whiteners in beverages. PEFA also provides emulsifier stabilization to prevent separation between milk constituents and coffee, tea or cocoa liquid. Examples of products that require PEFA include: coffee with milk, tea with milk and cocoa with milk. Supports the recommendation to adopt this provision at 5,000 ppm in 14.1.5. but suggests replacing Note 160 with Note 127 "On the served to the consumer basis". (Please Note: ABA defers to China for levels higher than 5,000 ppm.) Rationale: Note 160 does not include "concentrates", and is limited to ready-to-drink products and pre-mixes of these only. Yet, 'pre-mixes' and 'concentrates' are different from each other as reflected in the description in 14.1.5. "Includes the ready-to-drink products (e.g. canned), and their mixes and concentrates." By replacing Note 160 with Note 127, all use scenarios would be covered.

Provision for stearoyl lactylates in FC 14.1.5**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”

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	3 rd Circular Proposal	EWG Final Proposal
STEAROYL LACTYLATES	481 (i), 482(i)	2000	2	7	Emulsifier, Flour treatment agent, Foaming agent, Stabilizer	Remove Note 2 and Adopt with a new note “For use in beverages which contain beverage whiteners only” and Note 127 “On the served to the consumer basis” Request information for the use in mixes containing beverage whiteners only.	Remove Note 2 and Adopt with a new note “For use in beverages which contain beverage whiteners only” and Note 127 “On the served to the consumer basis”

STEAROYL LACTYLATES JECFA ADI: 0-20 mg/kg bw

Summary of information provided to 1st Circular on available exposure assessments for stearoyl lactylates

Several comments cited a 2013 assessment by EFSA that included the use in powders for the preparation of hot beverages in FC 14.1.4 and 14.1.5, but that EFSA assumed that this use did not added to exposure. EFSA assessment noted that exposure exceeds ADI for high percentile consumers.

One comment cited a Eurasian Commission assessment that did not include FC 14.1.4 or 14.1.5.

Overall summary of all comments by EWG Members:

Australia: There is no permission and no use for this food additive in this food category in Australia.

Canada: does not permit these additives in beverages. However, industry has advised that there is known use of up to 2,000 mg/kg, primarily in hot coffee and tea (FC 14.1.5) to emulsify whiteners. Unless other product-specific examples are provided, Canada might not object to use in beverages containing whiteners, specifically.

Colombia: Supports to remove Note 2 and Adopt with a new note “For use in beverages which contain beverage whiteners only” and Note 127 “On the served to the consumer basis”

Costa Rica, ICBA: Suggests discontinuation of this provision as this additive is used in a limited number of products.

EU: Accepts

Russian Federation: Does not support proposal; no technological justification

Spain: 2000 PPM; only powders for the preparation of hot beverages. (The additives may be added individually or in combination).

Note 2: On the dry ingredient, dry weight, dry mix or concentrate basis.