CODEX ALIMENTARIUS COMMISSION E

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Agenda Item 5(a) **CX/FA 12/44/7**

November 2011

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fourth Session

Hangzhou, China, 12-16 March 2012

PENDING DRAFT AND PRPOSED DRAFT FOOD ADDITIVES PROVISIONS AND RELATED MATTERS

BACKGROUND

1. The 43rd Session of the Codex Committee on Food Additives (CCFA) considered the recommendations of the physical Working Group (pWG) on the *General Standard for Food Additives* (GSFA) for the draft and proposed draft food additives provisions included in Part I (Colour additives) of CX/FA 11/43/7 and in CX/FA 11/43/8. The Committee noted that, due to time constraints, the pWG had not considered Part II (Miscellaneous additives) of CX/FA 11/43/7 and the proposals for several other food additives included in CX/FA 11/43/9 (Agenda Item 5c) and that the pWG had agreed to defer discussion on food additive provisions related to food categories 05.0, 05.1 05.2, 05.4 and 16.0 and related sub-categories, awaiting the outcomes of the Committee's discussion related to Agenda Item 5e and 5f (ref. REP11/FA para.50).

2. The present document compiles the following pending draft and proposed draft food additive provisions and related matters:

(i) Provisions included in Part II (Miscellaneous additives) of CX/FA 11/43/7 (*see* Appendix I);

(ii) Provisions for food categories 05.0, 05.1 05.2, 05.4 and 16.0 and related sub-categories, included in Part 1 (Colour additives) of CX/FA 11/43/7 (*see* Appendix II);

(iii) Comments and information on several food additives (replies to CL 2010/7-FA Part B (points 11-14) and CL 2010/39-FA), included in CX/FA 11/43/9 and in CRD 13-Rev (*see* Appendix III).

Appendix I

PROVISIONS INCLUDED IN PART II (MISCELLANEOUS) OF CX/FA 11/43/7

***Note**: To help the reader, the text of all of the Notes that appear in the tables has been moved to the end of the document.*

GENERAL CONSIDERATIONS

1. Outstanding recommendations for provisions for the use of food additives include the following:

INS	Food additive	INS	Food Additive
200 – 203	Sorbates	459	*beta*-Cyclodextrin
214, 218	*para*-Hydroxybenzoates	474	Sucroglycerides
234	Nisin	484	Stearyl citrate
304, 305	Ascorbyl esters	954(i)-(iv)	Saccharins
310	Propyl gallate	955	Sucralose (Trichlorogalactosucrose)
338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542	Phosphates	962	Aspartame-acesulfame salt
442	Ammonium salts of phosphatidic acid		

SORBATES (INS 200-203)

2. The 29th JECFA (1985) assigned a group ADI of 25 mg/kg bw for sorbates.

3. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose preservative with sorbates.

Recommendation 1 – Sorbates, INS 200-203
The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for sorbates in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comments
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	300	mg/kg	Note 42	6	
01.2.2	Renneted milk (plain)	1,000	mg/kg	Note 42	6	
03.0	Edible ices, including sherbet and sorbet	1,000	mg/kg	Note 42	6	**Comment** No need of preservatives in frozen technology
04.1.2.1	Frozen Fruit	1,000	mg/kg	Note 42	6	**Comment** 1) Freezing provides adequate preservation, no need for chemical preservatives~~s~~
04.1.2.7	Candied fruit	1,000	mg/kg	Note 42	6	**Justification** Used in glazed fruit to top Gammon and in cake mix.
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	1,000	mg/kg	Note 42	6	
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	1,000	mg/kg	Note 42	6	**Comment** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	2,000	mg/kg	Note 42	6	**Comment** Use should only be in potato dough and pre-fried potato slices
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	1,500	mg/kg	Note 42	6	
05.1.2	Cocoa mixes (syrups)	1,000	mg/kg	Note 42	6	
05.1.3	Cocoa-based spreads, including fillings	1,500	mg/kg	Note 42	6	

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Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comments
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1,000	mg/kg	Note 42	6	**Comment** Recommend a level of 1,500 mg/kg. Micro stability of low acid toppings is not achieved at 1,000 mg/kg.
06.2	Flours and starches (including soybean powder)	1,000	mg/kg	Note 42	6	**Comment** No technological justification, use .level would result in high intake in a basic foodstuff
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	1,000	mg/kg	Note 42	6	
08.4	Edible casings (e.g., sausage casings)	GMP		Note 42	6	**Justification** For use in collagen based casings with a water activity greater than 0.6
13.6	Food supplements	2,000	mg/kg	Note 42	6	**Comment** Only support for use in food supplements supplied in liquid form
14.1.2.2	Vegetable juice	1,000	mg/kg	Note 42	6	**Justification** Adopt based on corresponding levels established for fruit juices and nectars; add notes 91 and 122 for consistency with notes for fruit juices and nectars.
14.1.2.4	Concentrates for vegetable juice	1,000	mg/kg	Note 42	6	**Justification** Adopt based on corresponding levels established for fruit juices and nectars; add notes 91, 122 and 127 for consistency with notes for fruit juices and nectars.
14.1.3.2	Vegetable nectar	1,000	mg/kg	Note 42	6	**Justification** Adopt based on corresponding levels established for fruit juices and nectars; add notes 91 and 122 for consistency with notes for fruit juices and nectars
14.1.3.4	Concentrates for vegetable nectar	1,000	mg/kg	Note 42	6	**Justification** Adopt based on corresponding levels established for fruit juices and nectars; add notes 91, 122 and 127 for consistency with notes for fruit juices and nectars.
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	600	mg/kg	Note 42	6	

Recommendation 3 – Sorbates, INS 200-203
The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for sorbates in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comments
01.6.1	Unripened cheese	3,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated a technological need for sorbates at 3000 mg/kg. However, in the Codex Standard 221-2001, for Unripened Cheese including Fresh Cheese there is a provision for 1000 mg/k **2)** Support use level of 3,000 mg/kg, which is needed to prevent mould growth.

Recommendation 3 – Sorbates, INS 200-203 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for sorbates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
01.6.2	Ripened cheese	3,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated a technological need for sorbates at 3000 mg/kg. However, in the Codex Standard A-6-1978, amended in 2006, Cheese, there is a provision for 1000 mg/kg **2)** suggest adding Note 3: surface treatment only 3) ML is 1000 mg/kg in CODEX STAN 283
01.6.4	Processed cheese	3,000	mg/kg	Note 42	6	**Comment** **1)** Consistent with the Codex Standard A-8(b)-1978 for Processed Cheese, also in Canada industry has indicated a technological need for sorbates at this level of use. **2)** ML 3,000 mg/kg is necessary as anti-moulding agent for higher pH products
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	1,000	mg/kg	Note 42	6	**Comments** **1)** Not necessary in heat treated products as the heat treatment provides adequate preservation. Add note "Only for non-heat treated dairy based desserts" **2)** ML 1000 mg/kg necessary in dairy based desserts independent of heat treatment; suggest adding a note: "use only allowed in heat treated flavoured fermented milk" (STAN 243)
04.1.2.2	Dried fruit	2,000	mg/kg	Note 42	6	**Comment** **1)** ML seems high. A ML of 1000 mg/kg seems sufficient to achieve the technological function **2)** Necessary in rehydrated/soft fruit, but not in standard fruit
04.1.2.5	Jams, jellies, marmalades	1,000	mg/kg	Note 42	6	**Comment** **1)** In the past, industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg **2)** Add note "only in low-sugar jams" **3)** Used at ML of 1000 mg/kg in all jams.
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	1,500	mg/kg	Note 42	6	**Comment** **1)** ML seems high. A ML of 1000 mg/kg sufficient to achieve the technological function **2)** This additive functions as preservative and the level is necessary to achieve the intended technical need.
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	2,000	mg/kg	Note 42	6	**Comment** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	2,000	mg/kg	Note 42	6	**Comment** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg

Recommendation 3 – Sorbates, INS 200-203 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for sorbates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	2,000	mg/kg	Note 42	6	**Comment** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg
05.1.4	Cocoa and chocolate products	1,000	mg/kg	Note 42	6	**Comment** Sorbates are not allowed in standardized cocoa or chocolate products (as per the Codex Standard)
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	2,000	mg/kg	Note 42	6	**Comment** **1)** ML seems high. A ML of 1500 mg/kg seems sufficient to achieve the technological function **2)** 1500 mg/kg is required for technical application in products
06.4.2	Dried pastas and noodles and like products	2,000	mg/kg	Note 42	6	**Justification** Consistent with Codex Standard for Noodles **Comment** No additives are necessary in dried pasta
06.4.3	Pre-cooked pastas and noodles and like products	2,000	mg/kg	Note 42	6	**Justification** Consistent with Codex Standard for Noodles **Comment** Add note “only in noodles”
07.0	Bakery wares	2,000	mg/kg	Note 42	6	**Comment** **1)** industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg **2)** Add note “Only pre-packed sliced bread and rye bread and partially cooked bakery wares and energy reduced bakery wares”
08.2	Processed meat, poultry, and game products in whole pieces or cuts	2,000	mg/kg	Note 42	6	**Comment** **1)** Add note “for surface treatment of dried meat products” **2)** Used in Biltong snapsticks
08.3	Processed comminuted meat, poultry, and game products	2,000	mg/kg	Note 42	6	**Comment** Add note “for surface treatment of dried meat products”
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	2,000	mg/kg	Note 42	6	**Comment** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	2,000	mg/kg	Note 42	6	**Comment** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg
12.4	Mustards	1,500	mg/kg	Note 42	6	**Comment** **1)** ML seems high. A ML of 1000 mg/kg seems sufficient to achieve the technological function **2)** Technological purpose questioned
12.5	Soups and broths	1,500	mg/kg	Note 42	6	**Comment** **1)** Codex Standard for Bouillons and Consommés allows maximum 500 mg/kg **2)** ML seems high. A ML of 500 mg/kg seems sufficient to achieve the technological function

Recommendation 3 – Sorbates, INS 200-203
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Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comments
12.6.1	Emulsified sauces (e.g., mayonnaise, salad dressing)	3,350	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated a technological need for use of sorbates in this Category at 3,350 mg/kg **2)** ML seems high. A ML of 2000 mg/kg seems sufficient to achieve the technological function **3)** Used in Snoek pate at 3350 mg/kg
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	2,000	mg/kg	Note 42	6	**Comment** **1)** ML seems high. A ML of 1000 mg/kg seems sufficient to achieve the technological function **2)** The Additive functions as a preservative and the maximum use level of 1000mg/kg is safe and necessary to achieve the intended purpose.
12.6.3	Mixes for sauces and gravies	2,000	mg/kg	Note 42	6	**Comment** ML seems high. A ML of 1000 mg/kg seems sufficient to achieve the technological function
12.6.4	Clear sauces (e.g., fish sauce)	2,000	mg/kg	Note 42	6	**Comment** **1**) ML seems high. A ML of 1000 mg/kg seems sufficient to achieve the technological function **2)** The Additive functions as a preservative and the maximum use level of 1000 mg/kg is safe and necessary to achieve the intended purpose.
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	2,000	mg/kg	Note 42	6	ML seems high. A ML of 1500 mg/kg seems sufficient to achieve the technological function
14.1.4.1	Carbonated water-based flavoured drinks	1,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg **2)** ML seems high. A ML of 300 mg/kg sufficient to achieve the technological function **3)** Suggest collapsing the subcategories into 14.1.4. Although 1000 mg/kg is permitted in some countries, the current use levels typically do not exceed 500 mg/kg as sorbic acid due to inadequate solubility and sensory concerns at higher use levels.
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	1,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated a technological need for use of sorbates in this Category at 1000 mg/kg **2)** ML seems high. A ML of 300 mg/kg sufficient to achieve the technological function **3)** Collapse into 14.1.4
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	1,500	mg/kg	Note 42	6	**Comment** **1)** ML seems high. A ML of 300 mg/kg sufficient to achieve the technological function, add note 127. **2)** Collapse into 14.1.4. If CCFA decides to continue to maintain the subcategories, we suggest including Note 127 (As served to the consumer) in 14.1.4.3.

Recommendation 3 – Sorbates, INS 200-203 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for sorbates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	1,000	mg/kg	Note 42	6	**Comment** **1)** Set ML to 600 mg/kg. Add note "Only in liquid tea concentrates and liquid fruit and herbal infusion concentrates" **2)** Set ML to 500 mg/kg due to solubility concerns at higher use levels. **3)** Add Note 160 (For use in ready-to-drink products and premixes for ready-to-drink products only)
14.2.2	Cider and perry	1,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated that 500 mg/kg is technologically sufficient for these foods **2)** ML seems high. A ML of 300 mg/kg sufficient to achieve the technological function
14.2.3	Grape wines	2,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated that 500 mg/kg is technologically sufficient for these foods **2)** ML seems high. A ML of 200 mg/kg sufficient to achieve the technological function
14.2.4	Wines (other than grape)	1,000	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated that 500 mg/kg is technologically sufficient for these foods **2)** 200 mg/kg adequate for tech need
14.2.5	Mead	1,000	mg/kg	Note 42	6	**Comment** ML seems high. A ML of 200 mg/kg seems sufficient to achieve the technological function
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	500	mg/kg	Note 42	6	**Comment** **1)** Industry in Canada has indicated a technological need for use of sorbates in this Category at 500 mg/kg **2)** Level of 200 mg/kg adequate

HYDROXYBENZOATES, PARA- (INS 214, 218)

4. The 17th JECFA (1973) assigned a group ADI of 10 mg/kg bw for para-hydroxybenzoates.

5. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose preservative with para-hydroxybenzoates.

Recommendation 1 – Hydroxybenzoates, para-, INS 214, 218 The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for para-hydroxybenzoates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.6.4	Processed cheese	300	mg/kg	Note 27	6	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	120	mg/kg	Note 27	6	**Comment** Only allowed in flavoured fermented milks heat treated after fermentation per CODEX STAN 243.
02.2.2	Fat spreads, dairy fat spreads and blended spreads	300	mg/kg	Note 27	6	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	300	mg/kg	Note 27	6	
03.0	Edible ices, including sherbet and sorbet	1000	mg/kg	Note 27	6	**Comment** No need of preservatives and antioxidants in frozen technology.

Recommendation 1 – Hydroxybenzoates, para-, INS 214, 218 The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for para-hydroxybenzoates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
04.1.2.3	Fruit in vinegar, oil, or brine	800	mg/kg	Note 27	6	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	1000	mg/kg	Note 27	6	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	800	mg/kg	Note 27	6	
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	12	mg/kg	Note 27	6	**Comment** Request technological need, seems too low for efficacy
04.2.1.3	Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	12	mg/kg	Note 27	6	**Comment** Request technological need, seems too low for efficacy
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	300	mg/kg	Note 27	6	
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	700	mg/kg	Note 27	6	
05.1.3	Cocoa-based spreads, including fillings	300	mg/kg	Note 27	6	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	**1000**	**mg/kg**	Note 27	6	**Comment** 1000 mg/kg is sufficient for technical application in products
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	100	mg/kg	Note 27	6	
12.3	Vinegars	100	mg/kg	Note 27	6	**Comment** Preservative not required in products with minimum 5% acetic acid.
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	450	mg/kg	Note**s** 27 **& 160**	6	
14.2.1	Beer and malt beverages	200	mg/kg	Note 27	6	
14.2.3	Grape wines	50	mg/kg	Note 27	6	
14.2.4	Wines (other than grape)	200	mg/kg	Note 27	6	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	1000	mg/kg	Note 27	6	

Recommendation 2 – Hydroxybenzoates, para-, INS 214, 218 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for para-hydroxybenzoates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
04.1.2.5	Jams, jellies, marmalades	1000	mg/kg	Note 27	6	**Comments** Except for low-sugar jams, there is no technological justification to add p-hydroxybenzoate as the sugar ensures the preservative function

NISIN (INS 234)

6. The 12th JECFA (1968) assigned an ADI of 33,000 U/kg bw for nisin.

7. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose preservative with nisin.

8. Nisin preparation is the commercially available form of nisin. At the 68th JECFA (2007), the name of the additive "nisin" was changed to "nisin preparation" to clarify that the preparation also includes sodium chloride and several different types of nisin (WHO TRS 947 (2007) pp. 54-55). One gram of nisin

preparation contains 1,000,000 International Units (IU) of nisin (see specifications in JECFA Monographs 4 (2007)). Available information indicates that a typical nisin preparation contains 2.5 % nisin. As there is 0.025 µg nisin per IU, nisin preparation also contains 0.025 µg nisin per IU (i.e., (2.5 g nisin/100 g nisin preparation) x (1 g nisin preparation/1,000,000 IU)). The JECFA ADI of 33,000 IU/kg bw refers to nisin (WHO TRS 430 (1969), pp. 33-35). Therefore, to compare this ADI with the use levels in the GSFA, which are reported as nisin, the ADI should be converted to the mg/kg bw basis. The GSFA (Note 28) provides this calculation: (33,000 IU nisin/kg bw) x (0.025 µg nisin/IU) x (1 mg/1 000 µg) = 0.825 mg/kg bw. Therefore, both the JECFA ADI and use levels in the GSFA are on the "nisin" reporting basis.

9. Since the JECFA ADI and the use levels in the GSFA are on the "nisin" reporting basis, it is **proposed that the current Note 28 be revised to clarify this:**

Revised Note 28: As Nisin. Nisin preparation (as defined in the JECFA specifications monograph for "Nisin Preparation") typically contains 2.5 percent nisin. The maximum use level "as nisin" can be converted to a maximum use level for nisin preparation by dividing by 0.025. The ADI of 33,000 IU nisin/kg bw is equivalent to 0.825 mg/kg bw [(33,000 IU nisin/kg bw) x (0.025 µg nisin /IU) x (1 mg/1 000 µg)].

Recommendation 1 – Nisin, INS 234
The eWG of the 41st CCFA recommended **discontinuation** of the following food additive provisions for nisin in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
01.1	Milk and dairy-based drinks	500	mg/kg	Note 28	3	**Comment** Should not be discontinued – approved in milk products in certain Middle eastern countries at GMP and in China at 500 mg/kg as salt.
01.4	Cream (plain) and the like	500	mg/kg	Note 28	3	**Comment** **1)** There is no technological need. **2)** Permitted in 01.4.2 at 10 mg/kg as nisin in ANZ, EU and other countries.
01.6.2	Ripened cheese	500	mg/kg	Note 28	3	**Comment** The level of 12.5 mg/kg is technologically adequate. With a ML of 500 mg/kg, a child who would eat a portion of 25 g would reach the ADI
01.6.4	Processed cheese	500	mg/kg	Note 28	3	**Comment** The ML is far too high. Level of 12.5 mg/kg is technologically adequate
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	500	mg/kg	Note 28	3	
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds		GMP	Note 28	6	**Comment** **1)** There is no technological need **2)** Nisin controls outgrowth of heat resistant bacterial spores. Many of these vegetable products cannot be processed under full heat sterilization regimes without destroying their organoleptic and nutritive qualities
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	250	mg/kg	Note 28	6	**Comment** Suggest revision; 6.25 mg/kg as nisin required to produce desired preservative effect. Use permitted in several countries at 6.25 mg/kg.
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and frozen		GMP	Note 28	6	**Comment** Used in minimally processed, refrigerated soups to prevent spoilage of products that cannot be processed under full heat sterilization regimes without destroying their organoleptic and nutritive qualities.

Recommendation 2 – Nisin, INS 234 The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for nisin in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.6.1	Unripened cheese	12.5[1]	mg/kg	Note 28	6	**Comment** Broadly used in the manufacturing of cheese: inhibits spore germination and growth of clostridium, bacillus or listeria. For the latter, no alternative method allowed to reach the same level of safety

Recommendation 3 – Nisin, INS 234 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for nisin in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.6.4	Processed cheese	250	mg/kg	Note 28	6	**Comment** **1)** The ML is far too high. Level of 12.5 mg/kg is technologically adequate **2)** National legislation exists for use as an antimicrobial in pasteurized process cheese spreads (including those containing fruits, vegetables or meats) at a level of 250 mg/kg
08.0	Meat and meat products, including poultry and game	500	mg/kg	Note 28	3	**Comment** **1)** More information needed on the use of nisin in the general Category 8.0 "Meat and meat products" because the adoption of the provision would allow the use of a preservative in fresh meat products. **2)** Revise to subcategory provisions 08.1.2, 08.2 and 08.3
10.2.1	Liquid egg products		GMP	Note 28	3	

ASCORBYL ESTERS (INS 304, 305)

10. The 17th JECFA (1973) assigned a group ADI of 1.25 mg/kg bw for ascorbyl esters.

11. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose antioxidant with ascorbyl esters.

Recommendation 1 – Ascorbyl Esters, INS 304, 305 The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for ascorbyl esters in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.6.1	Unripened cheese	500	mg/kg	Note 10	3	

Recommendation 2 – Ascorbyl Esters, INS 304, 305 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for ascorbyl esters in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
06.4.3	Pre-cooked pastas and noodles and like products	500	mg/kg	Note 10	3	**Comment** **1)** Consistent with the Standard 249-2006 (Instant Noodles) as antioxidants at a maximum level of 500 mg/kg singly or in combination as ascorbyl stearate. **2)** Only in noodle but not in pre-cooked pasta **3)** Do not support "only in noodle" as fried, pre-cooked pasta may have tech need for antioxidant
06.4.3	Pre-cooked pastas and noodles and like products	20	mg/kg	Note 10	Adopted	

[1] **The Committee is invited to consider discontinuation of work on a proposed draft provision for nisin in food category 01.6.1 at 500 mg/kg**" (*Note of the Codex Secretariat*)

PROPYL GALLATE (INS 310)

12. The 46th JECFA (1996) assigned an ADI of 1.4 mg/kg bw for propyl gallate.

13. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose antioxidant with propyl gallate.

Recommendation 1 – Propyl Gallate, INS 310
The eWG of the 41st CCFA recommended **revocation** of the following food additive provision for propyl gallate in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
06.4.3	Pre-cooked pastas and noodles and like products	100	mg/kg	Notes 15 & 130	Adopted	**Justification** Consequential effect of recommendation to adopt provision in food category 06.4.3 at Step 3.

Recommendation 2 – Propyl Gallate, INS 310
The eWG of the 41st CCFA recommended **adoption** of the following food additive provision for propyl gallate in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
06.4.3	Pre-cooked pastas and noodles and like products	200	mg/kg	Notes 15 & 130	3	**Justification** Consistent with Codex STAN 249-2006 (Instant Noodles): provision for the use of propyl gallate as an antioxidant at a maximum level of 200 mg/kg singly or in combination with TBHQ, BHA, or BHT. **Comment** No technological justification for use in pre-cooked pastas.

Recommendation 3 – Propyl Gallate, INS 310
The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for propyl gallate in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
12.5	Soups and broths	200	mg/kg	Notes 15 & 130	3	**Justification** Consistent with Codex STAN 117-1981 (Bouillons and Consommés): provision for the use of propyl gallate as an antioxidant at a maximum level of 200 mg/kg singly or in combination with TBHQ, BHA, or BHT. **Comment** This additive is not technologically necessary in all soups, its antioxidant function is only needed in powdered and dehydrated products covered by category 12.5.2.
12.5.2	Mixes for soups and broths	200	mg/kg	Notes 15 & 130	Adopted	

PHOSPHATES (INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542)

14. The 29th JECFA (1985) assigned a group MTDI (maximum tolerable daily intake) of 70 mg/kg bw, as phosphorus, for phosphates.

15. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purposes acidity regulator, sequestrant, emulsifier, texturizing agent, stabilizer, and moisture-retention agent with phosphates.

Recommendation 1 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **discontinuation** of the following food additive provision for phosphates in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
09.1.1	Fresh Fish	GMP		Note 33	6	**Comment** Not needed in fresh fish (only necessary when fish is frozen to prevent drip loss)

Recommendation 2 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	1,320	mg/kg	Notes 33 **& 88**	6	**Comment** 2500 mg/kg necessary to stabilize the protein matrix in whey-based products
01.3.1	Condensed milk (plain)	880	mg/kg	Notes 33, 34, & **88**	6	
01.3.2	Beverage whiteners	22,000	mg/kg	Notes 33 **& 88**	6	
01.5.1	Milk powder and cream powder (plain)	4,400	mg/kg	Notes 33 **& 88**	6	
01.6.4	Processed cheese	14,050	mg/kg	Note 33	6	
01.6.5	Cheese analogues	13,200	mg/kg	Note 33	6	
02.1.2	Vegetable oils and fats	220	mg/kg	Notes 33 **& 88**	6	
02.1.3	Lard, tallow, fish oil, and other animal fats	220	mg/kg	Notes 33 **& 88**	6	
04.1.2.3	Fruit in vinegar, oil, or brine	2,200	mg/kg	Note 33	3	
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5,000	mg/kg	Notes 33 & 76	6	
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	2,200	mg/kg	Note 33	6	
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	2,200	mg/kg	Notes 33 & 76	6	
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	2,200	mg/kg	Notes 33	6	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	2,200	mg/kg	Notes 33 & 76	6	**Comment** Only for processed potato products
05.1.3	Cocoa-based spreads, including fillings	**2,200**	mg/kg	Notes 33 **& 88**	6	
05.3	Chewing gum	44,000	mg/kg	Note 33	6	**Comment** The use of phosphates in chewing gum does not raise safety concerns as phosphates are part of the nutrient source of Phosphorous to human bodies. Phosphates play an important role in a wide range of chewing gum and they are also specifically used with calcium in specialized chewing gum.
06.2.1	Flours	11,900	mg/kg	Note 33	6	**Comment** **1)** Revise ML to 2500 mg/kg (except in self-raising flour) **2)** Used as raising agent in self raising flour, and various cakes
06.6	Batters (e.g., for breading or batters for fish or poultry)	5,600	mg/kg	Note 33	3	
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	3,100	mg/kg	Note 33	6	
09.3.1	Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	2,200	mg/kg	Note 33	3	

Recommendation 2 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
09.3.2	Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	2,200	mg/kg	Note 33	6	
09.3.3	Salmon substitutes, caviar, and other fish roe products	2,200	mg/kg	Note 33	6	
10.3	Preserved eggs, including alkaline, salted, and canned eggs	1,000	mg/kg	Note 33	6	
12.1.2	Salt Substitutes	4,400	mg/kg	Note 33	6	
12.2.2	Seasonings and condiments	4,400	mg/kg	Note 33	3	
12.4	Mustards	1,320	mg/kg	Note 33	6	
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and frozen	1,320	mg/kg	Note 33	6	
12.5.2	Mixes for soups and broths	6,600	mg/kg	Note 33	6	**Comment** Revise ML to 10 000 mg/kg; is tech needed for dry soups that are high in fat, protein, dairy (cream/creamer/whey) content and reconstituted by the addition of milk and water. Product is cooked up and fat must remain stable after cooking
14.2.1	Beer and malt beverages	440	mg/kg	Notes 33 **& 88**	6	Question use of note 88
14.2.4	Wines (other than grape)	440	mg/kg	Notes 33 **& 88**	6	

Recommendation 3 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.1.1	Milk and buttermilk (plain)	1,500	mg/kg	Notes 33 **& 88**	3	**Comment** **1)** In the past, industry in Canada has indicated that the use of monoammonium phosphate in uncultured buttermilk at 270 ppm expressed as phosphorus is technologically sufficient. **2)** Only in UHT and sterilised milk. In addition the ML should be lowered to 400 mg/kg, which is sufficient to achieve the technological function. **3)** Question use of note 88 **4)** support ML of 1500 mg/kg for UHT goat milk to stabilize calcium due to higher temperatures
01.4	Cream (plain) and the like	2,200	mg/kg	Notes 33 **& 88**	6	**Comment** **1)** A value of 1100 mg /kg (as P) has been proposed by the ALINORM 08/31/11 Appendix V for creams and prepared creams **2)** Used to stabilize prepared cream in products such as chocolate mousse. **3)** ML of 2000 mg/kg as phosphate (880 mg/kg as phosphorus) in CODEX STAN 288 for Cream
01.6.1	Unripened cheese	10,000	mg/kg	Note 33	6	**Comment** **1)** 1000 mg/kg (as P) seems sufficient to achieve the technological function (Stan 273-1968;STAN 275-1973). **2)** Reduce maximum level to 3500 mg/kg, as referenced in the Codex Standard 221 (2001) for Unripened Cheese.

Recommendation 3 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10,500	mg/kg	Note 33	3	**Comment** **1)** A ML of 1500 mg/kg (as P) seems sufficient to achieve the technological function **2)** Used to stabilize prepared cream (chocolate mousse) **3)** Add note stating "a level of 1000 mg/kg as phosphorus for flavoured fermented milks (CODEX STAN 243)
01.8.1	Liquid whey and whey products, excluding whey cheeses	880	mg/kg	Note 33	6	**Comment** **1)** Industry in Canada has indicated a technological need for use of calcium phosphate, tribasic, in liquid whey, as a carrier for benzoyl peroxide but at lower levels than that proposed here. **2)** ML of 1320 necessary to stabilize higher protein liquid whey used for further processing into whey protein concentrates
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	7,000	mg/kg	Note 33	6	**Comment** A ML of 1500 mg/kg (as P) seems sufficient to achieve the technological function
03.0	Edible ices, including sherbet and sorbet	12,000	mg/kg	Note 33	6	**Comment** **1)** A ML of 500 mg/kg (as P) seems sufficient to achieve the technological function **2)** Recommends reducing the maximum value to 7500
04.1.2.1	Frozen fruit	200	mg/kg	Note 33	6	**Comment** **1)** Technological need is not recognized in such products **2)** Maximum level be raised to 350 mg/kg, as such a limit is needed to get proper water activation and stabilize the colour throughout the shelf-life of such foods.
04.1.2.2	Dried fruit	10	mg/kg	Note 33	6	**Comment** **1)** Technological need is not recognized in such products **2)** Maximum level be raised to 500 mg/kg, as such a limit is needed to get proper water activation and stabilize the colour throughout the shelf-life of such foods.
04.1.2.4	Canned or bottled (pasteurized) fruit	200	mg/kg	Note 33	6	**Comment** Questions the technological need.
04.1.2.5	Jams, jellies, marmalades	530	mg/kg	Note 33	6	**Comment** Questions the technological need.
04.1.2.7	Candied fruit	10	mg/kg	Note 33	6	**Comment** Revise maximum level to 350 mg/kg, such a limit is needed to get proper water activation and stabilize the colour throughout the shelf-life of such foods.
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	7,000	mg/kg	Note 33	6	**Comment** ML of 400 mg/kg (as P) seems sufficient to achieve the technological function
04.1.2.9	Fruit-based desserts, including fruit-flavoured water based desserts	7,000	mg/kg	Note 33	6	**Comment** ML of 1500 mg/kg (as P) seems sufficient to achieve the technological function
04.1.2.11	Fruit fillings for pastries	7,000	mg/kg	Note 33	6	**Comment** ML seems excessive.
04.2.1.3	Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5,600	mg/kg	Notes 33 & 76	6	**Comment** Add note "only in processed potato products"

Recommendation 3 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5,000	mg/kg	Notes 33 & 76	6	**Comment** Add note "only in processed potato products"
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	2,200	mg/kg	Note 33	6	**Comment** Technological need questioned as Phosphates are primarily used as water-retention agents~~.~~
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	6,000	mg/kg	Notes 33 **& 88**	6	**Comment** **1)** Not permitted in the Commodity standard on cocoa powder Stan 105- 1981 **2)** questions use of note 88
05.1.4	Cocoa and chocolate products	2,200	mg/kg	Note 33	6	**Comment** **1)** Phosphates have technological function as emulsifier and the level is necessary to achieve the intended use. **2)** Not permitted in the Commodity standard on chocolate products Stan 87-1981
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	2,200	mg/kg	Note 33	6	**Comment** 10,000 mg/kg is required for technical application in hard and soft candy products.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	7,000	mg/kg	Note 33	6	**Comment** ML of 1500 mg/kg (as P) seems sufficient to achieve the technological function
06.1	Whole, broken, or flaked grain, including rice	440	mg/kg	Note 33	6	**Comment** **1)** Technological need questioned in this basic product **2)** For Anti- Caking Aid, higher levels of approximately 4000 mg/kg may be required
06.2.2	Starches	6,200	mg/kg	Note 33	3	**Comment** More information requested
06.4.1	Fresh pastas and noodles and like products	2,000	mg/kg	Note 33	3	**Comment** Need in fresh pasta not recognized
06.4.2	Dried pastas and noodles and like products	2,200	mg/kg	Note 33	3	**Comment** Need in dried pasta not recognized
06.4.3	Pre-cooked pastas and noodles and like products	2,200	mg/kg	Note 33	3	**Comment** **1)** Technological need as emulsifier and the maximum level is necessary to achieve the intended function. **2)** Add note " only in noodles"
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	7,000	mg/kg	Note 33	6	**Comment** ML of 1500 mg/kg (as P) seems sufficient to achieve the technological function
07.0	Bakery wares	9,300	mg/kg	Note 33	6	**Comment** **1)** Basic foodstuff highly consumed. Technological need questioned for all products within this category **2)** Used as raising agent in self-raising flour
08.2.1	Non-heat treated processed meat, poultry, and game products in whole pieces or cuts	2,200	mg/kg	Note 33	6	**Comment** **1)** This additive is not needed in unprocessed fresh meat **2)** Used in processed meats, even when not heat treated (e.g., marinated meat)
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	2,200	mg/kg	Note 33	6	**Comment** **1)** Add note "excluding fish products" **2)** Only in unprocessed fish, frozen and deep frozen

Recommendation 3 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	2,200	mg/kg	Note 33	6	**Comment** Add note "excluding fish products"
09.2.3	Frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	2,200	mg/kg	Note 33	6	**Comment** Add note "only in frozen mollusk and crustacean"
09.2.4.1	Cooked fish and fish products	2,200	mg/kg	Note 33	6	**Comment** Add note " only in surimi, fish and crustacean paste"
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	2,200	mg/kg	Note 33	6	**Comment** Add note "only in frozen mollusk and crustacean"
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	2,200	mg/kg	Note 33	3	**Comment** Add note "only in fish paste"
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	2,200	mg/kg	Note 33	6	**Comment** Reduce ML to 400 mg/kg and add note "only in surimi and canned crustacean products".
10.4	Egg-based desserts (e.g., custard)	7,000	mg/kg	Note 33	6	**Comment** ML of 1000 mg/kg (as P) seems sufficient to achieve the technological function
12.2.1	Herbs and spices		GMP	Note 33	6	**Comment** Replace GMP by a numerical level of use
12.6	Sauces and like products	8,000	mg/kg	Note 33	6	**Comment** **1)** Level seems higher then technologically necessary **2)** ML of 50 000 is technologically needed for dry sauces that are high in fat, protein, dairy (cream / creamer / whey) content and reconstituted by the addition of milk and water. Product are either instant or is cooked up and must remain stable after cooking and storing in a fridge.
13.2	Complementary foods for infants and young children	2,200	mg/kg	Note 33	6	**Comment** **1)** INS 339) is used as an acidity regulator and its use is consistent with the criteria in Section 3.2 of the GSFA Preamble. **2)** If this provision is to be consistent with the Codex Standard 074-1981, rev. 2006, Processed Cereal-Based Foods for Infants and Young Children, the proposed level would be higher since 4400 mg/kg as phosphorus is stipulated in the Standard
14.1.2.2	Vegetable juice	**2,500**	**mg/kg**	Notes 33 **& 88**	**6**	**Comment** **1)** Suggests harmonizing with the permitted level of 1000 mg/kg in fruit juices and nectars **2)** reduce level to 1000 mg/kg and add notes 40 and 122 for consistency with provisions for fruit juices and nectars
14.1.2.4	Concentrates for vegetable juice	2,500	mg/kg	Notes 33 & 88	6	**Comment** **1)** Suggests 1000 mg/kg **2)** reduce level to 1000 mg/kg and add notes 40, 122 and 127 for consistency with provisions for fruit juices and nectars
14.1.3.2	Vegetable nectar	2,500	mg/kg	Notes 33 & 88	6	**Comment** Reduce level to 1000 mg/kg and add notes 40 and 122 for consistency with provisions for fruit juices and nectars

Recommendation 3 – Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The eWG of the 41st CCFA recommended **further discussion** of the following food additive provisions for phosphates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
14.1.3.4	Concentrates for vegetable nectar	2,500	mg/kg	Notes 33 & 88	6	**Comment** Reduce level to 1000 mg/kg and add notes 40, 122 and 127 for consistency with provisions for fruit juices and nectars.
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	12,000	mg/kg	Note 33	6	**Comment** **1)** ML seems very excessive. A ML of 500 mg/kg (as P) seems sufficient to achieve the technological function **2)** We believe that the proposed ML is based on phosphates and not expressed as phosphorus (P, Note 33). Suggest adopting 3000 mg/kg as phosphorus (Note 33) based on the technological need of INS 452i. For all other phosphates, a maximum level of 1000 mg/kg as P would be sufficient **3)** Maximum level should be changed to GMP, to meet the nutritional requirements of a particular country/region.
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	880	mg/kg	Note 33	6	**Comment** Add note: "Only for coffee based drinks for vending machine, instant tea and instant herbal infusions"
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	12,000	mg/kg	Notes 33 **& 88**	6	**Justification** This level, 12000 mg/kg, of phosphates is needed due to specific yeast growing conditions of the aromatized alcoholic beverage.
16.0	Composite foods - foods that could not be placed in categories 01 - 15	2,000	mg/kg	Note 33	6	**Comment** **1)** Foodstuffs should be clearly defined **2)** The amount of phosphate needed depends on the specific food application. The maximum level should be changed to GMP, to meet the nutritional requirements of the particular country/region. **3)** INS 341iii at ML 4366 mg/kg as anticaking agent for dehydrated composite foods

Phosphates, INS 338, 339i-iii, 340i-iii, 341i-iii, 342i-ii, 343i-ii, 450i-iii, 450v-vii, 451i-ii, 452i-v, 542 The following provisions were included in the GSFA at Step 3 by the 41st CCFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
06.8.1	Soybean-based beverages	1,300	mg/kg	Note 33	3	
06.8.2	Soybean-based beverage film	35,000	mg/kg	Note 33	3	
06.8.3	Soybean curd (tofu)	35,000	mg/kg	**Note 33**	3	
06.8.4	Semi-dehydrated soybean curd	35,000	mg/kg	**Note 33**	3	
06.8.5	Dehydrated soybean curd (kori tofu)	35,000	mg/kg	**Note 33**	3	
06.8.6	Fermented soybeans (e.g., natto, tempe)	35,000	mg/kg	**Note 33**	3	
06.8.7	Fermented soybean curd	35,000	mg/kg	**Note 33**	3	
08.1.2	Fresh meat, poultry, and game, comminuted	2,200	mg/kg	Note 33	6	
12.9	Soybean-based seasonings and condiments	35,000	mg/kg	Note 33	3	
12.10	Protein products other than from soybeans	35,000	mg/kg	**Note 33**	3	

AMMONIUM SALTS OF PHOSPHATIDIC ACID (INS 442)

16. The 18th JECFA (1974) assigned an ADI of 30 mg/kg bw for ammonium salts of phosphatidic acid.

17. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose emulsifier with ammonium salts of phosphatidic acid.

Recommendation 1 – Ammonium Salts of Phosphatidic Acid, INS 442
The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for ammonium salts of phosphatidic acid in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	5000	mg/kg		6	**Justification** Consistent with Codex STAN 243-2003 (Fermented Milks (Flavoured, Heat Treated and Non-heat Treated): the use of additives belonging to the class "emulsifiers" is technologically justified in flavoured fermented milks and flavoured fermented milks heat treated after fermentation. Use is justified in the dairy portion. **Comment** Suggest adding note: INS 442 is not listed in Section 4 of CODEX STAN 243- Fermented Milks
03.0	Edible ices, including sherbet and sorbet	7500	mg/kg		6	

CYCLODEXTRIN, BETA- (INS 459)

18. The 44th JECFA (1995) assigned an ADI of 5 mg/kg bw for beta-cyclodextrin.

19. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purposes stabilizer, binder, and carrier with beta-cyclodextrin.

Recommendation 1 – Cyclodextrin, beta-, INS 459
The eWG of the 41st CCFA recommended **adoption** of the following food additive provisions for beta-cyclodextrin in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
06.4.3	Pre-cooked pastas and noodles and like products	1000	mg/kg	**Note 153**	3	**Justification** Consistent with the Codex Standard 249-2006, Instant Noodles **Comment** For use in noodles only, not needed in pasta

SUCROGLYCERIDES (INS 474)

20. The 49th JECFA (1997) assigned an ADI of 30 mg/kg bw for sucroglycerides.

21. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose emulsifier with sucroglycerides.

Recommendation 1 – Sucroglycerides, INS 474
The eWG for the 41st CCFA recommended **adoption** of the following food additive provisions for sucroglycerides in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
13.6	Food supplements		GMP		6	

Recommendation 1 – Sucroglycerides, INS 474 The eWG for the 41st CCFA recommended **adoption** of the following food additive provisions for sucroglycerides in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	5000	mg/kg	**Note A**	6	**Comment** 1**)** Sucroglycerides are permitted for use at 5000 mg/kg in many countries, such as the ECMS, in non-alcoholic coconut, almond and aniseed-based drinks. At lower use levels in soft drinks (200 mg/kg), they also can be used as **1)** alternate stabilisers, 2) to provide cloudiness in citrus drinks and 3) as substitutes or extenders of gum arabic. **2)** Revise with Note "Only in non-alcoholic aniseed-based, coconut and almond drinks."
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	5000	mg/kg		6	

STEARYL CITRATE (INS 484)

22. The 17th JECFA (1973) assigned an ADI of 50 mg/kg bw for stearyl citrate.

23. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purposes emulsifier and sequestrant with stearyl citrate.

Recommendation 1 - Stearyl Citrate, INS 484 The eWG for the 41st CCFA recommended **adoption** of the following food additive provisions for stearyl citrate in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
02.2.2	Fat spreads, dairy fat spreads and blended spreads	100	mg/kg	Note 15	3	**Comment** **1)** Industry in Canada has indicated a technological need for this additive in margarine at this level of use **2)** Not listed in CODEX STAN 253-2006, Dairy fat spreads

SACCHARINS (INS 954 I - IV)

24. The 41st JECFA (1993) assigned an ADI of 5 mg/kg bw for saccharins.

25. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose sweetener with saccharins.

Recommendation 1 - Saccharins, INS 954 i-iv The following food additive provisions for saccharins in the GSFA were recommended for **adoption** by the eWG of the 39th CCFA (CX/FA 07/39/09 part 1) and were listed in FA/40 INF 01. However, these two provisions were unintentionally omitted from the report of the eWG of the 40th CCFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
14.1.3.4	Concentrates for vegetable nectar	300	mg/kg	Notes 127 & 161	6	

Saccharins, INS 954 i-iv The following provisions were included in the GSFA at Step 3 by the 41st CCFA						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
12.9.1	Fermented soybean paste (e.g., miso)	200	mg/kg		3	
12.9.2.1	Fermented soybean sauce	500	mg/kg		3	

SUCRALOSE (TRICHLOROGALACTOSUCROSE) (INS 955)

26. The 37th JECFA (1990) assigned an ADI of 15 mg/kg bw for sucralose.

27. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose sweetener with sucralose.

Sucralose (Trichlorogalactosucrose), INS 955 The 41st CCFA agreed to circulate for comment at Step 3 the following food additive provisions for sucralose in the GSFA.						
Food Cat No.	28. **Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
01.5.2	Milk and cream powder analogues	400	mg/kg		3	

Sucralose (Trichlorogalactosucrose), INS 955 The following provisions were included in the GSFA at Step 3 by the 41st CCFA						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
06.8.1	Soybean-based beverages	400	mg/kg		3	**Justification** To sweeten soybean-based beverages. This level is needed to sweeten the products, which are consumed as is.

ASPARTAME-ACESULFAME SALT (INS 962)

28.The 55th JECFA (2000) concluded that the aspartame and acesulfame moieties are covered by the ADIs for aspartame (40 mg/kg bw) and acesulfame potassium (acesulfame K) (15 mg/kg bw).

29. The Codex *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989) associates the technological purpose sweetener with aspartame-acesulfame salt.

30. The report of the eWG to the 39th CCFA noted that the proposed draft acceptable maximum use levels for these provisions are currently expressed in the GSFA in terms of aspartame-acesulfame salt or equivalents of aspartame or acesulfame K.[2] Because JECFA concluded that the aspartame and acesulfame moieties in aspartame-acesulfame salt are included in the ADIs established for aspartame (INS 951) and acesulfame K (INS 950), the equivalent level of aspartame and acesulfame K from the use of the double salt should not exceed the individual maximum use level for aspartame or for acesulfame K.

31. The *ad hoc* Working Group on the GSFA to the 40th CCFA recommended, and the Committee agreed, to examine the provisions for the aspartame-acesulfame salt in order to ensure that these provisions are consistent with those for aspartame and for acesulfame K and are reported on a consistent basis.[3] As part of its mandate, the eWG established by the 40th CCFA was requested to develop recommendations for ensuring consistency between the provisions for aspartame-acesulfame salt and those for aspartame and for acesulfame K.[4]

32. The eWG to the 41st CCFA considered an Options Paper that contained four approaches to resolve the issue of the reporting basis for aspartame-acesulfame salt.[5] Based upon the comments to the Options Paper, the eWG to the 41st CCFA recommended that the CCFA agree to the approach presented in para. 29 of CX/FA 09/41/6, namely: (i) to revise the text of Notes 113[6] and 119[7] as recommended, and (ii) to add new

[2] CX/FA 07/39/9.
[3] ALINORM 08/31/12, para 72.
[4] ALINORM 08/31/12, para 78.
[5] The Options Paper was made available to all members of the eWG on the electronic forum and is not included in this report.
[6] **Note 113**: Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68).
[7] **Note 119**: Use level reported as aspartame equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.64). Combined use of aspartame-acesulfame salt with individual aspartame or acesulfame potassium should not exceed the individual maximum levels for aspartame or acesulfame potassium (the reported maximum level can be converted to ~~aspartame~~ acesulfame potassium equivalents by ~~dividing~~ multiplying by 0.68).

notes (i.e., Notes 188[8] and 191[9]) to all of the provisions for acesulfame K and aspartame, in order to ensure that combined use of aspartame-acesulfame salt and aspartame or acesulfame K would not lead to exceeding the maximum levels established for these sweeteners.[10] The 41st CCFA agreed with these recommendations.[11]

33. The 41st CCFA put forward a total of 16 aspartame-acesulfame salt provisions for adoption.

34. The following are the remaining proposed draft (Step 3) food additive provisions for aspartame-acesulfame salt presented in CX/FA 09/41/6. The provisions have been updated to correct errors to maximum use levels and notes that were not consistent with the approach outlined in the box above.

35. The *ad hoc* Working Group on the GSFA to the 39th CCFA agreed that sweeteners are technologically justified in the food categories[12] that are highlighted in grey.

Recommendation 1 – Aspartame-Acesulfame Salt, INS 962
The eWG for the 41st CCFA recommended that the following food additive provisions for aspartame-acesulfame salt be **included in the GSFA at Step 3**.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification
14.1.3.1	**Fruit nectar**	**350**	**mg/kg**	**Note 113**		Both aspartame and acesulfame K have established maximum levels in this category in the GSFA. If the key components of the salt are permitted in a food category, there should be no reason to prevent the use of the salt of them
14.1.3.3	**Concentrates for fruit nectar**	**350**	**mg/kg**	**Note 113 & Note 127**		

Recommendation 2 - Aspartame-Acesulfame Salt, INS 962
The eWG for the 41st CCFA recommended **adoption** of the following food additive provisions for aspartame-acesulfame salt in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
03.0	Edible ices, including sherbet and sorbet	**1,000**	mg/kg	**Note 119** & Note 161	3	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	**1,000**	mg/kg	**Note 119** & Note 161	3	
06.3	Breakfast cereals, including rolled oats	**1,000**	mg/kg	**Note 119** & Note 161	3	
10.4	Egg-based desserts (e.g., custard)	**350**	mg/kg	**Note 113**	3	
11.6	Table-top sweeteners, including those containing high-intensity sweeteners	GMP			3	
12.4	Mustards	**350**	mg/kg	**Note 119** & Note 161	3	
12.5	Soups and broths	**110**	mg/kg	**Note 113** & Note 161	3	
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	**350**	mg/kg	**Note 119** & Note 161	3	
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	**500**	mg/kg	**Note 113**	3	
13.6	Food supplements	**2000**	mg/kg	**Note 113**	3	

[8] **Note 188:** Not to exceed the maximum use level for acesulfame potassium (INS 950) singly or in combination with aspartame-acesulfame salt (INS 962).
[9] **Note 191:** Not to exceed the maximum use level for aspartame (INS 951) singly or in combination with aspartame-acesulfame salt (INS 962).
[10] ***N.B.:*** Notes 188 and 191, which the 41st CCFA agreed to add to all provisions for acesulfame potassium and aspartame respectively, are relevant only in food categories that also contain provisions for the aspartame-acesulfame salt. It is therefore suggested that the Committee consider removing Notes 188 and 191 from acesulfame potassium and aspartame provisions in the GSFA *which do not have a corresponding aspartame-acesulfame salt provision*.
[11] ALINORM 09/32/12, para 95.
[12] 39th CCFA, CRD 1 App. V.

Recommendation 2 - Aspartame-Acesulfame Salt, INS 962
The eWG for the 41st CCFA recommended **adoption** of the following food additive provisions for aspartame-acesulfame salt in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	**600**	mg/kg	**Note 119** & Note 161		
15.0	Ready-to-eat savouries	**500**	mg/kg	**Note 119** & Note 161	3	

Recommendation 4 – Aspartame-Acesulfame Salt, INS 962
The eWG for the 41st CCFA recommended **further discussion** of the following food additive provisions for aspartame-acesulfame salt in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
01.3.2	Beverage whiteners	**2,000**	mg/kg	**Note 113**	3	**Comment** The use could mislead the consumer
01.4.4	Cream analogues	**1,000**	mg/kg	**Note 119**	3	**Comment** The use could mislead the consumer
01.5.2	Milk and cream powder analogues	**1,000**	mg/kg	**Note 113**	3	**Comment** The use could mislead the consumer
01.6.5	Cheese analogues	**350**	mg/kg	**Note 113**	3	**Comment** The use could mislead the consumer
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	**1,000**	mg/kg	**Note 119**	3	**Comment** The use could mislead the consumer, add note 161.
04.1.2.1	Frozen fruit	**500**	mg/kg	**Note 113**	3	**Comment** The use could mislead the consumer, add note 161,
04.1.2.2	Dried fruit	**500**	mg/kg	**Note 113**	3	**Comment** **1)** There are existing provisions in the GSFA for the use of aspartame and acesulfame K in Food Category 04.1.2.2. Proposes revising the proposed ML to 500 mg/kg with the inclusion of Note 113 to reflect the ML for Acesulfame K in this Food Category. **2)** The use could mislead the consumer
04.1.2.3	Fruit in vinegar, oil, or brine	**200**	mg/kg	**Note 113** & Note 161	3	**Comment** The use could mislead the consumer
04.1.2.7	Candied fruit	**500**	mg/kg	**Note 113**	3	**Comment** Add Note 116
04.1.2.10	Fermented fruit products	**350**	mg/kg	**Note 113**	3	**Comment** Add Note 116
04.1.2.11	Fruit fillings for pastries	**350**	mg/kg	**Note 113**	3	**Comment** **1)** Industry in Canada has indicated a technological need for ace-K in this Category at a maximum level of 1000 mg/kg. Revise ML to 1000 mg/kg, consistent with Cat. 4.1.25 and 4.1.2.6, Jams and spreads **2)** Add Note 116
04.1.2.12	Cooked fruit	**500**	mg/kg	**Note 113**	3	**Comment** Technical need questioned
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	**350**	mg/kg	**Note 113**	3	**Comment** Technical need questioned

Recommendation 4 – Aspartame-Acesulfame Salt, INS 962
The eWG for the 41st CCFA recommended **<u>further discussion</u>** of the following food additive provisions for aspartame-acesulfame salt in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	**1,000**	mg/kg	**Note 119**	3	**Comment** **1)** Industry in Canada has Indicated a technological need for aspartame at 2000 mg/kg in this Category. It is noted that there is provision at step 6 in the GSFA for aspartame with a ML of 3000 mg/kg in this food category. **2)** Add note 161
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	**1,000**	mg/kg	**Note 113**	3	**Comment** Add note 161
05.1.2	Cocoa mixes (syrups)	**350**	mg/kg	**Note 113**	3	**Comment** Add notes 97 and 161 for consistency with acesulfame potassium provision.
05.1.3	Cocoa-based spreads, including fillings	**1,000**	mg/kg	**Note 113** & Note 161	3	**Comment** Industry in Canada has indicated a technological need for ace-K at 2500 mg/kg in confectionery.
05.1.4	Cocoa and chocolate products	**500**	mg/kg	**Note 113** & Note 161	3	**Comment** Industry in Canada has indicated a technological need for ace-K at 2500 mg/kg in confectionery.
05.3	Chewing gum	**5,000**	mg/kg	**Note 113** & Note 161	3	**Comment** The technological justification for such a high level is requested. A ML of 2000 mg/kg expressed as Acesulfame K should be sufficient to reach the desired effect.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	**500**	mg/kg	**Note 113**	3	**Comment** Industry in Canada has indicated a technological need for ace-K at 1000 mg/kg in this Category.
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	**350**	mg/kg	**Note 113** & Note 161	3	**Comment** Industry in Canada has indicated a technological need for ace-K at 1000 mg/kg in desserts in general
07.1	Bread and ordinary bakery wares	**1,000**	mg/kg	**Note 113**	3	**Comment** **1)** Possible intake will exceed ADI due to high consumption of such basic foodstuffs **2)** Industry in Canada has indicated a technological need for ace-K in this Category.
12.2.2	Seasonings and condiments	**2,000**	mg/kg	**Note 119**	3	**Comment** **1)** Industry in Canada has indicated a technological need for aspartame at 2000 mg/kg , not ace-K, in condiments. **2)** No technological need. The use could mislead the consumer **3)** Add note 161
14.1.3.4	Concentrates for vegetable nectar	**350**	mg/kg	**Note 113** & Note 127	3	**Comment** Add note 161
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	**600**	mg/kg	**Note 119**	3	**Comment** Use could mislead the consumer

Recommendation 4 – Aspartame-Acesulfame Salt, INS 962
The eWG for the 41st CCFA recommended **further discussion** of the following food additive provisions for aspartame-acesulfame salt in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
14.2.1	Beer and malt beverages	790	mg/kg	**Note 113** & Note 161	3	**Comment** **1)** The ML is too high. A ML of 350 mg/kg (as expressed as AcK) should be sufficient to reach the desire effect **2)** There are no existing provisions in the GSFA for the use of aspartame or acesulfame K in food Category 14.2.1, the provision should be discontinued

Notes

Note 10: As ascorbyl stearate.

Note 15: Fat or oil basis. **Note 27:** As para-hydroxybenzoic acid.

Note 28: ADI conversion: if a typical preparation contains 0.025 µg/U, then the ADI of 33 000 U/kg bw becomes: [(33 000 U/kg bw) x (0.025 µg/U) x (1 mg/1 000 µg)] = 0.825 mg/kg bw.

Note 33: As phosphorus.

Note 34: Anhydrous basis.

Note 42: As sorbic acid.

Note 76: Use in potatoes only.

Note 88: Carryover from the ingredient.

Note 113: Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68).

Note 119: Use level reported as aspartame equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.64). Combined use of aspartame-acesulfame salt with individual aspartame or acesulfame potassium should not exceed the individual maximum levels for aspartame or acesulfame potassium (the reported maximum level can be converted to acesulfame potassium equivalents by multiplying by 0.68).

Note 127: As served to the consumer.

Note 130: Singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321),tertiary butylated hydroquinone (INS 319), and propyl gallate (INS 310).

Note 153: For use in instant noodles only.

Note 160: For use in ready-to-drink products and pre-mixes for ready-to-drink products only.

Note 161: Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.

Note A: For use in non-alcoholic aniseed-based, coconut and almond drinks only.

Appendix II

PROVISIONS FOR FOOD CATEGORIES 05.0, 05.1, 05.2, 05.4 AND 16.0 AND RELATED SUB-CATEGORIES, INCLUDED IN PART I (COLOUR ADDITIVES) OF CX/FA 11/43/7

1. Outstanding recommendations for provisions for the use of colour additives include the following:

INS	Food additive	INS	Food Additive
129	Allura red AC	160a (ii)	*beta*-Carotenes, vegetable
133	Brilliant blue FCF	161 (g)	Canthaxanthin
150 (c)	Caramel III – ammonia process	163 (ii)	Grape Skin Extract
150 (d)	Caramel IV – ammonia sulfite process	172 (i, ii, iii)	Iron Oxides
160a (i, iii), 160e, 160f	Carotenoids		

2. The recommendations on the food additive provisions contained in this Appendix were developed based on comments submitted by participants of the eWGs of the 40th and 41st CCFA, as well as written comments of Members and Observers (CRD 9 of the 40th CCFA, CXFA 08/40/05 Add 1, Add 2, and CRD 9 of the 41st CCFA).

3. The 38th CCFAC agreed that the eWG should take a "horizontal" approach to its discussion of the GSFA provisions for colour additives. The eWG reached general consensus on a positive list of food categories in which the use of one or more colour additives is technologically justified (see Appendix IIA). These food categories are highlighted in grey in the tables below.

***Note**:*

This Appendix includes new information, related to food additive provisions of the GSFA (adopted or in the Step process), that was not included in CX/FA 11/43/7. This information, presented in **underlined and bold font**, *has been included either for information purposes or to correct errors in CX/FA 11/43/7.*

To help the reader, the text of all of the Notes that appear in the tables has been moved to the end of the document.

ALLURA RED AC (INS 129)

4. The 25th JECFA (1981) assigned an ADI of 7 mg/kg bw/d for allura red AC.

Recommendation 1 - Allura Red AC, INS 129
The eWG for the 40th CCFA recommended the **adoption** of the following food additive provision for allura red AC in the GSFA ; however, the 41st CCFA agreed to hold decisions on food additive provisions in food category 16.0 until the Committee clarifies the need for this category.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment provided to eWG
16.0	Composite foods - foods that could not be placed in categories 01 – 15	**300**	**mg/kg**		6	**Justification** Potentially used for complex foods

BRILLIANT BLUE FCF (INS 133)

5. The 13th JECFA (1969) assigned an ADI of 12.5 mg/kg bw/d for brilliant blue FCF.

Recommendation 1 – Brilliant Blue FCF, INS 133
The eWG for the 40th CCFA recommended **further discussion** of the following food additive provision for brilliant blue FCF in the GSFA; however, the 41st CCFA agreed to hold decisions on food additive provisions in food category 16.0 until the Committee clarifies the need for this category..

Food Cat No.	Food Category	Max Level		Comments	Step	Justification/Comment
16.0	Composite foods - foods that could not be placed in categories 01 - 15	100	mg/kg	Note 2	6	**Justifications** **1)** Used to colour bean-paste; maximum levels achieve the intended technological need) **2)** If provisions are proposed for category 16, the products must be fully defined and the additive uses restricted to these products. In the vast majority of cases products can be covered by other food categories or as composite products

Recommendation 1 – Brilliant Blue FCF, INS 133 The eWG for the 40th CCFA recommended **further discussion** of the following food additive provision for brilliant blue FCF in the GSFA; however, the 41st CCFA agreed to hold decisions on food additive provisions in food category 16.0 until the Committee clarifies the need for this category..						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
						(and therefore subject to carry over provisions) **Comment** Justification should be provided why the carry over wouldn't be sufficient

CARAMEL III - AMMONIA PROCESS (INS 150(c))

6. The 29th JECFA (1985) assigned an ADI of 200 mg/kg bw/d for caramel III – ammonia process.

7. The 41st CCFA agreed to hold any decision on food additive provisions in food category 16.0 until the Committee clarifies the need for this food category (ALINORM 09/32/12, para 86).

8. The following are the outstanding recommendations for caramel III – ammonia process from the report of the eWG to the 40th CCFA.

Recommendation 1 - Caramel III – Ammonia Process, INS 150c The eWG of the 40th CCFA recommended **further discussion** of the following food additive provisions for caramel III – ammonia process in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
05.0	Confectionery	50000	mg/kg	**Note 183**	3	**Justification** Recommendation for broader food category 5.0 will have consequential effects on adopted provisions in subcategories 05.1.2, 05.1.3, **05.1.4, 05.1.5**, 05.2, 05.3, and 05.4 **1)** There are no non-standardized foods in subcategory 05.1.1 **2)** The relevant commodity standards (CX STAN 105 (Codex Standards for Cocoa powders and dry mixtures of cocoa and sugar) & CX STAN 141 (Codex Standard for cocoa mass (cocoa/chocolate liquor) and cocoa cake)) do not contain any provisions for the use of colours. **3)** Used to colour rice biscuits and biscuits. **4)** To provide colour (other colours are permitted **5)** To improve organoleptic properties of food **6)** Caramel colour is one of the most widely used colorants in foods. It is used in soft drinks, baked goods, candy, ice cream, gravies and meats to impart a brown colour. See recommendation for food category 05.0; revise accordingly
05.1.2	**Cocoa mixes (syrups)**	**50000**	**mg/kg**		**Adopted**	
05.1.3	Cocoa-based spreads, including fillings		GMP		Adopted	
05.1.4	**Cocoa and chocolate products**	**50000**	**mg/kg**	**Note 183**	**Adopted**	
05.1.5	**Imitation chocolate, chocolate substitute products**	**50000**	**mg/kg**		**Adopted**	
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4		GMP		Adopted	
05.3	Chewing gum	20000	mg/kg		Adopted	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces		GMP		Adopted	
16.0	Composite foods - foods that could not be placed in categories 01 - 15	20000	mg/kg		**3**	**Justification** Consequential effects on adopted provision for food category 16.0, currently adopted at ML of 1000 mg/kg. **1)** Used to colour bean-paste. **2)** To improve organoleptic properties of food. **3)** maximum levels are enough to achieve the intended technological need) **Comment** **1)** Technological need is questioned. Justification should be provided why the carry over wouldn't be sufficient. **2)** If provisions are proposed for category 16, the products must
16.0	Composite foods - foods that could not be placed in categories 01 - 15	**1000**	~~GMP~~ **mg/kg**		Adopted	

Recommendation 1 - Caramel III – Ammonia Process, INS 150c The eWG of the 40th CCFA recommended **<u>further discussion</u>** of the following food additive provisions for caramel III – ammonia process in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
						be fully defined and the additive uses restricted to these products. In the vast majority of cases products can be covered by other food categories or as composite products (and therefore subject to carry over provisions)

CARAMEL IV – SULFITE AMMONIA PROCESS (INS 150(d))

9. The 29th JECFA (1985) assigned an ADI of 200 mg/kg bw/d for caramel IV – sulphite ammonia process.

10. The following are the outstanding recommendations for caramel IV – sulphite ammonia process from the report of the eWG to the 40th CCFA:

Recommendation 1 - Caramel IV – Ammonia Sulphite Process, INS 150(d) The eWG of the 40th CCFA recommended the **<u>adoption</u>** of the following food additive provisions for caramel IV – sulphite ammonia process in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
05.1.2	Cocoa mixes (syrups)	**50000**	**mg/kg**		6	**Justification** **1)** Used to colour cocoa mixes (syrups); **2)** Maximum levels are enough to achieve the intended technological need) **3)** Consistent with proposed use levels in other food categories; current use level of 5000 mg/kg in some cocoa mixes (syrups) in the US.
05.1.3	Cocoa-based spreads, including fillings	**50000**	**mg/kg**	**Note 161**		**Justification** Consequential effect is to revoke adopted provision 05.1.3 Revision: provides numeric ML to replace adopted GMP limit. **1)**Used to colour cocoa-based spreads; **2)** Maximum levels are enough to achieve the intended technological need **3)** Consistent with proposed use levels in other food categories; current use level of 2000 to 5000 mg/kg in some fillings for chocolates in the US.
05.1.3	Cocoa-based spreads, including fillings		GMP		Adopted	
05.1.4	Cocoa and chocolate products	**50000**	**mg/kg**	Note 183	6	**Justification** Revision: provides numeric ML to replace GMP limit **1)** Used to colour cocoa, chocolates **2)** To improve organoleptic properties of food **3)** maximum levels are enough to achieve the intended technological need **4)** Consistent with proposed levels in other food categories. **5)** Caramel IV is approved for use in candies within Food Category 5.2 (Hard and Soft Candy, Marzipan and Nougat) at GMP levels. The candies within Category 5.2 fall into category 5.1.4 when they are covered with chocolate. Therefore the use levels for categories 5.1.4 and 5.2 should be considered at the same time. **6)** Caramel IV use in candies

Recommendation 1 - Caramel IV – Ammonia Sulphite Process, INS 150(d) The eWG of the 40th CCFA recommended the **adoption** of the following food additive provisions for caramel IV – sulphite ammonia process in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
						including liquorice can be 10,000 mg/kg **Comments**: **1)** Use may mislead consumer. **2) I**nconsistencies between non-standardized chocolate product among 05.1.4 & 05.2, 05.4 - recommends CCFA ensure provisions for use of colour additive in non-standardized chocolate products are consistent with approach for use of colours in other confections without compromising colour limitations in Codex Standard for Chocolate and chocolate products. **3)** Request that no actions be taken to limit level of colours in 5.1.4 or create disparity with 5.2 but also do not effect chocolate meeting Codex Standard 87.
05.1.5	Imitation chocolate, chocolate substitute products	**50000**	**mg/kg**		6	**Justification** Revision: provides numeric ML to replace GMP limit
16.0	Composite foods - foods that could not be placed in categories 01 - 15	20000	mg/kg		3	**Justification** Consequential effect is to revoke adopted provision 16.0 at 1000 mg/kg **1)** Used to colour bean-pastes **2)** To improve organoleptic properties of food
16.0	Composite foods - foods that could not be placed in categories 01 - 15	1000	~~**GMP**~~ mg/kg		Adopted	

Recommendation 2 - Caramel IV – Ammonia Sulphite Process, INS 150(d) The eWG of the 40th CCFA recommended **further discussion** of the following food additive provisions for caramel IV – sulphite ammonia process in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
05.0	Confectionery	50000	mg/kg		3	**Justification** **Recommendation for broader food category 5.0 will have consequential effects on adopted provisions in subcategories 05.1.3, 05.2, 05.3, and 05.4, and provisions currently in the step process 05.1.3, 05.1.4, and 05.1.5.** **1)** No non-standardized foods in sub-category 05.1.1 **2)** There are no provisions for colours in Codex Standards for Cocoa powders and dry mixtures of cocoa and sugar (Std. 105-1981, rev. 1-2001) or in the Codex Standard for cocoa mass (cocoa/chocolate liquor) and cocoa cake (Std. 141-1983, rev. 1-2001).
05.1.3	**Cocoa-based spreads, including fillings**		**GMP**		**Adopted**	
05..2	**Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4**		**GMP**		**Adopted**	
05.3	**Chewing gum**	**20000**	**mg/kg**		**Adopted**	
05.4	**Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces**		**GMP**		**Adopted**	

CAROTENOIDS ((INS 160a(i), 160a(iii), 160e, 160f)

11. The 18th JECFA (1974) assigned a group ADI of 5 mg/kg bw/d for β-Apo-8-carotenal (160e), synthetic β-Carotene (160ai), and β -Apo-8-carotenoic acid, methyl or ethyl ester (160f). The 57th JECFA (2001) assigned β -Carotene from *Blakeslea trispora* (160aii) to the group ADI for synthetic β-carotenes. These substances are collectively referred to in the GSFA as carotenoids.

12. The following are the outstanding recommendations for carotenoids from the report of the eWG to the 40th CCFA.

Recommendation 1 - Carotenoids, INS 160a(i), 160a(iii), 160e, 160f The eWG of the 40th CCFA recommended **adoption** of the following food additive provisions for carotenoids in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
05.1.2	Cocoa mixes (syrups)	**100**	**mg/kg**		6	**Justification** **1)** Potentially used in cocoa

Recommendation 1 - Carotenoids, INS 160a(i), 160a(iii), 160e, 160f The eWG of the 40th CCFA recommended **adoption** of the following food additive provisions for carotenoids in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
						mixtures **2)** Colour supports the various flavour and types of products. **Comment:** doesn't support, mislead consumer

Recommendation 2 - Carotenoids, INS 160a(i), 160a(iii), 160e, 160f The eWG of the 40th CCFA recommended **further discussion** of the following food additive provisions for carotenoids in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
16.0	Composite foods - foods that could not be placed in categories 01 - 15	500	mg/kg		6	**Justification** **1)** Used to colour bean-paste; maximum levels are enough to achieve the intended technological need. **2)** Used for complex foods which are not covered by the other categories. **3)** Colour used to improve the organoleptic properties of food **4)** If provisions are proposed for category 16, the products must be fully defined and the additive uses restricted to these products. In the vast majority of cases products can be covered by other food categories or as composite products (and therefore subject to carry over provisions).

CAROTENES, BETA (VEGETABLE) (INS 160A(ii))

13. The 41st JECFA (1993) determined vegetable carotenes to be acceptable for use as a colour, provided the level of use does not exceed the level normally found in vegetables.

14. The following are the outstanding recommendations for vegetable carotenes from the report of the eWG to the 40th CCFA.

Recommendation 1 - Carotenes, Beta-, (Vegetable), INS 160a(ii) The eWG of the 40th CCFA recommended **adoption** of the following food additive provisions for vegetable beta-carotenes in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comment**
05.1.3	Cocoa-based spreads, including fillings	**100**	**mg/kg**		3	**Comment:** Use may mislead consumer
05.1.4	Cocoa and chocolate products	**100**	**mg/kg**	Note 183	6	Adopt 100 mg/kg with Note 180 **Comments**:
05.1.4	Cocoa and chocolate products	1000	mg/kg	Note 183	3	**1)** Use may mislead consumer. **2) I**nconsistencies between non-standardized chocolate product between 05.1.4 & 05.2, 05.4 - recommends CCFA ensure provisions for use of colour additive in non-standardized chocolate products are consistent with approach for use of colours in other confections without compromising colour limitations in Codex Standard for Chocolate and chocolate products. **3)** Request that no actions be taken to limit level of colours in 5.1.4 or create disparity with 5.2 but also do not effect chocolate meeting Codex Standard 87.
16.0	Composite foods - foods that could not be placed in categories 01 – 15	1000	mg/kg		3	**Justification** Used for complex foods.

Carotenes, Beta-, (Vegetable), INS 160a(ii) The 41st CCFA agreed to **circulate for comment at Step 3** the following food additive provisions for vegetable beta-carotene in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification**
05.1.2	Cocoa mixes (syrups)	100	mg/kg		3	**Justification**

Carotenes, Beta-, (Vegetable), INS 160a(ii) The 41st CCFA agreed to **circulate for comment at Step 3** the following food additive provisions for vegetable beta-carotene in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification**
						1) Used to colour cocoa mixes (syrups); levels are enough to achieve the intended technological need **Comment:** Technological need questioned, mislead consumer

CANTHAXANTHIN (INS 161G)

15. The 28th CAC has adopted one provision for the use of canthaxanthin in the GSFA.

16. The JECFA (1995) assigned an ADI of 0.03 mg/kg bw/d for canthaxanthin.

17. The 30th CCFAC requested that JECFA perform intake estimates for canthaxanthin based on the pending levels of maximum use in the GSFA and national food consumption data. The 53rd JECFA (1999) evaluated national intake assessments of canthaxanthin, which were based on data on poundage (disappearance), model diets, and individual dietary records. Intake estimates based on national regulatory or measured data, and combined with mean food intakes, did not exceed the ADI of 0-0.03 mg/kg bw. JECFA noted that the estimates of intake based on the assumption that canthaxanthin is used directly in all foods at the maximum levels proposed in the draft GSFA greatly exceed the ADI; however, JECFA also recognized that indirect exposure to canthaxanthin from its use as a colourant in animal feeds is the major source of canthaxanthin in food taking into account the conservative nature of the estimate using draft maximum GSFA levels as well as the knowledge that the draft GSFA proposed much broader use in food than occurs in countries in which canthaxanthin is used, JECFA concluded that use of canthaxanthin will not result in long-term intake that exceeds the ADI.

18. The following are the outstanding recommendations of the report of the eWG to the 40th CCFA.

Recommendation 1 -- Canthaxanthin, INS 161g The eWG to the 40th CCFA recommended the **adoption** of the following food additive provisions for canthaxanthin in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	**15**	**mg/kg**		6	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	**15**	**mg/kg**		6	
16.0	Composite foods - foods that could not be placed in categories 01 – 15	**80**	**mg/kg**	Note 2	6	

GRAPE SKIN EXTRACT (INS 163(ii))

19. The 26th JECFA (1982) assigned an ADI of 2.5 mg/kg bw/d for grape skin extract.

20. The following are the outstanding recommendations of the report of the eWG to the 40th CCFA.

Recommendation 1 - Grape Skin Extracts, INS 163(ii) The eWG of the 40th CCFA recommended **adoption** of the following food additive provisions for grape skin extracts in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	**500**	**mg/kg**	**Note 181**	3	**Justification** Colour supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.

Recommendation 2 - Grape Skin Extracts, INS 163(ii) The eWG of the 40th CCFA recommended **further discussion** of the following food additive provisions for grape skin extract in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
16.0	Composite foods - foods that could not be placed in categories 01 - 15	1500	mg/kg		3	**Comment** **1)** Used for composite food; maximum

Recommendation 2 - Grape Skin Extracts, INS 163(ii) The eWG of the 40th CCFA recommended **further discussion** of the following food additive provisions for grape skin extract in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
16.0	Composite foods - foods that could not be placed in categories 01 - 15	10	mg/kg		6	

Grape Skin Extracts, INS 163(ii) The 41st CCFA agreed to **circulate for comment at Step 3** the following food additive provisions for grape skin extracts in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification**
05.1.2	Cocoa mixes (syrups)	200	mg/kg	Note 181	3	**Justification** **1)** Used for cocoa mixtures; maximum level is enough to achieve the technological need **2)** Colour supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted. **3)** Support for max use of 200 mg/kg pigment. **Comment**: Use may mislead consumer
05.1.3	Cocoa-based spreads, incl. fillings	200	mg/kg	Note 181	3	**Justification** **1)** Used for fillings; maximum level is enough to achieve the technological need **2)** Colour supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted. **3)** Support for max use of 200 mg/kg pigment. **Comment**: Use may mislead consumer
05.1.4	Cocoa and chocolate products	200	mg/kg	Note 181 & 183	3	**Justification** **1)** Used for chocolate products; maximum level is enough to achieve the technological need **2)** Colour supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted. **3)** Support for max use of 200 mg/kg pigment. **4)** The current eWG recommendation is to adopt 500 mg/kg for Category 5.2 (Hard and Soft Candy, Marzipan and Nougats). The candies under 5.2 would fall into category 5.1.4 when covered with chocolate. Examples of these products include chocolate covered mints (e.g. Dark Chocolate Covered Altoids), chocolate covered gummy bears, chocolate covered marzipan, chocolate covered nougat, etc. Therefore, the same use level of grape skin extract that is allowed in 5.2 should be permitted for candies under 5.1.4 Cocoa and Chocolate. **Comments:** **1)** Use may mislead consumer. **2)** Inconsistencies between non-standardized chocolate product among 05.1.4 & 05.2, 05.4 - recommends CCFA ensure provisions for use of colour additive in non-standardized chocolate products are consistent with approach for use of colours in other confections without compromising colour limitations in Codex Standard for Chocolate and chocolate products. **3)** Request that no actions be taken to limit level of colours in 5.1.4 or create disparity with 5.2 but also do not effect chocolate meeting Codex Standard 87.

IRON OXIDES (INS 172(i), 172(ii), 172(iii))

21. The 28th CAC has adopted several provisions in the GSFA for the use of iron oxides.

22. The 23rd JECFA (1979) assigned an ADI of 0.5 mg/kg bw/d for iron oxides (172(i), 172(ii), 172(iii)).

23. The 30th CCFAC requested that JECFA perform intake assessments for iron oxides based on the pending levels of use in the GSFA and national food consumption data. The 53rd JECFA (1999) concluded that it is unlikely that intake of iron oxides would exceed the ADI of 0-0.5 mg/kg bw.

24. The following are the outstanding recommendations of the report of the eWG to the 40th CCFA.

Recommendation 1 - Iron Oxides, INS 172(i), 172(ii), 172(iii) The eWG of the 40th CCFA recommended **further discussion** of the following food additive provisions for iron oxides in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification/Comments**
05.1.3	Cocoa-based spreads, including fillings		GMP		6	**Justification** **1)**Food category in which use of one or more colours is justified **2)** Provision requires a numeric level of use instead of level consistent with good manufacturing practice (GMP), because of a numerical ADI **Comment** Additional information; numerical level needed to achieve technological effect and justification

Notes

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

Note 161: Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.

Note 181: Expressed as anthocyanin.

Note 183: Products conforming to the *Standard for chocolate and chocolate products* [CODEX STAN 87-1981] may only use colours for surface decoration.

APPENDIX IIA

The use of colours in the food categories listed in the table below is technologically justified. The use of colours in other food categories should be considered on a case-by-case basis. The list of food categories in this Appendix is intended to be used as a working document during the CCFA's discussions of food additive colours.

Appendix IIA		
GSFA Categories in which the use of one or more colours is technologically justified		
FCS No.	**Title**	**Justification**
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	Include because the CCMMP is revising the standard for fermented milk drinks that will likely contain provisions for colours.
01.3.2	Beverage whiteners	Include because there are adopted provisions for colours in these GSFA food categories
01.4.4	Cream analogues	
01.5.2	Milk and cream powder analogues	
01.6.1	Unripened cheese	Include because CODEX STANs 275-1973, A-6-1978, 221-2001 and the draft mozzarella standard contain provisions for colours
01.6.2	Ripened cheese	
01.6.2.1	Ripened cheese, includes rind	
01.6.2.2	Rind of ripened cheese	
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	Include because there are adopted provisions for colours in this GSFA food category
01.6.4	Processed cheese	Include because CODEX STANs A-8(a)-1978, A-8(b)-1978 and A-8(c)-1978 contains provisions for colours that apply to these food categories
01.6.4.1	Plain processed cheese	
01.6.4.2	Flavoured processed cheese, including containing fruit, vegetables, meat, etc.	
01.6.5	Cheese analogues	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	Include because there are provisions for colours adopted for this GSFA food category
02.1.3	Lard, tallow, fish oil, and other animal fats	Include because CODEX STAN 19-1978 contains provisions for colours that apply to this food category
02.2.1	Emulsions containing at least 80% fat	Add at request of European Commission
02.2.1.1[13]	Butter and concentrated butter	Include because CODEX STAN 1-1985 contains provisions for colours that apply to this food category
02.2.1.2	Margarine and similar products	Include because CODEX STAN 256-2007 contains provisions for colours and there are adopted provisions for colours in these GSFA food categories
02.2.1.3	Blends of butter and margarine	
02.2.2	Emulsions containing less than 80% fat	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	
03.0	Edible ices, including sherbet and sorbet	
04.1.1.2	Surface-treated fresh fruit	Include with Notes 4[14] and 16[15]
04.1.2.2	Dried fruit	Include because of the following justification: due to the effect of temperature during processing and storage affecting the discolouration of the dried fruit. Dried fruit will loose original natural flesh colour in processing and aging
04.1.2.3	Fruit in vinegar, oil, or brine	Include because there are adopted provisions for colours in this GSFA food category
04.1.2.4	Canned or bottled (pasteurized) fruit	Include because CODEX STANs 60-1981, 61-1985, 78-1981, 99-1981, 159-1987, and 242 -2003 all contain provisions for colours that apply to this food category
04.1.2.5	Jams, jellies, marmalades	Include because CODEX STANs 79-1981 and 80-1981 contain provisions for colours and there are adopted provisions for colours in these GSFA food categories
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	
04.1.2.7	Candied fruit	

[13] CX/FA 08/40/6 proposes to revise the GSFA food category system. If endorsed by the CCFA, food categories 02.2.1.1, 02.2.1.2 and 02.2.1.3 would be deleted.

[14] **Note 4:** For decoration, stamping, marking or branding the product.

[15] **Note 16**: for use in glaze, coatings or decorations for fruit, vegetables, meat or fish.

Appendix IIA		
GSFA Categories in which the use of one or more colours is technologically justified		
FCS No.	**Title**	**Justification**
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts	
04.1.2.10	Fermented fruit products	
04.1.2.11	Fruit fillings for pastries	
04.1.2.12	Cooked fruit	
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	Include with Notes 4 and 16
04.2.2.2	Dried vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	Include because of the following justification: due to the effect of temperature during processing and storage affecting the discolouration of the dried fruit. Dried fruit will loose original natural flesh colour in processing and aging
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soy sauce	
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	
04.2.2.5	Vegetable, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	
04.2.2.6	Vegetable, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food category 12.10	Include because CODEX STANs 55-1981, 58-1981, 81-1981, and 115-1981 contain provisions for colours and there are adopted provisions for colours in these GSFA food categories
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	
05.1.2	Cocoa mixes (syrups)	
05.1.3	Cocoa-based spreads, incl. fillings	
05.1.4	Cocoa and chocolate products	
05.1.5	Imitation chocolate, chocolate substitute products	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	
05.2.1	Hard candy	
05.2.2	Soft candy	
05.2.3	Nougats and marzipans	
05.3	Chewing gum	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces	
06.1	Whole, broken, or flaked grain, including rice	Include with Note 184[16]
06.3	Breakfast cereals, including rolled oats	Include because CODEX STANs 55-1981, 58-1981, 81-1981, and 115-1981 contain provisions for colours and there are adopted provisions for colours in these GSFA food categories
06.4.3	Pre-cooked pastas and noodles and like products	Include because CODEX STAN 249-206 (Instant Noodles) contains colour provisions
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	Include because there are adopted provisions for colours in these GSFA food categories
06.6	Batters (e.g., for breading or batters for fish or poultry)	
06.7	Pre-cooked or processed rice products, including rice cakes (Oriental type only)	
06.8	Soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10)	
07.1.2	Crackers, excluding sweet crackers	Include because there are adopted provisions for

[16] **Note 184**: For use in nutrient coated rice grains only.

Appendix IIA		
GSFA Categories in which the use of one or more colours is technologically justified		
FCS No.	**Title**	**Justification**
07.1.4	Bread-type products, including bread stuffing and bread crumbs	colours in these GSFA food categories
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	
08.1	Fresh meat, poultry and game	Include with Notes 4 & 16
08.1.1	Fresh meat, poultry and game, whole pieces or cuts	
08.1.2	Fresh meat, poultry and game, comminuted	
08.2	Processed meat, poultry, and game products in whole pieces or cuts	Include with Note 16
08.2.1	Non-heat treated processed meat, poultry, and game products in whole pieces or cuts	
08.2.1.1	Cured (including salted) non-heat treated processed meat, poultry, and game products in whole pieces or cuts	
08.2.1.2	Cured (including salted) and dried non-heat treated processed meat, poultry, and game products in whole pieces or cuts	
08.2.1.3	Fermented non-heat treated processed meat, poultry, and game products in whole pieces or cuts	
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	
08.2.3	Frozen processed meat, poultry, and game products in whole pieces or cuts	
08.3	Processed comminuted meat, poultry, and game products	
08.3.1	Non-heat treated processed comminuted meat, poultry, and game products	
08.3.1.1	Cured (including salted) non-heat treated processed comminuted meat, poultry, and game products	
08.3.1.2	Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	
08.3.1.3	Fermented non-heat treated processed comminuted meat, poultry, and game products	
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	
08.3.3	Frozen processed comminuted meat, poultry, and game products	
08.4	Edible casings (e.g., sausage casings)	
09.1	Fresh fish and fish products, including mollusks, crustaceans, and echinoderms	Include with Notes 4 & 16
09.1.1	Fresh fish	
09.1.2	Fresh mollusks, crustaceans and echinoderms	
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	Include because there are adopted provisions for colours in this GSFA food category
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	Include with Note 95[17]
09.2.2	Frozen battered fish, fish fillets and fish products, including mollusks, crustaceans, and echinoderms	Include with Note 16
09.2.3	Frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	Include with Note 95
09.2.4	Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	Include because there are adopted provisions for colours in this GSFA food category
09.2.4.1	Cooked fish and fish products	Include with Note 95
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	Include because there are adopted provisions for colours in this GSFA food category
09.2.4.3	Fried fish and fish products, including mollusks, crustaceans, and echinoderms	Include with Note 16
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	Include because there are adopted provisions for colours in these GSFA food categories
09.3	Semi-preserved fish and fish products, including mollusks,	

[17] **Note 95:** For use in surimi and fish roe products only.

Appendix IIA		
GSFA Categories in which the use of one or more colours is technologically justified		
FCS No.	**Title**	**Justification**
	crustaceans, and echinoderms	
09.3.1	Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	Include with Note 16
09.3.2	Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	
09.3.3	Salmon substitutes, caviar, and other fish roe products	Include because there are adopted provisions for colours in this GSFA food category
09.3.4	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	Include because there are adopted provisions for colours in this GSFA food category
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	Include with Note 95
10.1	Fresh eggs	Include with Note 4
10.3	Preserved eggs, including alkaline, salted, and canned eggs	Include with Note 4 (For decoration stamping, marking or branding the product)
10.4	Egg-based desserts (e.g., custard)	Include because there are adopted provisions for colours in this GSFA food category
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	
12.2.2	Seasonings and condiments	Include because CODEX STAN 117-1981 contains provisions for colours and there are adopted provisions for colours in this GSFA food category
12.3	Vinegars	
12.4	Mustards	
12.5	Soups and broths	
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and frozen	
12.5.2	Mixes for soups and broths	
12.6	Sauces and like products	
12.6.1	Emulsified sauces (e.g., mayonnaise, salad dressing)	
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	
12.6.3	Mixes for sauces and gravies	
12.6.4	Clear sauces (e.g., fish sauce)	
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa-and nut-based spreads of food categories 04.2.2.5 and 05.1.3	
12.9	Protein products	
12.9.1	Soybean protein products	
12.9.1.1	Soybean beverage	
12.9.1.2	Soybean beverage film	
12.9.1.3	Other soybean protein products (including non-fermented soy sauce)	
12.9.2	Fresh bean curd (tofu)	
12.9.3	Semi-dehydrated bean curd	
12.9.3.1	Thick gravy-stewed semi-dehydrated bean curd	
12.9.3.2	Deep fried semi-dehydrated bean curd	
12.9.3.3	Semi-dehydrated bean curd, other than food categories 12.9.3.1 and 12.9.3.2	
12.9.4	Dehydrated bean curd (kori tofu)	
12.9.5	Other protein products	
12.10	Fermented soybean products	
12.10.1	Fermented soybeans (e.g., natto)	
12.10.2	Fermented soybean curd (soybean cheese)	
12.10.3	Fermented soybean paste (e.g., miso)	
12.10.4	Fermented soy sauce	
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	Include because there are adopted provisions for colours in this GSFA food category
13.4	Dietetic formulae for slimming purposes and weight reduction	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1- 13.4 and 13.6	
13.6	Food supplements	

Appendix IIA		
GSFA Categories in which the use of one or more colours is technologically justified		
FCS No.	**Title**	**Justification**
14.1.4	Water-based flavoured drinks, including "sport," “energy,” or "electrolyte" drinks and particulated drinks	
14.1.4.1	Carbonated water-based flavoured drinks	
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	Include based on the following justifications. 1) Caramel colour, flavours and caffeine are dried on maltodextrin, which is added to dried coffee, in order to make an extended mix which is used as a coffee substitute in Russia (e.g. by the Russian military). 2) This category includes canned coffees that are served hot. The use of caramel colour is technologically justified in such products due to a specific manufacturing method (retort sterilization) that may change the colour during processing. Caramel colour is added to provide a consistent colour of the product that is expected by consumers. Such coffees are widely marketed in Japan. Include with Note 160[18]
14.2.1	Beer and malt beverages	Include because there are adopted provisions for colours in this GSFA food category
14.2.2	Cider and perry	
14.2.3.3	Fortified grape wine, grape liquor wine, and sweet grape wine	
14.2.4	Wines (other than grape)	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)	
15.0	Ready-to-eat savouries	
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	
15.2	Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	
15.3	Snacks - fish based	

[18] **Note 160:** For use in ready-to-drink products and pre-mixes for ready-to-drink products only.

Appendix III

COMMENTS AND INFORMATION ON SEVERAL FOOD ADDITIVES (REPLIES TO CL 2010/7-FA PART B (POINTS 11-14) AND CL 2010/39-FA) INCLUDED IN CX/FA 11/43/9 AND IN CRD 13-REV

(1) USES OF CARAMEL III, AMMONIA PROCESS (INS 150C), NISIN (INS 234) AND PHOSPHATES IN VARIOUS FOOD CATEGORIES (CL 2010/7-FA Part B, Point 14);

IDF (INTERNATIONAL DAIRY FEDERATION)

In reply to the request for Specific additional information on several food additives (paras 58, 60, 63 and Appendix VI) in the Circular Letter CL 200/7-FA part B, the International Dairy Federation (IDF) wished to provide information for the use of caramel III and Nisin in category 1.6.1 Unripened cheese as follows.

1/ Caramel III – Ammonia Process (INS 150c)

The CCFA agreed not to discontinue work on the provisions for caramel III, ammonia process (INS 150c) in food categories 01.6.1 "Unripened cheese" and 01.6.2 "Ripened cheese" and nisin (INS 234) in food category 01.6.1 "Unripened cheese"., and to request specific information on the products in these food categories in which these food additives were used, the technological justification for their use and the maximum use levels proposed, as well as for caramel III, ammonia process (INS 150c) in food category 01.6.4 "Processed cheese".

IDF wishes to propose the following level for use of caramel III in categories 1.6.1:

GFSA Food Category	Proposed Revised Maximum Level (step 3)	Cheeses which employ the additive	Level of use (mg/kg)	Technological Justification
01.6.1 Unripened Cheese	50,000 mg/kg	*Flavoured unripened cheese*	*15,000 mg/kg*	*Colour adjustment in chocolate cream cheese for example*

IDF assumes that any decision to discontinue work on Caramel III in FC 01.6.2 will not affect the provisions for this colour already adopted to permit the use of this colour in FC 01.6.2.2 (rind of ripened cheese).

2/ Nisin (INS 234)

The CCFA agreed not to discontinue work on the provisions for nisin (INS 234) in food category 01.6.1 "Unripened cheese", and to request specific information on the products in these food categories in which these food additives were used, the technological justification for their use and the maximum use levels proposed. Different levels of nisin can be used for different type of unripened cheeses.

IDF wishes to support the level of 12.5 mg/kg of pure nisin for the category 1.6.1 – Unripened cheese, see below for examples and technological justification:

GFSA Food Category	Proposed Revised Maximum Level (step 3)	Cheeses which employ the additive	Level of use (mg/kg)	Technological Justification
01.6.1 Unripened Cheese	500 mg/kg, note 28	***Paneer, Mascarpone***	***12.5 mg/kg as pure nisin***	***To Inhibit germination of spores and growth of some specific spoilage bacteria***

(2) USES AND USE LEVELS OF CYCLOTERAGLUCOSE (INS 1504(i)) AND CYCLOTETRAGLUCOSE SYRUP (INS 1504(ii)) (CL 2010/39-FA).

THAILAND

Thailand would like to inform that currently the food industries in our country have not used cyclotetraglucose (INS 1504 (i)) and cyclotetraglucose syrup (INS 1504 (ii)) so we have no comments/proposals on uses and use levels of these substances.

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(original language only)

EUROPEAN UNION

The European Union (EU) would like to submit the following comments:

Lycopene

The EU would like to reiterate its concern regarding the proposed conditions of use of lycopene and the recommendation of the CCFA during its 42nd session to include lycopene in the Table 3 of the GSFA, bearing in mind the recent conclusion from the European Food Safety Authority (EFSA) which derived in January 2008 a low numerical ADI of 0.5 mg/kg bw/d for lycopene from all food additive sources[19] (synthetic lycopene, lycopene from *Blakesla trispora* and lycopene from tomatoes), including also the intake of lycopene from natural occurrence.

Nisin

The EU supports the use of nisin in mascarpone. However, the understanding of the EU is that the proposed revised maximum limit (500 mg/kg) is expressed on the basis of nisin commercial product. The EU suggests standardizing the expression of the maximum limit in terms of pure nisin. The EU could support the proposed ML of 12.5 mg/kg as pure nisin.

INDIA

Comments on CL 2010/7-FA (Part B: Request for Comments and Information) are reproduced below:

i. Point 11. Comments at Step 3 for provisions for lycopenes (INS 160d(i)(ii)(iii)) and sodium hydrogen sulfate (INS 514) in Table 3 of the GSFA (ALINORM 10/33/12, paras 36 and 39)

It has been proposed to include lycopene and sodium hydrogen sulfate in the Table 3 of the GSFA as the JECFA has indicated the ADI as '*Not Specified'* for these food additives.

The proposal is acceptable.

ii. Point 12. Proposals on uses and use levels for lycopenes (INS 160d(i)(ii)(iii)) and sodium hydrogen sulfate (INS 514) for food categories listed in the Annex to Table 3 (ALINORM 10/33/12, paras 36 and 39)

We do not have any proposal on use and use levels for lycopenes and sodium hydrogen sulfate for food categories listed in Annex to Table 3.

iii. Point 13. Use and use levels of sucrose oligoesters (SOE) type I and type II (INS 473a) (ALINORM 10/33/12, para. 40)

We do not have any proposal on use and use levels for sucrose oligoesters.

iv. Point 14. Specific additional information on several food additives (ALINORM 10/33/12, paras 58, 60, 63 and Appendix VI).

Our comments on the dairy related draft provisions are as follows

- **Caramel III – Ammonia Process (INS 150c):** The draft proposal at step 3 is to allow its use in food categories 01.6.1 Unripened cheese, 01.6.2 Ripened cheese and 01.6.4 Processed cheese at a maximum level of 50,000 mg/kg each, for which information on their use including the cheeses which employ the additive and use levels has been sought.

Use of Caramel III – Ammonia Process (INS 150c) is not permitted in Indian food laws in the above products.

- **Nisin:** The draft proposal at Step 3 is to allow its use in food category 01.6.1 Unripened cheese at a maximum level of 500 mg/kg, for which information on their use including the cheeses which employ the additive and use levels has been sought.

[19] http://www.efsa.europa.eu/en/scdocs/doc/afc_ej674_lycopene_op_en,3.pdf

Use of nisin is allowed in cheeses, processed cheese, processed cheese spread and paneer at maximum 12.5 mg/kg each in the Indian food laws.

JAPAN

Japan would like to discard our previous comments in page.1 of CX/FA 11/43/9 and replace them with following comments.

Sucrose oligoesters (SOE) type I and type II (INS 473a)

Food Category No.	Food Category	Proposed ML (mg/kg)	Justification
01.3.2	Beverage whiteners	5,000	To inhibit solidification of fat.
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	5,000	To produce high over-run and fine structure based on demulsification properties.
01.4.4	Cream analogues	5,000	To provide stable emulsification.
01.6.4	Processed cheese	1,500	To emulsify mixtures of cheese.
01.7.	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	5,000	To emulsify contents of ice cream uniformly.
02.1.2	Vegetable oils and fats	50,000	To inhibit crystalization of triglyceride.
02.1.3	Lard, tallow, fish oil, and other animal fats	5,000	To prevent oil splashing.
02.2.2	Fat spreads, dairy fat spreads and blended spreads	10,000	To provide stable emulsification in oil.
02.3.	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	5,000	To produce high over-run and fine structure based on demulsification properties.
05.1.4	Cocoa and chocolate products	6,000	To prevent fat bloom and sugar bloom.
05.1.5	Imitation chocolate, chocolate substitute products	6,000	To prevent fat bloom and sugar bloom.
05.2.1	Hard candy	50,000	To lower viscosity in tablet candy.
05.2.2	Soft candy	5,000	To prevent soft candy from adhering to teeth and make mixing easily.
05.3.	Chewing gum	50,000	To prevent chewing gum from adhering to teeth and make mixing easily.
06.8.8	Other soybean protein products	10,000	To disperse protein powder uniformly to water.
12.2.1	Herbs and spices	2,000	To make mixing of spice with oil easily and disperse curry roux uniformly to water.
12.2.2	Seasonings and condiments	20,000	To provide better fluidity of powdered ingredients.
12.6.3	Mixes for sauces and gravies	5,000	To make mixing of hydrophilic ingredients with lipophilic ingredients easily and disperse granulated stew uniformly to water.
13.6.	Food supplements (Hard capsule)	50,000	To provide better fluidity of powdered ingredients.
	Food supplements (Tablet)	50,000	To lower viscosity in tablet food supplements.

IADSA (INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS)

Sucrose Oligoesters – SOE Type I and II (INS 473a)

IADSA supports the proposals of Japan to consider a new provision that is to adopt the use in food supplements in pressed tablet form of Sucrose Oligoesters – SOE Type I and II (INS 473a) at 20,000 mg/kg in food category 13.6.

ICGA (INTERNATIONAL CHEWING GUM ASSOCIATION)

The ICGA would like to thank you for the opportunity to reiterate its comments made in 2007 to the electronic working group on the GSFA. We would appreciate the following comments to be shared with Codex member countries and observer organisations related to the use of Lycopenes in chewing gum.

1) Technological needs

Chewing gum producers are considering lycopene from all sources (INS 160i, ii, iii) as a very valuable alternative as a red pigment for use in some chewing gum. Lycopenes are a more and more attractive colour that chewing gum producers may want to be able to use in the future as part of new alternative colour applications.

The ICGA submits that a maximum level of use of 300 mg/kg in chewing gum would cover most of these applications in chewing gum worldwide.

2) Safety aspects

The acceptable daily intake (ADI) established by JECFA for Lycopenes is 0.5 mg/kg body weight.

Assuming a consumption of 3g of chewing gum per day containing Lycopenes at the level of 300 mg/kg, it would result in the ingestion of only 0.9 mg per day, assuming that all the Lycopenes present in the gum is extracted during chewing. This is also assuming that all chewing gum would contain Lycopene colour and that the colour would be ingested totally which is know not to be the case. With this quite conservative and theorical estimated level of intake, it would then correspond to 0.015 mg/kg b.w. for a 60 kg adult per day, i.e. **about 3% of the ADI only**.

3) Past Codex discussions

The ICGA would like to recall that during the preparation of the 39th session of the Codex Committee on Food Additives (March 2009), the electronic working group on GSFA recommended in its report the adoption by the Committee of a level of 1000 mg/kg for synthetic Lycopenes in chewing gum, as initially proposed by Japan.

In conclusion, the ICGA submits that a permitted maximum use level of 300 ppm Lycopenes in GSFA food category 05.3 Chewing gum is a safe use level, which would cover most of the technological needs for applications in chewing gum worldwide address benefits for the consumer in alternative red coloured chewing gum.