codex alimentarius commissio E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5(a) **CX/FA 08/40/5 Part 1**

February 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fortieth Session

Beijing, China, 21-25 April 2008

REPORT OF THE ELECTRONIC WORKING GROUP ON THE GSFA

PART 1[1]

(Prepared by the United States of America with the assistance of Brazil, Canada, European Community, Japan, Malaysia, AIDGUM, CEFIC, CEFS, EFEMA, IADSA, ICA, ICBA, ICGA, IDF, IFAC, ISA, NATCOL, and OIV)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the report of the electronic Working Group on the GSFA are invited to do so **no later than 31 March 2008** as follows: Secretariat, Codex Committee on Food Additives, National Institute of Nutrition and Food Safety, China CDC, 7 Panjiayuan Nanli, Chaoyang District, Beijing 100021, China (Telefax: + 86 10 67711813, E-mail: secretariat@ccfa.cc ***preferably***), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - ***preferably***).

1. The 39th Session of the Codex Committee on Food Additives (CCFA) reestablished its electronic Working Group (eWG), working in English, to consider the outstanding recommendations contained in document CX/FA 07/39/9 Part 1 and Part 2, taking into account comments submitted (contained in document CX/FA 07/39/9 Add.1, CX/FA 07/39/9 Add.2 and relevant CRDs), relevant decisions made at the session, and new comments received in response to CL 2007/28-FA.[2]

2. The Committee also agreed to request comments, at Step 3 and Step 6, and additional information on the food additive provisions listed in Appendix IX of ALINORM 07/30/12 REV.with the understanding that if this information was not provided, the 40th CCFA would discontinue work on these food additive provisions and remove them from the GSFA.[3]

3. In addition, the Committee agreed to request: 1) proposals for acceptable maximum use levels for annatto extracts based on bixin or norbixin; 2) information on technological need and maximum levels for lycopene, expressed as lycopene; and 3) information on technological need and acceptable maximum levels for aluminium-containing food additives, with a view toward including such provisions in the GSFA.[4]

4. The Committee further agreed to request proposals for new food additive uses and comments on adopted food additive provisions.[5] These requests were included in CL 2007/28-FA. The Committee agreed that the eWG would provide a report with its recommendations on draft maximum use levels for all such additive provisions to be circulated for comment and consideration at the 40th session of the Committee.[2]

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[1] Due to its size this document has been divided into two parts: Part 1 (Introduction, Miscellaneous Food Additives and Sweeteners) and Part 2 (Colours and Appendices 1, 2 and 3)

[2] ALINORM 07/30/12 Rev., para. 104

[3] ALINORM 07/30/12 Rev., para. 107

[4] ALINORM 07/30/12 Rev. - Appendix IV

[5] ALINORM 07/30/12 Rev., para 109

5. Also included in this report are proposed draft provisions for EDTAs, polydimethylsiloxane, saccharin, and sulphites that are included as new proposals for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables, which was endorsed by the 39th CCFA.

6. The recommendations in this report are based on a "weight of evidence" approach. They take into account the report of the 39th CCFA's eWG (see CX/FA 07/39/8), the deliberations and comments received by the 39th CCFA (CX/FA 07/39/8 Add. 1, CX/FA 07/39/8 Add. 2, and relevant CRDs), comments submitted in response to CL 2007/FA-28[6] and comments submitted by the participants in the eWG. Comments containing justifications supporting a particular recommendation were given more weight than comments with no supporting justification. The recommendations contained in this report do not reflect a unanimous opinion of the eWG members. Rather, the recommendations herein reflect an attempt to reach consensus to facilitate the committee's discussion at its 40th session. Individual members of the eWG reserve their right to provide additional comments and recommendations to the CCFA.

7. The CCFA's electronic Working Group (eWG) on the GSFA offers the following recommendations for consideration by the CCFA. The eWG only discussed provisions for the additives listed in the table below. The additives listed in **bold** font in this table are those for which the 39th CCFAC agreed that, if additional information on specific food additive provisions was not provided in response to CL 2007/28-FA, these provisions would be revoked (if Step 8) or discontinued (if Step 3 or 6).

INS No.	Additive		INS No.	Additive
	Miscellaneous			**Colours**
160b(i), (ii)	Annatto Extracts, Bixin-based and Norbixin based		101(i), 101(ii)	Riboflavins
160d(i), (ii)	Lycopene		**110**	**Sunset Yellow FCF**
414	Gum Arabic (Acacia Gum)		**120**	**Carmines**
523, 541(i), (ii), 554, 556, 559	Food Additives Containing Aluminium (Aluminium Ammonium Sulphate, Sodium Aluminium Phosphates, Sodium Aluminosilicate, Calcium Aluminium Silicate, Aluminium Silicate)		**124**	**Ponceau 4R (Cochineal Red A)**
220, 221, 222, 223, 224, 225, 227, 228, 539	**Sulphites**		127	Erythrosine
385, 386	EDTAs		**129**	**Allura Red AC**
432,433, 434, 435, 436	**Polysorbates**		**132**	**Indigotine (indigo Carmine)**
472e	**Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM)**		**133**	**Brilliant Blue FCF**
900a	Polydimethylsiloxane		**141(i) & 141(ii)**	**Chlorophylls, Copper**
	Sweeteners		143	Fast Green FCF
950	**Acesulfame Potassium**		**150c**	**Caramel III – Ammonia Process**
951	**Aspartame**		**150d**	**Caramel IV – Sulphite Ammonia Process**
962	**Aspartame-Acesulfame Salt**		**160a(i), a(iii), e, f**	**Carotenoids**
952	**Cyclamic Acid (Sodium, Potassium, and Calcium Salts)**		**160a(ii)**	**Carotenes, Beta, (Vegetable)**
954	**Saccharin**		161g	Canthaxanthin
955	**Sucralose**		**163(ii)**	**Grape Skin Extract**
956	**Alitame**		172(i), 172(ii), 172(iii)	Iron Oxides
961	**Neotame**			

[6] Comments submitted in response to CL 2007/28-FA were made available to all members of the electronic working group on the electronic forum and are not included in this report

8. Revisions to existing Proposed Draft (Step 3), Draft (Step 6) or adopted food additive provisions proposed by the eWG are indicated in **bold font** in the following tables for each additive. Where appropriate, the additional information provided, either in response to CL 2007/28-FA or as part of the eWG deliberations, is included in the recommendations below.

MISCELLANEOUS FOOD ADDITIVES

ANNATTO EXTRACTS, BIXIN-BASED AND NORBIXIN-BASED (INS 160b(i), 160b(ii))

9. The 67th JECFA (2006) established two new ADIs for annatto extracts: an ADI of 0-12 mg/kg for bixin-based (INS 160b(i)), with the exception of oil-processed bixin, and a group ADI of 0-0.6 for norbixin-based (INS 160b(ii)) and its sodium and potassium salts.

10. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function colouring with annatto extracts.

11. The 39th CCFA (CL 2007/28-FA and ALINORM 07/30/12, App. IV) requested proposals and information on maximum use levels and technological need for annatto extracts. Proposals for inclusion in Tables 1 and 2 of the GSFA should clarify the type of annatto extracts used and the basis (either bixin or norbixin) for requested maximum use levels.

ANNATTO EXTRACTS, BIXIN-BASED (INS 160b(i))

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	50	mg/kg	Note 8	Required to identify flavour, to provide colour
01.3.2	Beverage whiteners	50	mg/kg	Note 8	Colour used to standardize natural variations
01.4.4	Cream analogues	100	mg/kg	Note 8	
01.5.2	Milk and cream powder analogues	100	mg/kg	Note 8	Colour used to standardize natural variations
01.6.1	Unripened cheese	60	mg/kg	Note 8	This level is necessary to balance seasonal color variations in the raw milk so a uniform cheese color results. Higher levels provide a characteristic "orange" color to traditional varieties of cheese in certain countries. Applies to CODEX STAN 221-2001, 272-1968, 274-1969, 262-2007 & A-6-1978.
01.6.2.1	Ripened cheese, incl. rind	100	mg/kg	Note 8	This level is necessary to balance seasonal color variations in the raw milk so a uniform cheese color results. Higher levels provide a characteristic "orange" color to traditional varieties of cheese in certain countries. Applies to CODEX STAN A-6-1978, 263-1966, 264-1966, 265-1966, 26601966, 267-1966, 268-1966, 269-1967, 270-1968, 271-1968, 275-1973, 276-1973, & 277-1973.
01.6.2.2	Rind of ripened cheese	1000	mg/kg	Note 8	Colour used to standardize natural variations
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	50	mg/kg	Note 8	
01.6.3	Whey cheese	50	mg/kg	Note 8	
01.6.4.1	Plain processed cheese	80	mg/kg	Note 8	Colour used to standardize natural variations
01.6.4.2	Flavoured processed cheese	100	mg/kg	Note 8	Colour used to standardize natural variations and to support the various flavour and types of products
01.6.5	Cheese analogues	50	mg/kg	Note 8	Colour used to standardize natural variations
01.6.6	Whey protein cheese	50	mg/kg	Note 8	Colour used to standardize natural variations
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt and ice cream)	500	mg/kg	Note 8	Provides colour and supports the various flavour and types of products.
01.8.1	Liquid whey and whey products, excluding whey cheeses	20	mg/kg	Note 8	

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
01.8.2	Dried whey and whey products excluding whey cheeses	20	mg/kg	Note 8	
02.1.1	Butter oil, anhydrous milk fat, ghee	100	mg/kg	Note 8	
02.1.2	Vegetable oils and fats	10	mg/kg	Note 8	
02.1.3	Lard, tallow, fish oil, and other animal fats	10	mg/kg	Note 8	
02.2.1.1[7]	Butter and concentrated butter	30	mg/kg	Note 8	Revise current adopted provision at 20 mg/kg - Note 9[8]. Necessary to balance seasonal color variations in raw milk so butter is uniform color. Applies to CODEX STAN A-01-1971.
02.2.1.2	Margarine and similar products	100	mg/kg	Note 8	The use of annatto extract provides yellow color to the product. The procedure with annatto extracts is easier than with other colours as it can be prepared in the water or oil solution. These colours are available in practical forms to handle. Due to the different kinds of annatto extract, the colour achieved is more homogeneous and efficient for products containing two phases, such as margarine.
02.2.1.3	Blends of butter and margarine	10	mg/kg	Note 8	
02.2.2	Emulsions containing less than 80% fat	30	mg/kg	Note 8	Colour used to standardize natural variations
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	100	mg/kg	Note 8	The use of annatto extract provides yellow color to the product. The procedure with annatto extracts is easier than with other colours as it can be prepared in the water or oil solution. These colours are available in practical forms to handle. Due to the different kinds of annatto extract, the colour achieved is more homogeneous and efficient for products containing two phases, such as vegetable cream.
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	30	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
03.0	Edible ices, including sherbet and sorbet	20	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
04.1.2.3	Fruit in vinegar, oil, or brine (e.g. pickled fruits)	20	mg/kg	Note 8	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
04.1.2.4	Canned or bottled (pasteurized) fruit	20	mg/kg	Note 8	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
04.1.2.5	Jams, jellies, marmalades	20	mg/kg	Note 8	
04.1.2.6	Fruit based spreads (e.g. Chutney) excluding products of food categories 04.1.2.5	20	mg/kg	Note 8	
04.1.2.7	Candied fruit	20	mg/kg	Note 8	
04.1.2.8	Fruit preparation, including pulp, purrees, fruit toppings and coconut milk	100	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	30	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
04.1.2.11	Fruit fillings for pastries (e.g. cherry pie filling)	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted

[7] 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.
[8] **Note 9:** As total bixin or norbixin.

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
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	20	mg/kg	Note 8	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
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)	100	mg/kg	Note 8	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
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	20	mg/kg	Note 8	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
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	20	mg/kg	Note 8	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	100	mg/kg	Note 8	
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products.
05.1.2	Cocoa mixes (syrups)	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products.
05.1.3	Cocoa-based spreads, including fillings	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products.
05.1.4	Cocoa and chocolate products	25	mg/kg	Note 8	Provides colour and supports the various flavour and types of products.
05.1.5	Imitation chocolate, chocolate substitute products	25	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
05.2.1	Hard Candy	200	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
05.2.2	Soft candy	200	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
05.2.3	Nougats and marzipans	100	mg/kg	Note 8	
05.3	Chewing gum	500	mg/kg	Note 8	Annatto extracts are used in certain categories of chewing gum in some parts of the world. Mixtures of Norbixin and Bixin are the most in use and those chewing gum are subject to international trade. The JECFA ADI for Annatto extracts expressed as Norbixin is 0.6 mg/kg body weight whereas it is 12

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
					mg/kg as bixin. Assuming a consumption of 3 g of chewing gum[9] per day, containing a mixture 50/50 of Annatto extracts with Bixin/Norbixin, at a level of 500 mg/kg, it would result in the ingestion of 0,75 mg per day for each bixin and norbixin, if all of the Annatto extract present is extracted during chewing as a conservative hypothesis. This would correspond to 0.0125 mg/kg b.w. for a 60 kg adult that is to say about 2% of the Norbixin's ADI and 0,1% of the Bixin ADI. These low figures give reassurance on their safe use in chewing gum at the proposed level of 500 mg/kg.
05.4	Decorations (e.g. for fine bakery wares) and sweet sauces	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
06.1	Whole,broken,or flanked grain, including rice	500	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
06.3	Breakfast cereals, including rolled oats	75	mg/kg	Note 8	
06.4.2	Dried pastas and noodles and like products	20	mg/kg	Note 8	Used for different kinds of dried pastas, provides a natural color to the pastas
06.4.3	Pre-cooked pastas and noodles and like products	20	mg/kg	Note 8	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	30	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
06.6	Batters (e.g., for breading or batters for fish or poultry)	100	mg/kg	Note 8	
07.1.1	Breads and rolls	200	mg/kg	Note 8	
07.1.2	Crackers, excluding sweet crackers	200	mg/kg	Note 8	
07.1.4	Bread-type products, including bread stuffing and bread crumbs	200	mg/kg	Note 8	
07.1.5	Steamed breads and buns	200	mg/kg	Note 8	
07.1.6	Mixes for breads and ordinary bakery wares	200	mg/kg	Note 8	
07.2.1	Cakes, cookies and pies (e.g. fruit filled or custard types)- sweet types	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
07.2.2	Other fine bakery products (e.g. doughnuts, sweet rolls, scones, and muffins)	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
07.2.3	Mixes for fine bakery wares (e.g. cakes, pancakes)	25	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
08.1.2	Fresh meat, poultry and game, comminuted	1000	mg/kg	Note 8 & B	
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cut	100	mg/kg	Note 8	
08.3.1.1	Cured (including salted) non-heat treated products	1000	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
08.3.1.2	Cured (including salted) and dried non-heat treated products	100	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.

[9] Figures collected in all EC countries show that the daily per capita consumption of chewing gum in the EC is 1g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: " Guidelines for simple evaluation of food additive intake" and confirmed by an EC survey conducted in some EC countries

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
08.3.1.3	Fermented non-heat treated products	100	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	50	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
08.3.3	Frozen processed comminuted meat, poultry, and game products as in 8.3.1 and 8.3.2	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
08.4	Edible casings (e.g. sausage casings)	1000	mg/kg	Note 8 & C	Provides colour. A wide range of colours is equally justified and should be equally permitted.
9.1	Fresh fish and fish products, including molluscs, crustaceans, and echinoderms	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.2.1	Frozen fish, fish fillets, and fish products, including molluscs, crustaceans, and echinoderms	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.2.2	Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans, and echinoderms	50	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.2.3	Frozen minced and creamed fish products, including mollusks	50	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.2.4	Cooked and/or fried fish and fish products, including molluscs, crustaceans, and echinoderms	50	mg/kg	Note 8	
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms	15	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.3.1	Fish and fish products, including molluscs, crustaceans, and echinoderms, marinated and/or in jelly	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.3.2	Fish and fish products, including molluscs, crustaceans, and echinoderms, pickled and/or in brine	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.3.3	Salmon substitutes, caviar and o2ther fish roe products	50	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.3.4	Semi-preserved fish and fish products, including molluscs, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	30	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.4	Fully preserved including canned or fermented fish and fish products	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
10.4	Egg-based desserts	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
11.3	Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	25	mg/kg	Note 8	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	25	mg/kg	Note 8	Provides colour. A wide range of colours is equally justified and should be equally permitted.
12.2	Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.2.2	Seasonings and Condiments	200	mg/kg	Note 8	Annatto extract provides red or orange color, depending on the amount used. It does not provide flavour or taste to the product.
12.4	Mustards	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.5	Soups and broths	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.1	Emulsified sauces (e.g. mayonnaise, and salad dressing)	100	mg/kg	Note 8	The use of annatto extract provides yellow color to the product. The procedure with annatto extracts is easier than with other colours, because it can be prepared in the water or oil solution. These colours are available in practical forms to handle with. Due to the different kinds of annatto extract, the colour achieved is more homogeneous and efficient for products containing two phases
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	100	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.3	Mixes for sauces and gravies	100	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.4	Clear sauces (e.g. fish sauce)	400	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
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	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.9.1.1	Soybean beverages	15	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.9.3.2	Deep fried semi-dehydrated bean curd	10	mg/kg	Note 8	
12.9.5	Other protein products	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
13.3	Dietetic foods for special medical purposes	20	mg/kg	Note 8	
13.4	Dietetic formulae for slimming purposes and weight reduction	20	mg/kg	Note 8	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1- 13.4 and 13.6	20	mg/kg	Note 8	
13.6	Food supplements	60	mg/kg	Note 8	

Recommendations – Annatto Extracts, Bixin-based, INS 160b(i)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, bixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
14.2.3.2	Sparkling and semi-sparkling grape wines	10	mg/kg	Note 8	
14.2.3.3	Fortified grape wine, grape liquor wine, and sweet grape wine	20	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
14.2.4	Wines (other than grape)	20	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	30	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	30	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	50	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
15.2	Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	30	mg/kg	Note 8	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
15.3	Snacks - fish based	20	mg/kg	Note 8	
16.0	Composite foods - foods that could not be placed in categories 01 - 15	200	mg/kg	Note 8	

ANNATTO EXTRACTS, NORBIXIN-BASED (INS 160b(ii))

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	25	mg/kg	Note X	The use of annatto extract provides yellow color to the product. Annatto extracts present good stability during heating and low color loss. These characteristics make its use important for bakery products, which are submitted to heating. Due to its different forms, water and oil-soluble, annatto extract is the most natural colour useful in Brazil. In addition, it is the only one that is originally found in Brazilian soil.
01.4.4	Cream analogues	300	mg/kg	Note X	The use of annatto extract provides yellow color to the product. Annatto extracts present good stability during heating and low color loss. These characteristics make its use important for bakery products, which are submitted to heating. Due to its different forms, water and oil-soluble, annatto extract is the most natural colour useful in Brazil. In addition, it is the only one that is originally found in Brazilian soil.
01.5.2	Milk and cream powder analogues	55	mg/kg	Note X	Used to standardize natural variations
01.6.1	Unripened cheese	60	mg/kg	Note X	This level is necessary to balance seasonal color variations in the raw milk so a uniform cheese color results. Higher levels provide a characteristic “orange” color to traditional varieties of cheese in certain countries. Applies to CODEX STAN 221-2001, 272-1968, 274-1969, 262-2007 & A-6-1978.

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
01.6.2.1	Ripened cheese, incl. rind	100	mg/kg	Note X	This level is necessary to balance seasonal color variations in the raw milk so a uniform cheese color results. Higher levels provide a characteristic "orange" color to traditional varieties of cheese in certain countries. Applies to CODEX STAN A-6-1978, 263-1966, 264-1966, 265-1966, 26601966, 267-1966, 268-1966, 269-1967, 270-1968, 271-1968, 275-1973, 276-1973,
01.6.2.2	Rind of ripened cheese	50	mg/kg	Note X	Colour used to standardize natural variations
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	50	mg/kg	Note X	Colour used to standardize natural variations
01.6.3	Whey cheese	10	mg/kg	Note X	Colour used to standardize natural variations
01.6.4	Processed cheese	100	mg/kg	Note X	This level is necessary to balance color that may vary due to color variations with dairy ingredients. Applies to CODEX STAN A-8(a)-1978, A-8(b)-1978 & A-8(c)-1978.
01.6.6	Whey protein cheese	10	mg/kg	Note X	Colour used to standardize natural variations
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt and ice cream)	20	mg/kg	Note X	The use of annatto extract provides yellow color to the product. Annatto extracts present good stability during heating and low color loss. These characteristics make its use important for bakery products, which are submitted to heating. Due to its different forms, water and oil-soluble, annatto extract is the most natural colour useful in Brazil. In addition, it is the only one that is originally found in Brazilian soil; Provides colour and supports the various flavour and types of products.
01.8.1	Liquid whey and whey products, excluding whey cheeses	20	mg/kg	Note X	Colour used to standardize natural variations.
01.8.2	Dried whey and whey products excluding whey cheeses	20	mg/kg	Note X	Colour used to standardize natural variations.
02.2.1.1[10]	Butter and concentrated butter	30	mg/kg	Note X	Revise current adopted provision at 20 mg/kg. Necessary to balance seasonal color variations in raw milk so butter is uniform color. Applies to CODEX STAN A-01-1971.
02.2.2	Emulsions containing less than 80% fat	10	mg/kg	Note X	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	10	mg/kg	Note X	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	10	mg/kg	Note X	
03.0	Edible ices, including sherbet and sorbet	200	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
04.1.1.2	Surface-treated fresh fruit	20	mg/kg	Note X	
04.1.2.4	Canned or bottled (pasteurized) fruit	200	mg/kg	Note X	Fruits and vegetables discolour during processing and storage. Therefore use as restoration of colour which was destroyed during heat processing.
04.1.2.5	Jams, jellies, marmalades	20	mg/kg	Note X	
04.1.2.6	Fruit based spreads (e.g. Chutney) excluding products of food categories 04.1.2.5	20	mg/kg	Note X	
04.1.2.7	Candied fruit	20	mg/kg	Note X	
04.1.2.8	Fruit preparation, including pulp, purrees, fruit toppings and coconut milk	20	mg/kg	Notes A & X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted

[10] 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.

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	150	mg/kg	Notes B1 & X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
04.1.2.10	Fermented fruit products	200	mg/kg	Note X	
04.1.2.11	Fruit fillings for pastries (e.g. cherry pie filling)	200	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
04.1.2.12	Cooked fruit	20	mg/kg	Note X	
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	300	mg/kg	Note X	
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	10	mg/kg	Note X	
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)	100	mg/kg	Note X	
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	10	mg/kg	Note X	
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	200	mg/kg	Note X	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	100	mg/kg	Note X	
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	50	mg/kg	Note X	
05.1.2	Cocoa mixes (syrups)	50	mg/kg	Note X	

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
05.1.3	Cocoa-based spreads, including fillings	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products.
05.1.5	Imitation chocolate, chocolate substitute products	25	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
05.2	Confectionary including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
05.3	Chewing gum	500	mg/kg	Note X	Annatto extracts are used in certain categories of chewing gum in some parts of the world. Mixtures of Norbixin and Bixin are the most in use and those chewing gums are subject to international trade. The JECFA ADI for Annatto extracts expressed as Norbixin is 0.6 mg/kg body weight whereas it is 12 mg/kg as bixin. Assuming a consumption of 3 g of chewing gum[11] per day, containing a mixture 50/50 of Annatto extracts with Bixin/Norbixin, at a level of 500 mg/kg, it would result in the ingestion of 0,75 mg per day for each bixin and norbixin, if all of the Annatto extract present is extracted during chewing as a conservative hypothesis. This would correspond to 0.0125 mg/kg b.w. for a 60 kg adult that is to say about 2% of the Norbixin's ADI and 0,1% of the Bixin ADI. These low figures give reassurance on their safe use in chewing gum at the proposed level of 500 mg/kg.
05.4	Decorations (e.g. for fine bakery wares) and sweet sauces	1000	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
06.1	Whole,broken,or flanked grain, including rice	500	mg/kg	Note X	
06.3	Breakfast cereals, including rolled oats	75	mg/kg	Note X	To uniform the color, since different fiber sources are used. Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted
06.4.2	Dried pastas and noodles and like products	100	mg/kg	Note X	provides a natural color to the pastas
06.4.3	Pre-cooked pastas and noodles and like products	100	mg/kg	Note X	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	40	mg/kg	Notes C1 & X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
06.6	Batters (e.g., for breading or batters for fish or poultry)	100	mg/kg	Note X	Provides colour. A wide range of colours is equally justified and should be equally permitted.
06.7	Pre-cooked or processed rice products, including rice cakes (Oriental type only)	500	mg/kg	Note X	
06.8	Soybean products (excluding soybean products of food category 12.9 and fermented products of food category 12.10)	100	mg/kg	Note X	
07.1.1	Breads and rolls	200	mg/kg	Note X	
07.1.2	Crackers, excluding sweet crackers	200	mg/kg	Note X	

[11] Figures collected in all EC countries show that the daily per capita consumption of chewing gum in the EC is 1g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: " Guidelines for simple evaluation of food additive intake" and confirmed by an EC survey conducted in some EC countries.

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
07.1.4	Bread-type products, including bread stuffing and bread crumbs	200	mg/kg	Note X	
07.1.5	Steamed breads and buns	200	mg/kg	Note X	
07.1.6	Mixes for breads and ordinary bakery wares	200	mg/kg	Note X	
07.2.1	Cakes, cookies and pies (e.g. fruit filled or custard types)- sweet types	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
07.2.2	Other fine bakery products (e.g. doughnuts, sweet rolls, scones, and muffins)	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
07.2.3	Mixes for fine bakery wares (e.g. cakes, pancakes)	25	mg/kg	Note X	The use of annatto extract provides yellow color to the product. Annatto extracts present good stability during heating and low color loss. These characteristics make its use important for bakery products, which are submitted to heating. Due to its different forms, water and oil-soluble, annatto extract is the most natural colour useful in Brazil. In addition, it is the only one that is originally found in Brazilian soil; Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
08.1.2	Fresh meat, poultry and game, comminuted	1000	mg/kg	Notes D & X	
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cut	100	mg/kg	Note X	
08.3.1.1	Cured (including salted) non-heat treated products	1000	mg/kg	Note X	
08.3.1.2	Cured (including salted) and dried non-heat treated products	100	mg/kg	Note X	
08.3.1.3	Fermented non-heat treated products	100	mg/kg	Note X	
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	50	mg/kg	Note X	
08.3.3	Frozen processed comminuted meat, poultry, and game products as in 8.3.1 and 8.3.2	20	mg/kg	Note X	
08.4	Edible casings (e.g. sausage casings)	20	mg/kg	Notes E & X	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.2	Processed fish and fish products, including molluscs, crustaceans, and echinoderms	100	mg/kg	Note X	
09.3.1	Fish and fish products, including molluscs, crustaceans, and echinoderms, marinated and/or in jelly	100	mg/kg	Note X	Provides colour. A wide range of colours is equally justified and should be equally permitted.

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
09.3.2	Fish and fish products, including molluscs, crustaceans, and echinoderms, pickled and/or in brine	100	mg/kg	Note X	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.3.3	Salmon substitutes, caviar and o2ther fish roe products	50	mg/kg	Notes X and F	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.3.4	Semi-preserved fish and fish products, including molluscs, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	30	mg/kg	Note X	Provides colour. A wide range of colours is equally justified and should be equally permitted.
09.4	Fully preserved including canned or fermented fish and fish products	10	mg/kg	Note X	
10.4	Egg-based desserts	25	mg/kg	Note X	Provides colour. A wide range of colours is equally justified and should be equally permitted.
11.3	Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	100	mg/kg	Note X	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	60	mg/kg	Note X	
12.2	Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.4	Mustards	140	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.5	Soups and broths	150	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.1	Emulsified sauces (e.g. mayonnaise, and salad dressing)	100	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	100	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.3	Mixes for sauces and gravies	100	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.6.4	Clear sauces (e.g. fish sauce)	400	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
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	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.9.1.1	Soybean beverages	15	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.9.1.2	Soybean milk film	10	mg/kg	Note X	

Recommendations – Annatto Extracts, Norbixin-based, INS 160b(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for annatto extracts, norbixin-based, in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
12.9.1.3	Other soybean protein products (including non-fermented soy sauce)	10	mg/kg	Note X	
12.9.2	Fresh bean curd (tofu)	10	mg/kg	Note X	
12.9.3	Semi-dehydrated bean curd	10	mg/kg	Note X	
12.9.5	Other protein products	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
12.10	Fermented soybean products	10	mg/kg	Note X	
13.3	Dietetic foods for special medical purposes	10	mg/kg	Note X	
13.4	Dietetic formulae for slimming purposes and weight reduction	10	mg/kg	Note X	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1-13.4 and 13.6	10	mg/kg	Note X	
13.6	Food supplements	100	mg/kg	Note X	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
14.2.2	Cider and perry	10	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
14.2.3.1	Still grape wine	10	mg/kg	Note X	
14.2.3.2	Sparkling and semi-sparkling grape wines	10	mg/kg	Note X	
14.2.3.3	Fortified grape wine, grape liquor wine, and sweet grape wine	15	mg/kg	Note X	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	10	mg/kg	Note X	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	10	mg/kg	Note X	
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	50	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
15.2	Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	30	mg/kg	Note X	Provides colour and supports the various flavour and types of products. A wide range of colours is equally justified and should be equally permitted.
15.3	Snacks - fish based	20	mg/kg	Note X	
16.0	Composite foods - foods that could not be placed in categories 01 - 15	200	mg/kg	Note X	

LYCOPENE, SYNTHETIC LYCOPENE (INS 160d(I)) AND LYCOPENE FROM *BLAKESLEA TRISPORA* (INS 160d(III))

12. The 67th JECFA (2006) established a "group" ADI of 0-0.5 mg/kg for INS 160d(i) and INS 160d(iii).

13. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function colouring with lycopene.

14. The 39th CCFA (CL 2007/28-FA and ALINORM 07/30/12, App. IV) requested proposals and information on maximum levels and technological needs for lycopene. Proposals for inclusion in Tables 1 and 2 of the GSFA should express the maximum levels as lycopene.

Recommendations – Lycopene, INS 160d(i), 160(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for lycopene in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	1000	mg/kg		Colour needed for matching flavour. Fermented milk drinks contain provision for colours – STAN 243-2003 for flavoured products
01.3.2	Beverage whiteners	100	mg/kg		
01.4.4	Cream analogues	1000	mg/kg		
01.5.2	Milk and cream powder analogues	100	mg/kg		
01.6.1	Unripened cheese	100	mg/kg		
01.6.2.1	Ripened cheese, incl. rind	1000	mg/kg		
01.6.2.2	Rind of ripened cheese	1000	mg/kg		
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	100	mg/kg		
01.6.3	Whey cheese	1000	mg/kg		
01.6.4.1	Plain processed cheese	100	mg/kg		
01.6.4.2	Flavoured processed cheese	2000	mg/kg		
01.6.5	Cheese analogues	1000	mg/kg		
01.6.6	Whey protein cheese	1000	mg/kg		
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt and ice cream)	1000	mg/kg		Colour needed for matching flavour. Colours already have provisions in this GSFA category
01.8	Whey and whey products, excluding whey cheeses	100	mg/kg		
02.1.1	Butter oil, anhydrous milkfat, ghee	100	mg/kg		
02.1.2	Vegetable oils and fats	10	mg/kg		
02.1.3	Lard, tallow, fish oil, and other animal fats	10	mg/kg		
02.2.1	Emulsions containing at least 80% fat	100	mg/kg		
02.2.2	Emulsions containing less than 80% fat	100	mg/kg		
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	100	mg/kg		
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	100	mg/kg		
03.0	Edible ices, including sherbet and sorbet	1000	mg/kg		CX Stan 32 contains provision for colours and GSFA has adopted provisions for colours in this category
04.1.2.3	Fruit in vinegar, oil, or brine (e.g. pickled fruits)	1000	mg/kg		
04.1.2.4	Canned or bottled (pasteurized) fruit	100	mg/kg		
04.1.2.5	Jams, jellies, marmalades	1000	mg/kg		Used for restoration of colour destroyed during production. CX Stan 79 and 80 contains provisions for colours and the GSFA has adopted provisions for colours in this category
04.1.2.6	Fruit based spreads (e.g. Chutney) excluding products of food categories 04.1.2.5	1000	mg/kg		Used for restoration of colour destroyed during production. CX Stan 79 and 80 contains provisions for colours and the GSFA has adopted provisions for colours in this category
04.1.2.7	Candied fruit	200	mg/kg		Used for restoration of colour destroyed during production. CX Stan 79 and 80 contains provisions for colours and the GSFA has adopted provisions for colours in this category
04.1.2.8	Fruit preparation, including pulp, purrees, fruit toppings and coconut milk	100	mg/kg		Used for restoration of colour destroyed during production. CX Stan 79 and 80 contains provisions for colours and the GSFA has adopted provisions for colours in this category

Recommendations – Lycopene, INS 160d(i), 160(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for lycopene in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	1000	mg/kg		Used for restoration of colour destroyed during production. CX Stan 79 and 80 contains provisions for colours and the GSFA has adopted provisions for colours in this category
04.1.2.10	Fermented fruit products	1000	mg/kg		
04.1.2.11	Fruit fillings for pastries (e.g. cherry pie filling)	1000	mg/kg		Restoration of colour destroyed during production. CX Stan 79 and 80 contains provisions for colours and GSFA adopted provisions in this category
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	100	mg/kg		
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	100	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)	100	mg/kg		
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	100	mg/kg		
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	200	mg/kg		In candied vegetables
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	100	mg/kg		
05.1.4	Imitation chocolate,chocolate substitute products	1000	mg/kg		
05.1.5	Imitation chocolate, chocolate substitute products	1000	mg/kg		
05.2	Confectionnary including hard and soft candies, etc.	1000	mg/kg		Colour needed to match flavour. CX Stan 55, 58, 81 and 115 contain provisions for colours and GSFA has adopted provisions for colours in this category
05.3	Chewing gum	1000	mg/kg		Since chewing gum base absorbs the colour, chewing gum requires significant quantities of colour to overcome dull shades when low quantities of colours are used. Colour needed for matching flavour. CX Stan 55, 58, 81 and 115 contain provisions for colours and GSFA adopted provisions in this category Lycopene is a very valuable alternative as a red pigment for use in some chewing gum. The JECFA ADI for Lycopene is 0.5 mg/kg body weight. A consumption of 3g of chewing gum[12] per day containing Lycopene at the level of 300 mg/kg would result in

[12] Figures collected in all EC countries show that the daily per capita consumption of chewing gum in the EC is 1g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: " Guidelines for simple evaluation of food additive intake" and confirmed by an EC survey conducted in some EC countries

Recommendations – Lycopene, INS 160d(i), 160(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for lycopene in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
					ingestion of only 0,9 mg per day, if all of the lycopene present is extracted during chewing. This corresponds to 0.015 mg/kg bw for a 60 kg adult or about 3% of the ADI.
05.4	Decorations (e.g. for fine bakery wares) and sweet sauces	1000	mg/kg		To allow fine bakery industry to create dark red decorations as needed; CX Stan 55, 58, 81 and 115 contain provisions for colours and GSFA has adopted provisions for colours in this category
06.1	Whole,broken,or flanked grain,including rice	1000	mg/kg		
06.3	Breakfast cereals, including rolled oats	1000	mg/kg		CX Stan 55, 58, 81 and 115 contain provisions for colours and GSFA has adopted provisions for colours in this category
06.4.2	Dried pastas and noodles and like products	1000	mg/kg		
06.4.3	Pre-cooked pastas and noodles and like products	1000	mg/kg		
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	150	mg/kg	Note A1	Colour needed for matching flavour. GSFA has adopted provisions for colours in this category
06.6	Batters (e.g., for breading or batters for fish or poultry)	1000	mg/kg		
06.7	Pre-cooked or processed rice products, including rice cakes (Oriental type only)	1000	mg/kg		
06.8	Soybean products (excluding soybean products of food category 12.9 and fermented products of food category 12.10)	1000	mg/kg		
07.1.1	Breads and rolls	1000	mg/kg		
07.1.2	Crackers, excluding sweet crackers	1000	mg/kg		Reason for use is to provide colour. GSFA has adopted provisions for colours in this category
07.1.4	Bread-type products, including bread stuffing and bread crumbs	1000	mg/kg		
07.1.5	Steamed breads and buns	1000	mg/kg		
07.1.6	Mixes for breads and ordinary bakery wares	1000	mg/kg		
7.2	Fine bakery wares (sweet, salty, savoury) and mixes	1000	mg/kg		Reason for use is to provide colour. GSFA has adopted provisions for colours in this category
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cut	1000	mg/kg		
08.3	Processed comminuted meat, poultry, and game products	1000	mg/kg		
08.4	Edible casings (e.g. sausage casings)	1000	mg/kg		
09.2.2	Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans, and echinoderms	1000	mg/kg		
09.2.3	Frozen minced and creamed fish products, including mollusks	1000	mg/kg		
09.2.4	Cooked and/or fried fish and fish products, including molluscs, crustaceans, and echinoderms	1000	mg/kg		
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms	100	mg/kg		
09.3.1	Fish and fish products, including molluscs, crustaceans, and echinoderms, marinated and/or in jelly	1000	mg/kg		
09.3.3	Salmon substitutes, caviar and other fish roe products	1000	mg/kg		

Recommendations – Lycopene, INS 160d(i), 160(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for lycopene in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
09.3.4	Semi-preserved fish and fish products, including molluscs, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	100	mg/kg		
09.4	Fully preserved including canned or fermented fish and fish products	30	mg/kg	Note B2	Use of colour in sauce to restore tomato colour.
10.4	Egg-based desserts	1000	mg/kg		Colour needed for matching flavour. Provisions for colours are already adopted for this category.
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000	mg/kg		
12.2	Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	1000	mg/kg		CX Stan 117 contains provisions for colors and the GSFA contains adopted provisions for the use of colours in this food category.
12.4	Mustards	300	mg/kg		
12.5	Soups and broths	1000	mg/kg		
12.6	Sauces and like products	1000	mg/kg		
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	1000	mg/kg		
12.9.1	Soybean protein products	1000	mg/kg		
12.9.2	Fresh bean curd (tofu)	1000	mg/kg		
12.9.3	Semi-dehydrated bean curd	1000	mg/kg		
12.9.5	Other protein products	1000	mg/kg		For giving a pleasant palatable appearance to meat and fish analogues based on vegetable proteins.
12.10	Fermented soybean products	1000	mg/kg		
13.3	Dietetic foods for special medical purposes	1000	mg/kg		Colour provisions are adopted already for this category.
13.4	Dietetic formulae for slimming purposes and weight reduction	1000	mg/kg		Colour provisions are adopted already for this category.
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1- 13.4 and 13.6	1000	mg/kg		Colour provisions are adopted already for this category.
13.6	Food supplements	50000	mg/kg		Lycopene is used to colour the coating or shells. When manufactured most food supplements are white or beige even when containing various ingredients. Surface colouration has been shown to be the best method for differentiation during production as well as for consumer recognition and control. Use levels vary depending on thickness of the coating or capsule shell in relation to their weight. Therefore this amount needed to achieve a real dark red shell. For this category there are already adopted colour provisions in the GSFA
14.1.2	Fruit and vegetable juices	1000	mg/kg	Note 127	
14.1.3.1	Canned or bottled (pasteurized) fruit nectar	1000	mg/kg		
14.1.3.2	Canned or bottled vegetable nectar	1000	mg/kg		
14.1.3.3	Concentrate (liquid or solid) for fruit nectar	1000	mg/kg	Note 127	
14.1.3.4	Concentrate (liquid or solid) for vegetable nectar	1000	mg/kg	Note 127	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	1000	mg/kg		
14.1.5	Coffee,coffee substitutes,tea,herbal infusions,and other hot cereal and grain beverages,excluding cocoa	1000	mg/kg		
14.2.2	Cider and perry	200	mg/kg		
14.2.4	Wines (other than grape)	1000	mg/kg		

Recommendations – Lycopene, INS 160d(i), 160(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for lycopene in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
14.2.5	Mead	1000	mg/kg		
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	1000	mg/kg		
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	1000	mg/kg		
15.0	Ready-to-eat savouries	1000	mg/kg		
16.0	Composite foods - foods that could not be placed in categories 01 - 15	1000	mg/kg		

GUM ARABIC (ACACIA GUM) (INS 414)

15. The 35th JECFA (1989) established an ADI of "not specified" for INS 414.

16. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions thickener and stabilizer with gum arabic (acacia gum).

17. The 39th CCFA (CL 2007/28-FA and ALINORM 07/30/12, App. IV) requested proposals for new food additive uses.

Recommendations – Gum Arabic (Acacia Gum), INS 414
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for gum arabic in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)		GMP		Acacia Gum, due to its own nature of pH is acidic resistant. It is used to strengthen the protein network giving better mouthfeel and texture to the finished milk product. Listed & used in other dairy based drinks.
01.4.1	Pasteurized cream (plain)		GMP		Used as an emulsifier. Improves stability of the fat emulsion during mechanical and heating treatment. (High temperature resistant)
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)		GMP		Stabilizes foam by increasing viscosity of the milk phase and/or to stabilize the fat emulsion against any destabilisation process (can act as a fat replacement).
02.2.1.1[13]	Butter and concentrated butter		GMP		Avoids creaming (fat agglomeration) in the butter emulsion (high temperature resistant).
06.4.1	Fresh pastas and noodles and like products		GMP		Binder and film former to reduce moisture exchanges between air and pastas (egg yolk reinforcer or replacer in egg free pasta)
06.4.2	Dried pastas and noodles and like products		GMP		Regulator of moisture activity and thickener
08.1.2	Fresh meat, poultry and game, comminuted		GMP		Texturiser of comminuted meat by increasing viscosity and a binder between meat proteins and brine. It is a fat emulsifier &/or replacer in fatless products.
11.5	Honey		GMP		Anticristallisation agent for Honey syrup where its low cal. /low GI functions are also very important.
12.2.1	Herbs and spices		GMP	Note 51	Encapsulating – film former to avoid oxidation of the active principle of the herbs and spices. It is an absorbing agent for replacing salt in plate moulded herbs & spices and emulsifier for herbs & spices oils & oleoresins.
13.1	Infant formulae, follow-up formulae, and formulae for special medical purposes for infants		GMP		Stabilizer of the different components avoiding sedimentation and thickener to improve mouthfeel. Low cal. / low GI
13.2	Complementary foods for infants and young children		GMP		Acts as a stabilizer by binding and emulsifying behaviour and mouthfeel improvement. Low cal. /low GI.

[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

Recommendations – Gum Arabic (Acacia Gum), INS 414
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for gum arabic in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Justification
14.1.2	Fruit and vegetable juices		GMP		Works to avoid sedimentation of components such as pulp and as mouthfeel improvement. Used in fruits and vegetable juices, natural essential oil emulsions. In pasteurized juices avoids sugar protein Maillard reaction & browning.
14.1.3	Fruit and vegetable nectars		GMP		Works to stabilize oil in the fruit & vegetable extract and avoid sedimentation (inhibits Maillard reaction) as a texturiser.
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa		GMP		Works to stabilize foam in whipped hot drinks to emulsify and protects existing essential oils or added ones when added to infusions. In Coffee, protects flavouring in coffee based liquid or dry preparations
14.2.3	Grape wines		GMP		Works to stabilize wine against polyphenols floculation in avoiding polymerisation of polyphenolic matters & tannins thus avoiding their precipitation. Equally used to avoid iron & copper "breakdown" (casse). Ref. International Codex Oenologic – Resolution OENO 27/2000.

FOOD ADDITIVES CONTAINING ALUMINIUM (ALUMINIUM AMMONIUM SULFATE (INS 523), SODIUM ALUMINIUM PHOSPHATES (541(i), 541(ii)), SODIUM ALUMINOSILICATE (INS 554), CALCIUM ALUMINIUM SILICATE (INS 556), AND ALUMINIUM SILICATE (INS 559))

18. The 67th JECFA (2006) established a new provisional tolerable weekly intake (PTWI) of 1 mg/kg for aluminum from all sources, including food additives.

19. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function anticaking agent with aluminium containing food additives INS 554, 556, and 559.

20. The 39th CCFA (CL 2007/28-FA and ALINORM 07/30/12, App. IV) requested proposals and information on maximum levels and technological needs for aluminium containing food additives for inclusion in the GSFA, in particular for those food additives for which the use level is only limited by GMP. Proposals for inclusion in Tables 1 and 2 of the GSFA should express the numerical maximum use levels for these food additives as aluminium.

ALUMINIUM AMMONIUM SULPHATE (INS 523)

Recommendations – Aluminium Ammonium Sulphate
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for aluminium ammonium sulphate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	350	mg/kg	Note 6	Used as stabilizer in ferment milk drinks
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	150	mg/kg	Note 6	Used as stabilizer in ice creams
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	**1800**	**mg/kg**	Note 6	Used as color stabilizer in salted eggplant. Revision of current Step 4 provision
06.2.2	Starches	**10000**	**mg/kg**	**Note 6**	Revision of current Step 7 provision
06.4.1	Fresh pastas and noodles and like products	470	mg/kg	Note 6	used as firming agent in noodles
07.1.2	Crackers, excluding sweet crackers	10000	mg/kg	**Note 6**	Revision of current Step 4 provision
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	10000	mg/kg	**Note 6**	Revision of current Step 4 provision
07.1.4	Bread-type products, including bread stuffing and bread crumbs	10000	mg/kg	**Note 6**	Revision of current Step 4 provision

Recommendations – Aluminium Ammonium Sulphate
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for aluminium ammonium sulphate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
07.1.5	Steamed breads and buns	10000	mg/kg	**Note 6**	Revision of current Step 4 provision
7.2	Fine bakery wares (sweet, salty, savoury) and mixes	10000	mg/kg	**Note 6**	Used as raising agent in biscuits and cookies. Revision of current Step 4 provision
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	5	mg/kg	Note 6	Used as firming agent in sausages
09.2	Processed fish and fish products, including molluscs, crustaceans, and echinoderms	1500	mg/kg	Note 6	Used as firiming agent for boiled octopuses
09.3	Semi-preserved fish and fish products, including molluscs, crustaceans, and echinoderms	1500	mg/kg	Note 6	Used as firming agent for boiled jerry fishes
14.1.4.1	Carbonated water-based flavoured drinks	40	mg/kg	Note 6	Used as a stabilizer in carbonated drinks

SODIUM ALUMINIUM PHOSPHATES (INS 541(i), 541(ii))

Recommendation 1 – Sodium Aluminium phosphates, INS 541(i), 541(ii)
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for sodium aluminium phosphates in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
01.6.1	Unripened cheese	**35000**	**mg/kg**	Note 6	As a stabilizer, gelling agent, or emulsifier. Revision of current Step 4 provision
01.6.4	Processed cheese	35000	mg/kg	**Note 6**	As a stabilizer, gelling agent, or emulsifier. Revision of current Step 4 provision
05.2	Confectionery including hard and soft candy, nougats, etcetc.	350	mg/kg	**Note 6**	Revision of current Step 7 provision
06.2.1	Flours	45000	mg/kg	**Note 6**	Revision of current Step 7 provision
07.1	Bread and ordinary bakery wares	2000	mg/kg	Note 6	Revision of current Step 7 provision
07.2.3	Mixes for fine bakery wares (e.g. cakes, pancakes)	15300	mg/kg	**Note 6**	Revision of current Step 7 provision
09.2.2	Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans, and echinoderms	**1600**	**mg/kg**	Notes 6 & 41	Revision of current Step 7 provision Overlaps with provision for use in Food Category 06.6[14], therefore the levels should be the same.
12.5.2	Mixes for soups and broths	2000	mg/kg	**Note 6**	Revision of current Step 7 provision
12.6.3	Mixes for sauces and gravies	2000	mg/kg	**Note 6**	Revision of current Step 7 provision
14.1.4.3	Concentrates (liquid or solid) for water based flavoured drinks	2000	mg/kg	**Note 6**	Revision of current Step 7 provision

SODIUM ALUMINOSILICATE (INS 554)

Recommendations – Sodium Aluminosilicate, INS 554
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for sodium aluminosilicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	20000	mg/kg	Note 6	
01.3	Condensed milk and analogues (plain)	20000	mg/kg	Note 6	
01.4.4	Cream analogues	20000	mg/kg	Note 6	
01.5	Milk powder and cream powder and powder analogues (plain)	10000	mg/kg	Notes 6 & A3	As an anti-caking agent to provide good flowability characteristics to powders/ blends. These dairy based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.
01.6.2.1	Ripened cheese, includes rind	10000	mg/kg	Notes 6, A3 & B3	In sliced, grated hard and semi-hard cheese

[14] **Food Cat No. 06.6** Batters (e.g., for breading or batters for fish or poultry) at 1600 mg/kg – Note 6 – Step 7

Recommendations – Sodium Aluminosilicate, INS 554
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for sodium aluminosilicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
01.6.2.3	Cheese powder (for reconstitution, e.g., for cheese sauce)	10000	mg/kg	Notes 6 & A3	In dried, powdered foodstuffs
01.6.4	Processed cheese	10000	mg/kg	Notes 6, A3 & B3	In sliced, grated processed cheese
01.6.5	Cheese analogues	10000	mg/kg	Notes 6, A3 & B3	in sliced or grated cheese analogues and processed cheese analoges
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10000	mg/kg	Notes 6 & A3	As anti-caking agents to provide good flowability characteristics to dairy-based powders/ blends. These dairy based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.
01.8.1	Liquid whey and whey products, excluding whey cheeses	20000	mg/kg	Note 6	
01.8.2	Dried whey and whey products, excluding whey cheeses	10000	mg/kg	Notes 6 & A3	As anti-caking agents to provide good flowability characteristics to whey-based powders/ blends. These whey based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	20000	mg/kg	Note 6	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4		GMP	Notes 3, 6 & A3	
05.3	Chewing gum		GMP	Notes 3, 6 & A3	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces		GMP	Notes 3, 6 & A3	
06.1	Whole,broken,or flanked grain,including rice		GMP	**Notes 6 & A3**	Revision of current Step 7 provision
06.3	Breakfast cereals, including rolled oats	20000	mg/kg	Note 6	
06.4.3	Pre-cooked pastas and noodles and like products	20000	mg/kg	Note 6	
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	20000	mg/kg	Note 6	
06.6	Batters (e.g., for breading or batters for fish or poultry)	20000	mg/kg	Note 6	
07.1.6	Mixes for bread and ordinary bakery wares	10000	mg/kg	Notes 6 & A3	
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000	mg/kg	Notes 6 & A3	
08.3	Processed comminuted meat, poultry, and game products		GMP	Notes 6, A3 & C2	
08.4	Edible casings (e.g., sausage casings)		GMP	Notes 3, 6 & A3	
10.2.3	Dried and/or heat coagulated egg products	20000	mg/kg	Note 6	As an anticaking agent
11.1.2	Powdered sugar, powdered dextrose	15000	mg/kg	Note 6 & 56	As an anticaking agent in icing sugar.
12.1.1	Salt	20000	mg/kg	Note 6	
12.1.2	Salt substitutes	**1000**	**mg/kg**	**Note 6**	Revision of current Step 7 provision

Recommendations – Sodium Aluminosilicate, INS 554
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for sodium aluminosilicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
12.2.2	Seasonings and Condiments	30000	mg/kg	Notes 6 & A3	Anticaking agent. The quantity used ensures the anticaking effect required and the fluidity. These characteristics are essential for the appropriate processing of the product. This additive is needed due the high capacity of the powder in absorbing water. It ensures the fluidity of the product during the packing done by gravimetric draining.
12.5.2	Mixes for soups and broths	10000	mg/kg	Notes 6 & A3	
12.6.3	Mixes for sauces and gravies	10000	mg/kg	Notes 6 & A	Anticaking agent for sauces for food service. This additive is needed due the high capacity of the powder in absorbing water. It ensures the fluidity of the product during the packing done by gravimetric draining
13.6	Food supplements		GMP	Notes 6 & A3	In supplements and foodstuffs in tablet and coated tablet form
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10000	mg/kg	Notes 6 & A3	In dried powdered foodstuffs

CALCIUM ALUMINIUM SILICATE (INS 556)

Recommendations – Calcium Aluminium Silicate, INS 556
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for calcium aluminium silicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
01.5	Milk powder and cream powder and powder analogues (plain)	10000	mg/kg	Notes 6 & A3	As anti-caking agents to provide good flowability characteristics to powders/ blends. These dairy based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.
01.6.1	Unripened cheese	10000	mg/kg	Note 6	Included under CODEX STAN A-6-1978
01.6.2.1	Ripened cheese, includes rind	10000	mg/kg	Notes 6, A3 & B3	In sliced, grated hard and semi-hard cheese, included under CODEX STAN A-6-1978
01.6.2.3	Cheese powder (for reconstitution, e.g., for cheese sauce)	10000	mg/kg	Notes 6 & A3	
01.6.4	Processed cheese	10000	mg/kg	Notes 6, A3 & B3	Sliced, grated processed cheese, included under CODEX STAN A-8(a)-1978
01.6.5	Cheese analogues	10000	mg/kg	Notes 6, A3 & B3	Sliced, grated processed cheese
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10000	mg/kg	Notes 6 & A3	As anti-caking agents to provide good flowability characteristics to dairy-based powders/ blends. These dairy based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilizers are usually added to provide the desired functionality in the finished product.
01.8.2	Dried whey and whey products, excluding whey cheeses	10000	mg/kg	Notes 6 & A3	As anti-caking agents to provide good flowability characteristics to whey-based powders/ blends. These whey based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4),		GMP	Notes 3, 6 & A3	excluding chocolate, for surface treatment only

Recommendations – Calcium Aluminium Silicate, INS 556
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for calcium aluminium silicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
05.3	Chewing gum		GMP	Notes 3, 6 & A3	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces		GMP	Notes 3, 6 & A3	
06.1	Whole,broken,or flanked grain,including rice		GMP	**Notes 6 & A3**	Revision of current Step 7 provision
07.1.6	Mixes for bread and ordinary bakery wares	10000	mg/kg	Notes 6 & A3	
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000	mg/kg	Notes 6 & A3	
08.3	Processed comminuted meat, poultry, and game products		GMP	Notes 6, A3 & C2	Sausages surface treatment only
08.4	Edible casings (e.g., sausage casings)		GMP	Notes 3, 6 & A3	Sausages surface treatment only
11.1.2	Powdered sugar, powdered dextrose	15000	mg/kg	Note 56 & 6	
12.1.1	Salt	20000	mg/kg	Note 6	As anticaking agent in table salt
12.1.2	Salt substitutes	10000	mg/kg	**Note 6**	Revision of current Step 7 provision
12.2.2	Seasonings and Condiments	30000	mg/kg	Notes 6 & A3	
12.5.2	Mixes for soups and broths	10000	mg/kg	Notes 6 & A3	In dried powdered foodstuffs
12.6.3	Mixes for sauces and gravies	10000	mg/kg	Notes 6 & A3	In dried powdered foodstuffs
13.6	food supplements		GMP	Notes 6 & A3	In supplements and foodstuffs in tablet and coated tablet form
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10000	mg/kg	Notes 6 & A3	In dried powdered foodstuffs:
14.2.3	Grape wines		GMP	**Note 6**	Revision of current Step 7 provision

ALUMINIUM SILICATE, INS 559

Recommendations – Aluminium Silicate, INS 559
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for aluminium silicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
01.5	Milk powder and cream powder and powder analogues (plain)	10000	mg/kg	Notes 6 & A3	
01.6.1	Unripened cheese	10000	mg/kg	Note 6	Included under CODEX STAN A-6-1978 at 10000 mg/kg
01.6.2.1	Ripened cheese, includes rind	10000	mg/kg	Notes 6, A3 & B3	Included under CODEX STAN A-6-1978 at 10000 mg/kg
01.6.2.3	Cheese powder (for reconstitution, e.g., for cheese sauce)	10000	mg/kg	Notes 6 & A3	Used in dried, powdered foodstuffs:
01.6.4	Processed cheese	10000	mg/kg	Notes 6, A3 & B3	Included under CODEX STAN A-8(a)-1978 at 10000 mg/kg
01.6.5	Cheese analogues	10000	mg/kg	Note 6, A3 & B3	In sliced or grated cheese analogues and processed cheese analoges
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10000	mg/kg	Note 6 & A3	As anti-caking agents to provide good flowability characteristics to dairy-based powders/ blends. These dairy based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.
01.8.2	Dried whey and whey products, excluding whey cheeses	10000	mg/kg	Notes 6 & A3	Used as anti-caking agents to provide good flowability characteristics to whey-based powders/ blends. These whey based powders /blends are used for making desserts / frozen desserts after reconstitution in water. Most of these products have emulsifiers / stabilisers that may cause lumpiness or adversely affect flowability. Emulsifiers/stabilisers are usually added to provide the desired functionality in the finished product.

Recommendations – Aluminium Silicate, INS 559
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for aluminium silicate in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Justification
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4		GMP	Notes 3, 6 & A3	
05.3	Chewing gum		GMP	Notes 3, 6 & A3	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces		GMP	Notes 3, 6 & A3	
06.1	Whole,broken,or flanked grain,including rice		GMP	**Notes 6 & A3**	Revision of current Step 7 provision
07.1.6	Mixes for bread and ordinary bakery wares	10000	mg/kg	Notes 6 & A3	Used in dried powdered foodstuffs
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000	mg/kg	Notes 6 & A3	Used in dried powdered foodstuffs
08.3	Processed comminuted meat, poultry, and game products		GMP	Notes 6, A3 & C2	
08.4	Edible casings (e.g., sausage casings)		GMP	Notes 3, 6 & A3	
12.1.1	Salt	10000	mg/kg	Note 6	
12.1.2	Salt substitutes	10000	mg/kg	**Note 6**	Revision of current Step 7 provision
12.2.1	Herbs and spices		GMP	**Note 6**	Revision of current Step 4 provision
12.2.2	Seasonings and Condiments	30000	mg/kg	Note 6 & A3	
12.5.2	Mixes for soups and broths	10000	mg/kg	Notes 6 & A3	Used in dried powdered foodstuffs
12.6.3	Mixes for sauces and gravies	10000	mg/kg	Notes 6 & A3	Used in dried powdered foodstuffs
13.6	Food supplements		GMP	Notes 6 & A3	Used in supplements and foodstuffs in tablet and coated tablet form
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10000	mg/kg	Notes 6 & A3	Used in dried powdered foodstuffs

SULPHITES (INS 220, 221, 222, 223, 224, 225, 227, 228, 539)

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

22. The 22nd JECFA (1978) assigned a group ADI of 0.7 mg/kg bw/d for sulfites (Sulfur Dioxide (220), Sodium Sulfite (221), Sodium Hydrogen Sulfite (222), Sodium Metabisulfite (223), Potassium Metabisulfite (224), Potassium Sulfite (225), Calcium Hydrogen Sulfite (227), Potassium Hydrogen Sulfite (228), and Sodium Thiosulfate (539).

23. The 29th CCFAC requested that JECFA perform intake estimates for sulfites based on the pending levels of maximum use in the GSFA. The 51st JECFA (1998) concluded that the mean intake calculated using the maximum levels of use in the GSFA and national food consumption data exceeded the ADI of 0-0.7 mg/kg bw for the three Members that submitted such data. In national data submitted by six Members, estimates of mean intake of sulfites did not exceed the ADI. The potential exists for consumers of high levels of sulfites to exceed the ADI, but the available data were insufficient to estimate the number of such consumers or the magnitude and duration of intake above the ADI.

24. The Committee identified the following food categories as contributing significantly to intake of sulfites:

- 4.1.2.2 (dried fruit), 5000 mg/kg
- 4.1.2.5 (jams, jellies and marmalades); 3000 mg/kg
- 4.1.2.8 (fruit preparations, including pulp and fruit toppings); 3000 mg/kg
- 4.2.2.2 (dried vegetables); 5000 mg/kg
- 4.2.2.5 (vegetable, nut and seed purees and spreads); 2000 mg/kg
- 11.1 (white and semi-white sugar (sucrose or saccharose), fructose, glucose (dextrose), xylose, sugar solutions, and syrups and (partially) inverted sugars, including molasses, treacle and sugar toppings); 500 mg/kg
- 14.1.2.3 (concentrates (liquid or solid) for fruit juices); 2000 mg/kg,
- 14.2.3 (wines); 350 mg/kg
- 14.2.4 (fruit wines); 300 mg/kg

25. It should be noted that the food category system and some of the maximum limits indicated above have been amended by the CCFAC since the 51st JECFA.

Recommendation 1 - Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for sulphites in the GSFA.

Food Cat No.	Food Category	Max Level	Units	Comments	Step	Justification
04.1.2.5	Jams, jellies and marmelades	**100**	**mg/kg**	Note 44	6	Currently at step 6, 500 mg/kg – Note 44. The EC believes there is a technological need for sulphites as a preservative in jams, jellies, and marmalades. Nevertheless, the level of 500 mg/kg is considered high (e.g. for jams, jellies and marmalade, a child of 15kg would reach the ADI of 0.7 mg/kg bw by consuming 21g only of jams). The EC supports a level of 100 mg/kg which is sufficient for the technological purpose.
04.1.2.10	Fermented fruit products	100	mg/kg	Note 44	3	New proposal added for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables which were endorsed by the 39th CCFA . (Appendix V of ALINORM 07/30/12)

Recommendation 2 – Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539
The eWG recommends that the 40th CCFA **further discuss** the following food additive provisions for sulphites in the GSFA.

Food Cat No.	Food Category	Max Level	Units	Comments	Step	Justification
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	750	mg/kg	Note 44	6	Used as a preservative and an antioxidant. The shelf-life of the product is substantially reduced because of the development of a poor colour in absence of sulphites, long before the reduction of the nutritive value of the food. However, 750 mg/kg, is higher than a general provision for sulphites in unstandardized foods in Canada of 500 mg/kg, or of that used in the EC. No request from industry has been submitted to increase this maximum level. Canada believes that 500 mg/kg of sulphites expressed as sulphur dioxide is technologically sufficient to achieve the intended effect for this application of sulphites. The ADI for sulphites is relatively low and there are concerns about its possible exceedance from the combined food sulphite intakes (expressed in CL 2007/27-FA). The EC supports a level of 100 mg/kg which is sufficient for the technological purpose.
12.5	Soups and broths	1000	mg/kg	Note 44	6	

CALCIUM DISODIUM ETHYLENE DIAMINE TETRA-ACETATE & DISODIUM ETHYLENE DIAMINE TETRA-ACETATE (EDTAS), (INS 385 AND 386)

26. The CAC has adopted several provisions for the use of EDTAs.

27. The 17th JECFA (1973) assigned a group ADI of 2.5 mg/kg bw for calcium disodium ethylene diamine tetra-acetate (385) and disodium ethylene diamine tetra acetate (386) with a note stating "As calcium disodium EDTA; no excess disodium EDTA to remain in foods."

28. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions antioxidant, preservative, and sequestrant with EDTAs.

Recommendation - EDTAs, INS 385,386
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for EDTAs in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
04.1.2.3	Fruit in vinegar, oil, or brine	250	mg/kg	Note 21	3	New proposal added for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables which were endorsed by the 39th CCFA. (Appendix V of ALINORM 07/30/12)
04.1.2.10	Fermented fruit products	250	mg/kg	Note 21	3	New proposal added for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables which were endorsed by the 39th CCFA. (Appendix V of ALINORM 07/30/12)

POLYSORBATES (INS 432, 433, 434, 435, 436)

29. The 28th CAC has adopted several provisions in the GSFA for the use of polysorbates.

30. The 17th JECFA (1973) assigned a group ADI for polysorbates (Polyoxyethylene (20) Sorbitan Monolaurate (432), Polyoxyethylene (20) Sorbitan Monooleate (433), Polyoxyethylene (20) Sorbitan Monopalmitate (434), Polyoxyethylene (20) Sorbitan Monostearate (435), and Polyoxyethylene (20) Sorbitan Tristearate (436)) of 25 mg/kg bw/d.

31. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions emulsifier and dispersing agent with these polysorbates.

32. The 39th CCFA agreed to request information on the following provisions for polysorbates in the GSFA with the understanding that if no information is provided, the 40th CCFA should discontinue work on these provisions. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for polysorbates (CL 2007/28-FA and ALINORM 07/30/12, App. IX).

Recommendation 1 – Polysorbates, INS 432, 433, 434, 435, 436
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for polysorbates in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
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	500	mg/kg		6	No new information received
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	30	mg/kg	Note 7 & 100	6	No new information received
16.0	Composite foods - foods that could not be placed in categories 01 - 15	1000	mg/kg		6	No new information received

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for polysorbates in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	5000	mg/kg		6	1) 5000 mg/kg corresponds to the same numerical level of use of polyoxyethylene (20 sorbitan tristearate (polysorbate 65, INS 436) that dairy manufacturers in Canada confirm to be technologically justified in flavoured milk, flavoured skin, or partly skim milks. 2) Used as an emulsifier in these products to keep

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for polysorbates in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
						ingredients in the liquid phase and minimize "settling out."
01.4.1	Pasteurized cream (plain)	1000	mg/kg		3	New proposal added for consistency with the Codex Standard for Cream and Prepared Creams which includes polysorbates for use as thickeners and emulsifiers
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	1000	mg/kg		3	1) New proposal added for consistency with the Codex Standard for Cream and Prepared Creams which includes polysorbates for use as thickeners and emulsifiers 2) Dairy manufacturers in Canada confirm the use of polysorbate 80, INS 433, in this food category in accordance with Canadian regulations (maximum use level of 1000 mg/kg)
01.4.3	Clotted cream (plain	1000	mg/kg		3	For consistency with the Codex Standard for Cream and Prepared Creams which includes polysorbates for use as thickeners and emulsifiers
01.6.1	Unripened cheese	80	mg/kg	Note 38	6	1) Dairy manufacturers in Canada confirm the use of polyoxyehylene (20) sorbitan monooleate (polysorbate 80), INS 433, is used at 80 mg/kg in creamed cottage cheese. 2) The food additive functional class "emulsifiers" and specifically polysorbates are included in the Codex Standard for Unripened Cheese
06.4.2	Dried pastas and noodles and like products	5000	mg/kg		3	1) 3000 mg/kg meets technical need 2) Interaction with proteins: the arrangement of links between the chain of ethylene oxide present in the polysorbates and the protein portion of wheat flour enhances the net of gluten, without damaging the stability of the mass. This effect raises the retention of CO_2 in bakery products which are biologically fermented. It increases the resistance of the mass to the mechanical work and increases the volume of the breads. 3) Formation of emulsions: the hydrophilic and lypophilic groups present in the polysorbates molecules decrease the interfacial tension among the formulation components, allowing the better homogenization due to the formation of emulsions and colloid dispersions. Therefore, it is possible to get bakery products with more uniform distribution of marrow, better form and color. Besides that, the emulsifying action makes possible the optimization of fat amount in the cakes, breads and cookies formulations. The formation of stably emulsions

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436 The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for polysorbates in the GSFA.						
Food Cat No.	**Food Category**	**Max**	**Level**	**Comments**	**Step**	**Justification**
						allows enhancing the texture of edible ices too. 4) Aeration: the decrease of the superficial tension makes possible the more efficient incorporation of air into cakes, edible ices and other aerating products, which allows high volume and better texture. 5) Formation of starch complex: the polysorbates form complexes with amylose and amylopectin, which decreases the speed of retro gradation of the starch and allows the raise of the shelf-life and enhance the marrow soft in bakery products.3000 mg/kg
07.1.1	Breads and rolls	3000	mg/kg		6	1) Interaction with proteins: the arrangement of links between the chain of ethylene oxide present in the polysorbates and the protein portion of wheat flour enhances the net of gluten, without damaging the stability of the mass. This effect raises the retention of CO_2 in bakery products which are biologically fermented. It increases the resistance of the mass to the mechanical work and increases the volume of the breads. 2) Formation of emulsions: the hydrophilic and lypophilic groups present in the polysorbates molecules decrease the interfacial tension among the formulation components, allowing the better homogenization due to the formation of emulsions and colloid dispersions. Therefore, it is possible to get bakery products with more uniform distribution of marrow, better form and color. Besides that, the emulsifying action makes possible the optimization of fat amount in the cakes, breads and cookies formulations. The formation of stably emulsions allows enhancing the texture of edible ices too. 3) Aeration: the decrease of the superficial tension makes possible the more efficient incorporation of air into cakes, edible ices and other aerating products, which allows high volume and better texture. 4) Formation of starch complex: the polysorbates form complexes with amylose and amylopectin, which decreases the speed of retro gradation of the starch and allows the raise of the shelf-life and enhance the marrow soft in bakery products.3000 mg/kg 5) 3000 mg/kg meets technical need

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for polysorbates in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
07.1.2	Crackers, excluding sweet crackers	5000	mg/kg	Note 11	6	1) 3000 mg/kg meets technical need Same as 07.1.1 2) 5000 mg/kg is needed for crackers
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	**3000**	**mg/kg**	Note 11	**6**	3000 mg/kg meets technical need Same as 07.1.1
07.1.4	Bread-type products, including bread stuffing and bread crumbs	**3000**	**mg/kg**	Note 11	**6**	3000 mg/kg meets technical need Same as 07.1.1
07.1.5	Steamed breads and buns	**3000**	**mg/kg**	Note 11	**6**	3000 mg/kg meets technical need Same as 07.1.1
07.1.6	Mixes for breads and ordinary bakery wares	**3000**	**mg/kg**	Note 11	6	3000 mg/kg meets technical need Same as 07.1.1
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	**3000**	**mg/kg**		6	1) 3000 mg/kg meets technical need Same as 07.1.1 2) 5000 mg/kg needed for fine bakery wares and mixes.
12.2.1	Herbs and spices	2000	mg/kg		6	1) Polysorbate 80 is used in spice oils up to 2000 mg/kg dependant on oil or oleoresin physical characteristics – some require more polysorbate 80 to fully solubilize the spice oil in the brine or pickle. The level of spice oil in meat products determined by flavour impact. Used in brines and pickles up to 500 mg/kg. 2) 5000 mg/kg needed to achieve tech effect of emulsification and stabilization of hers and spices in food applications.

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL (DATEM) (INS 472(e))

33. The 61st JECFA (2003) assigned an ADI of 50 mg/kg for INS 472(e).

34. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions emulsifier, sequestrant and stabilizer with DATEM.

35. The 39th CCFA (CL 2007/28-FA and ALINORM 07/30/12, App. IX) requested justification for the technological need for the use of DATEM with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendations – Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), INS 472(e)
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for DATEM in the GSFA.

Food Cat No.	Food Category	Max Level	Units	Comments	Step	Justification
01.4	Cream (plain) and the like	5000	mg/kg		6	1) sub-category 01.4.1 (pasteurized cream (plain)) would not be expected to need an emulsifier 2) already in 01.4.2, 01.4.3, and 01.4 4. 3) As a result of the high milkfat content of cream products, the use of emulsifiers is helpful to maintain the dispersion of the milkfat and reduce possibility of product separation. 4) If adopted then not needed in categories 01.4.2, 01.4.3, and 01.4 4 because of the hierarchical structure of the GSFA.

Recommendation 2 - Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), INS 472(e)
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for DATEM in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification
06.2	Flours and starches (including soybean powder)	3000	mg/kg		6	1) 3000 mg/kg achieves the intended tech effect - improve the protein chains interactions that form wheat flour gluten, making a strong matrix from protein. Improving the tolerance to the fermentation in bread production and the volume of biscuits; 2) To provide the formation of protein complexes with starches - reducing the retro gradation, improving the softer, decreasing solids in the baking water of dough. 3) 3000 mg/kg needed to achieve technical effect. 4) essential ingredient in flour-based yeast raised goods and is widely used in food categorty 06.2
06.4.2	Dried pastas and noodles and like products	5000	mg/kg		6	1) Brazil: 3000 mg/kg achieves the intended tech effect - improve the protein chains interactions that form wheat flour gluten, making a strong matrix from protein. Improving the tolerance to the fermentation in bread production and the volume of biscuits; 2) To provide the formation of protein complexes with starches - reducing the retro gradation, improving the softer, decreasing solids in the baking water of dough.

POLYDIMETHYLSILOXANE (INS 900(a))

36. The 23rd (1999) and 28th (2005) CAC adopted several provisions for the use of polydimethylsiloxane.

37. The 23rd JECFA (1979) assigned an ADI of 1.5 mg/kg bw for polydimethylsiloxane.

38. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions anticaking agent, antifoaming agent and emulsifier with polydimethylsiloxane.

Recommendation - Polydimethylsiloxane, INS 900(a)
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for polydimethylsiloxane in the GSFA.

Food Cat No.	Food Category	Max Level	Units	Comments	Step	Justification
04.1.2.10	Fermented fruit products	10	mg/kg		3	New proposal added for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables which were endorsed by the 39th CCFA. (Appendix V of ALINORM 07/30/12)
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	10	mg/kg		3	New proposal added for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables which were endorsed by the 39th CCFA. (Appendix V of ALINORM 07/30/12)

SWEETENERS

39. The 38th CCFAC agreed that the eWG should take a "horizontal" approach to its discussion of the GSFA provisions for sweeteners. The 39th CCFA reached general consensus on a positive list of food categories in which the use of one or more food additive sweeteners were technologically justified (see Appendix I). It was understood that the listing of sweetener additives in other food categories, while not excluded, would be considered on a case by case basis. The CCFA may wish to consider this list of food categories as work on the GSFA progresses.

ACESULFAME POTASSIUM (INS 950)

40. The 37th JECFA (1990) assigned an ADI of 15 mg/kg bw/d for acesulfame potassium.

41. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions flavour enhancer and sweetener with acesulfame potassium.

42. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for acesulfame potassium (CL 2007/28-FA and ALINORM 07/30/12, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 – Acesulfame Potassium, INS 950
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for acesulfame potassium in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	500	mg/kg		3	There are no sweeteners in a "plain" category

Recommendation 2 - Acesulfame Potassium, INS 950
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for acesulfame potassium in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
01.3.2	Beverage whiteners	2000	mg/kg		3	1) Acesulfame K use at a level up to 3000 mg/kg in this category allows for the manufacture of pre-sweetened beverage whiteners with no added carbohydrates. Beverage whiteners are produced for direct sale to or direct use by consumers and are mostly used in coffee. As many people prefer sweet over unsweetened coffee they also use table-top sweeteners. Listing of acesulfame K for this category allows production of combination products. It should be noted that addition of carbohydrates to such products may result in undesired browning reactions with impaired appearance of the product while Acesulfame K remains inert. Sweeteners justified in this category 2)Used in presweetened products at 2000 mg/kg
01.4.4	Cream analogues	1000	mg/kg		3	1) Acesulfame K use in this category allows for the manufacture of pre-sweetened cream analogues with no added carbohydrates, no added flavours and no other added foods. 2) Sweeteners justified in this category
01.5.2	Milk and cream powder analogues	1000	mg/kg		3	1) Acesulfame K use in this category allows for the manufacture of pre-sweetened milk and cream powders with no added carbohydrates, no added flavours and no other added foods. Addition of carbohydrates to such products may result in browning reactions with impaired appearance of the product and impaired value of proteins while Acesulfame K remains inert. 2) Tech need for intense sweetener in this category as agreed to by the 39th CCFA.
01.6.5	Cheese analogues	350	mg/kg		3	1) Acesulfame K use at a level up to 500 mg/kg in this category allows manufacture of certain types of pre-sweetened unripened cheese analogues with no added carbohydrates; no added flavours and no other added foods. 2) Carbohydrates may be degraded by

Recommendation 2 - Acesulfame Potassium, INS 950
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for acesulfame potassium in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
						lactic acid bacteria which results in loss of sweetness and increase in acidity while acesulfame K is not metabolised by these bacteria and remains inert.
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1000	mg/kg		3	Acesulfame K is proposed for this category to allow manufacture of pre-sweetened, flavoured products, as this category includes products with added flavours. They have the same technological requirements as their dairy-based counterparts.
04.1.2.1	Frozen fruit	500	mg/kg		6	Fruits are often frozen as such but sometimes also pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free products. The listed acesulfame K level provides adequate sweetness.
04.1.2.2	Dried fruit	500	mg/kg		6	Fruits are often dried as such but sometimes also pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free products. The listed acesulfame K level provides adequate sweetness.
04.1.2.12	Cooked fruit	500	mg/kg		6	Intense sweeteners allow production of pre-sweetened sugar-free products. The listed acesulfame K level provides adequate sweetness. Tech need for intense sweetener in this category as agreed to by the 39th CCFA.
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		6	Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. Acesulfame K was found to withstand the sterilisation conditions used for the common types of canned fruit. The listed acesulfame K level provides adequate sweetness.
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)	**1000**	**mg/kg**		6	Some products of this category are sweet. Acesulfame K allows production of sweet products with no added sugar as it withstands heat processing. The listed level seems higher than technologically required. It is proposed to replace it by 1000 mg/kg. Tech need for intense sweetener in this category as agreed to by the 39th CCFA
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	1000	mg/kg		3	Sweetening agents can balance the acidity in these products and provide a balanced sweet-sour taste. Acesulfame K is neither degraded by lactic acid bacteria which may occur in brined products and can therefore improve their shelf stability nor is it degraded during pasteurisation or storage of these products. The level is in line with 04.1.2.3, 04.1.2.10 and 04.2.2.3. Tech need for intense sweetener in this category agreed to by the 39th CCFA.
07.1	Bread and ordinary bakery wares	1000	mg/kg		3	1)To provide sweetness (other sweeteners are permitted) 2) Currently used in breads in various countries. In some countries sweetened products of this category are on the market. Acesulfame K allows production of sweetened products without addition of soluble carbohydrates. It is stable during baking. 3) In some countries sweetened products of this category are on the market. Acesulfame K allows

Recommendation 2 - Acesulfame Potassium, INS 950
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for acesulfame potassium in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
						production of sweetened products without addition of soluble carbohydrates. Acesulfame K is stable during baking. The right category for these products should be identified if this considered not the right category for such products. Instead, category 7.1.1 breads and rolls may better describe the presently available products.
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Note 144	3	
12.2	Herbs, spices, seasonings and condiments (e.g., seasoning for instant noodles)	2000	mg/kg		3	Herbs, spices, seasoning and condiments are sometimes rounded by addition of sweet-tasting and flavour-enhancing products. Acesulfame K is a sweetener and flavour enhancer. Seasonings and condiments are also directly sold to consumers; a listing of acesulfame K for use in this product category is necessary.
12.3	Vinegars	2000	mg/kg		3	Vinegar is sometimes rounded and mellowed by addition of sweet-tasting, flavour-enhancing products. Acesulfame K is stable in vinegar and balances its acidity well. Vinegar is also directly sold to consumers; a listing of acesulfame K for this category is necessary.
14.1.3.2	Vegetable nectar	350	mg/kg	Note 161	3	Owing to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. An ML of 500 mg/kg is technologically needed. Tech need for intense sweetener in this category was agreed to b 39th CCFA.
16.0	Composite foods - foods that could placed in categories 01 - 15	350	mg/kg		3	Permitted in jelly and dairy and fat based desserts, dips and snacks

ASPARTAME (INS 951)

43. The 25th JECFA (1981) assigned an ADI of 40 mg/kg bw/d for aspartame.

44. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions flavour enhancer and sweetener with aspartame.

45. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for aspartame (CL 2007/28-FA and ALINORM 07/302, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 – Aspartame, INS 951
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	2000	mg/kg		6	No sweeteners in a “plain” category
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	6000	mg/kg		3	No sweeteners in a “plain” category

Recommendation 1 – Aspartame, INS 951
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.5.1	Milk powder and cream powder (plain)	5000	mg/kg		3	1) No sweeteners in a "plain" category 2) Approved for Dried milk, milk powder, cream powder 3)5000 mg/kg is needed to achieve the tech. effect
08.2	Processed meat, poultry, and game products in whole pieces or cuts	300	mg/kg		6	No additional use information provided
08.3	Processed comminuted meat, poultry, and game products	300	mg/kg		6	No additional use information provided
12.3	Vinegars		GMP		3	No additional use information provided

Recommendation 2 - Aspartame, INS 951
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.3.2	Beverage whiteners	6000	mg/kg		3	1) Aspartame is used in place of sugars to make low and reduced joule sweetened plain (unflavoured) dairy products. Intense sweeteners such as aspartame allow for the manufacture of pre-sweetened beverage whiteners with no added carbohydrates. 2) 6000 mg/kg is required to achieve the tech. effect
01.4.4	Cream analogues	1000	mg/kg		6	1) Aspartame is used in place of sugars to make low and reduced joule sweetened plain (unflavoured) dairy products. Aspartame allows for the manufacture of pre-sweetened cream analogues with no added carbohydrates, no added flavours and no other added foods. 2)1000 mg/kg is required to achieve the tech. effect
01.6.1	Unripened cheese	1000	mg/kg		3	1) Some unripened cheeses such as low fat cottage cheese are deemed as dietary products and so retention of approval for aspartame would offer opportunities for flavoured versions where some sweetening is needed but without significantly affecting energy value. 2) 1000 mg/kg is required to achieve the tech. effect
01.6.5	Cheese analogues	1000	mg/kg		6	1) Aspartame allows for the manufacture of certain types of pre-sweetened unripened cheese analogues with no added carbohydrates; no added flavours and no other added foods. Carbohydrates may be degraded by lactic acid bacteria which results in loss of sweetness and increase in acidity while aspartame is not metabolised by these bacteria and remains inert. 2) 1000 mg/kg is required to achieve the tech. effect
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1000	mg/kg		3	1) Aspartame allows for the manufacture of pre-sweetened, flavoured products, as this category includes products with added flavours. They have the same technological requirements

Recommendation 2 - Aspartame, INS 951
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						as their dairy-based counterparts. 2) 1000 mg/kg is required to achieve the tech. effect
04.1.2.1	Frozen fruit	2000	mg/kg		3	1) Fruits are often frozen as such but sometimes also pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free products. The listed level provides adequate sweetness. 2) 2000 mg/kg is required to achieve the tech. effect
04.1.2.2	Dried fruit	**2000**	**mg/kg**		6	1) Fruits are often dried as such but sometimes also pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free products. The listed level provides adequate sweetness. 2) 2000 mg/kg provides adequate sweetness 3) revise to 10,000 mg/kg
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	1000	mg/kg		6	1) Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Aspartame is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2)1000 mg/kg is required to achieve the tech. effect
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	1000	mg/kg		6	1) Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Aspartame is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2) 1000 mg/kg is required to achieve the tech. effect
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)	3000	mg/kg	**Note 161**	6	1) Some products of this category are sweet. Aspartame allows production of sweet products with no added sugar. 2) use in energy reduced foods or foods with non added sugars 3) 1000 mg/kg is required to achieve tech. effect. 4) The technological need for using an intense sweetener in this category was agreed to by the 39th CCFA.
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	1000	mg/kg	Note 161	6	1) 1000 mg/kg is required to achieve tech. effect. 2) The technological need for using an intense sweetener in this category was agreed to by the 39th CCFA.
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	2500	mg/kg	Note 161	6	1) 2500 mg/kg is required to achieve tech. effect. 2) The technological need for using an intense sweetener in this category was agreed o by the 39th CCFA.

Recommendation 2 - Aspartame, INS 951
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
05.2.1	Hard candy	**2000**	**mg/kg**	**Notes 161 & ZZ**	6	1) 3000 with Note "for use in microsweets and breath-freshening mints at 10,000 mg/kg. 2) 1000 mg/kg in energy reduced foods or foods with non added sugars 3) supports 10,000 mg/kg, but would also support 3000 mg/kg for 5.2 with footnote "for use in microsweets and breath-freshening mints @ 10000 mg/kg" – history of use in microsweets @ 10000 mg/kg -1 brand containing 6,000 mg/kg available in the US 4) 2000 mg/kg in 05.2 with note 147 also supports 2000 mg/kg in 5.2.1 with footnote "for use in microsweets and breath-freshening mints at 10,000 mg/kg. 5) Tech need for intense sweetener in 5.2 justified as agreed o by the 39th CCFA. 6) revise to 10,000 mg/kg 7) 3000 in 05.2 including 5.2.1 and Note "For use in micro sweets and breath-freshening mints at 10,000 mg/kg be included for category 05.2.1
05.2.2	Soft candy	3000	mg/kg		6	1) An ML of 2000 mg/kg in the broader category (05.2) with Note 147 is technologically justified. 2) Sugar-free soft candy is based on sugar alcohols many of which have a lower sweetness than the sugar-glucose syrup basis of customary products. The sweetness is then rounded with sweeteners. Intense sweeteners are well suited for these products as their taste rounds the sweetness of sugar alcohols. Intense sweeteners are non-cariogenic. The proposed level of 3000 mg/kg represents the case of need for soft candy. 3) 3000 mg/kg is tech justified 4) 1000 mg/kg in energy reduced foods or foods with non added sugars 5)requests/suggests footnote "for use in micro sweets and breath-freshening mints at 10,000 mg/kg" 6) Supports ML of 2000 mg/kg in 05.2 with note 147, also supports 3000 mg/kg in 5.2.2 with footnote "for use in microsweets and breath-freshening mints at 10,000 mg/kg. 7) Tech need for intense sweetener in 5.2 justified as agreed to by the 39th CCFA. 8) based on past use, 30,000
05.2.3	Nougats and marzipans	3000	mg/kg		6	1) An ML of 2000 mg/kg in the broader category (05.2) with Note 147 is technologically justified. 2) Intense sweeteners are used as sugar-free products of this category, which are often based on polyols instead of sugar. Very often these products contain intense sweeteners to round their sweetness and bring it to the higher lever of sugar-based

Recommendation 2 - Aspartame, INS 951
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						products. Use of intense sweeteners in these products is common in many countries. The proposed level of 3000 mg/kg represents the case of need for nougats and marzipan 3) 3000 mg/kg is tech justified 4)1000 mg/kg in energy reduced foods or foods with non added sugars 5) 2000 needed to allow technical effect to be achieved.
07.1	Bread and ordinary bakery wares	4000	mg/kg		6	1) This level of use applies in Canada for use in encapsulated aspartame (to prevent its degradation during baking) in unstandardized bakery products and baking mixes. JP Used for bread and ordinary bakery wares. 2) To provide sweetness (other sweeteners are permitted) 3) Used in some breads to improve taste. 4) In some countries sweetened products of this category are on the market. Aspartame allows production of sweetened products without addition of soluble carbohydrates. Aspartame can also be used to improve the flavour of multigrain breads. The right category for these products should be identified if this is not considered the right category for such products. Instead, category 7.1.1 breads and rolls may better describe the presently available products. 5)use in bread could lead to high sweetener consumption/exceed ADI 6) ML of 4000 mg/kg needed to achieve technical effect 7) Adopt @ 250
12.2.2	Seasonings and condiments	2000	mg/kg		6	1) Seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as aspartame and other intense sweeteners. 2) 2000 mg/kg needed to achieve tech effect
12.5	Soups and broths	600	mg/kg		6	1) An ML of110 mg/kg with Note 138 is technologically justified. 2) An ML of 600 mg/kg is technologically justified. 3) 110 mg/L in energy reduced foods or foods with non added sugars 4) ML of 600 mg/kg is needed, sweetened soups are available in Asia, 5) Tech need for intense sweeteners in category 12.5 agreed to by the 39th CCFA. 6) 600
15.0	Ready-to-eat savouries	500	mg/kg		6	1) Snacks may be salted, spicy, or sweetened. For sugar-free sweetened products intense sweeteners like Aspartame have to be used. 2) supports use in certain flavours

Recommendation 2 - Aspartame, INS 951 The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
						3) 500 mg/kg needed to achieve technical effect 4) Tech need for intense sweetener in 15.0 justified as agreed to by the 39th CCFA.

Recommendation 3 - Aspartame, INS 951 The eWG recommends that the 40th Codex Committee on Food Additives **further discuss** the following food additive provisions for aspartame in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**	**Units**	**Comments**	**Step**	**Justification provided to eWG**
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	1000	mg/kg		6	1) Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed aspartame level provides adequate sweetness. 2) 300 mg/kg in sweet-sour preserves only 3) ML of 1000 mg/kg is required to achieve the tech. effect
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	1000	mg/kg		6	1) Sweetening agents can balance the acidity in these products and provide a balanced sweet-sour taste. Aspartame is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2)300 mg/kg in sweet-sour preserves only 3) 1000 mg/kg required to achieve tech. effect
05.1.3	Cocoa-based spreads, including fillings	3000	mg/kg		6	1) An ML of 1000 mg/kg with Note 145 is technologically justified. 2) An ML of 3000 mg/kg is technologically justified. 3) 1000 mg/kg in energy reduced foods or foods with non added sugars 4) history of at least 2000 mg/kg in the US market 5) 3000 mg/kg is required to achieve tech. effect. 6) The technological need for using an intense sweetener in this category was agreed to by the 39th CCFA.
05.1.4	Cocoa and chocolate products	2500	mg/kg		6	1) An ML of 2000 mg/kg with Note 145 is technologically justified. 2) An ML of 2500 mg/kg is technologically justified. EC: 2000 mg/kg in energy reduced foods or foods with non added sugars 3) 3000 mg/kg – candies under 5.2 would fall under 5.1.4 when covered in chocolate so same use level should be approved for both categories, history of at least 2000 mg/kg in this food category in the US market 4) ML of 2500 mg/kg is required to achieve tech. effect. 5) The technological need for using an intense sweetener in this category was agreed to by the 39th CCFA.

Recommendation 3 - Aspartame, INS 951
The eWG recommends that the 40th Codex Committee on Food Additives **further discuss** the following food additive provisions for aspartame in the GSFA.

Food Cat No.	Food Category	Max Level	Units	Comments	Step	Justification provided to eWG
05.1.5	Imitation chocolate, chocolate substitute products	3000	mg/kg		6	1) An ML of 2000 mg/kg with Note 145 is technologically justified. 2) An ML of 3000 mg/kg is technologically justified. 3)2000 mg/kg in energy reduced foods or foods with non added sugars 4) 3000 mg/kg is required to achieve tech. effect. 5) The technological need for using an intense sweetener in this category was agreed to by the 39th CCFA.

ASPARTAME-ACESULFAME, (INS 962)

46. The 55th JECFA (2000) concluded that the aspartame and acesulfame moieties of the salt would be covered by the ADI for aspartame (40 mg/kg bw) and acesulfame potassium (15 mg/kg bw).

47. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function sweetener with aspartame-acesulfame salt.

48. The report of the eWG[15] to the 39th CCFA noted that the proposed draft acceptable maximum use levels for aspartame-acesulfame salt are currently expressed in the GSFA in terms of aspartame-acesulfame salt. Expressing the use levels in terms of the salt is scientifically valid because the levels can easily be converted to their corresponding aspartame or acesulfame-K equivalents. Because JECFA concluded that the aspartame and acesulfame moieties in aspartame-acesulfame salt are included within the ADI established for aspartame and acesulfame-K, any combined use of the individual sweeteners and the equivalent level of the sweetener from the double salt should not exceed the maximum use level for the individual sweetener. Based on these concepts, the eWG recommended that the CCFA agree to the following approach for expressing the acceptable maximum use levels for aspartame-acesulfame salt.

Recommendation 1 - Aspartame-Acesulfame, INS 962
The acceptable maximum use levels will be expressed on the following:
a. Aspartame-acesulfame salt basis.
b. Singly or in combination with aspartame or acesulfame-potassium.
c. Replace the current notes 113[16] and 119[17] associated with the proposed draft provisions for aspartame-acesulfame with the following note:
Use levels are expressed as mg of aspartame-acesulfame salt per kg of food. When used as a mixture with aspartame or acesulfame-K: 1) Combined use of aspartame and aspartame-acesulfame salt (expressed as aspartame equivalents by multiplying the aspartame-acesulfame use level by 0.44) should not exceed the maximum use level for aspartame; 2) Combined use of acesulfame-K and aspartame-acesulfame salt (expressed as acesulfame-K equivalents by multiplying the use level for aspartame-acesulfame salt by 0.64) should not exceed the maximum use level for acesulfame-K.
d. Add the following note to all of the provisions for acesulfame-K
Not to exceed the maximum use level for acesulfame-K (INS 950) singly or in combination with aspartame-acesulfame salt (INS 952) expressed in the form of acesulfame-K equivalents (acesulfame-K equivalent level for aspartame-acesulfame salt calculated by multiplying aspartame-acesulfame salt use level by 0.44).
e. Add the following note to all of the provisions for aspartame:
Not to exceed the maximum use level for aspartame (INS 951) singly or in combination with aspartame-acesulfame salt (INS 952) expressed as aspartame equivalents (aspartame-equivalent level for aspartame-acesulfame salt calculated by multiplying aspartame-acesulfame salt use level by 0.64).

49. For a particular acceptable maximum use level for aspartame or acesulfame-K a conversion factor (1.55 or 2.27, respectively) is applied to obtain an equivalent acceptable maximum use level expressed in terms of aspartame-acesulfame salt. Examples for select aspartame and acesulfame-K use levels are shown, below.

[15] CX/FA 07/39/9
[16] **Note 113:** Use level reported as acesulfame potassium equivalents.
[17] **Note 119:** Use level reported as aspartame equivalents.

Aspartame		
Aspartame Level	**Aspartame level expressed as acesulfame-potassium salt**	**Level rounded up or down to nearest multiple of 50**
300	465	450
350	543	550
500	775	750
600	930	950
700	1085	1100
800	1240	1250
1000	1550	1550
2000	3100	3100
2500	3875	3850
3000	4650	4650
4000	6200	6200
5000	7750	7750
5500	8525	8500
6000	9300	9300
10000	15500	15500

Acesulfame		
Acesulfame-K Level	**Acesulfame-K level expressed as acesulfame-potassium salt**	**Level rounded up or down to nearest multiple of 50**
110	250	250
200	454	450
350	795	800
450	1022	1000
500	1135	1150
600	1362	1350
800	1816	1800
1000	2270	2250
1200	2724	2700
2000	4540	4550
2500	5675	5650
3000	6810	6800
3500	7945	7950
5000	11350	11350
15000	34050	34050

Recommendation 2 – Aspartame-Acesulfame, INS 962

The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for aspartame-acesulfame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	1130	mg/kg	Note 113	3	No sweeteners in a "plain" category

Recommendation 3 – Aspartame-Acesulfame, INS 962

The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame-acesulfame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	**800**	**mg/kg**	Notes 113 & **161**	**3**	
01.3.2	Beverage whiteners	**4550**	**mg/kg**	Note 113	3	
01.4.4	Cream analogues	1550	mg/kg	Note 119	3	
01.5.2	Milk and cream powder analogues	3100	mg/kg	Note 119	3	
01.6.5	Cheese analogues	**800**	**mg/kg**	Note 113	3	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	**1150**	**mg/kg**	Notes 113 & **161**	3	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1550	mg/kg	Note 119	3	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	**1150**	**mg/kg**	Notes 113 & **161**	**3**	
03.0	Edible ices, including sherbet and sorbet	1550	mg/kg	Notes 119 & **161**	3	
04.1.2.1	Frozen fruit	**1150**	**mg/kg**	Note 113	3	
04.1.2.2	Dried fruit	**1150**	**mg/kg**	Note 113	3	
04.1.2.3	Fruit in vinegar, oil, or brine	**1150**	**mg/kg**	Notes 113 & **161**	3	
04.1.2.4	Canned or bottled (pasteurized) fruit	**450**	**mg/kg**	Notes 113 & **161**	3	
04.1.2.5	Jams, jellies and marmelades	**550**	**mg/kg**	Notes 119 & **161**	3	
04.1.2.6	Fruit-based spreads (e.g., chutney) exlcuding products of food category 04.1.2.5	**2250**	**mg/kg**	Notes 113 & **161**	3	
04.1.2.7	Candied fruit	**1150**	**mg/kg**	Note 113	3	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings, and coconut milk	**800**	**mg/kg**	Notes 113 & **161**	3	
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts	**800**	**mg/kg**	Notes 113 & **161**	3	
04.1.2.10	Fermented fruit products	**800**	**mg/kg**	Note 113	3	
04.1.2.11	Fruit fillings for pastries	**800**	**mg/kg**	Note 113	3	
04.1.2.12	Cooked fruit	**1150**	**mg/kg**	Note 113	3	
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	**450**	**mg/kg**	Note 119 & **161**	3	

Recommendation 3 – Aspartame-Acesulfame, INS 962
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame-acesulfame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
04.2.2.4	Canned or bottles (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	**800**	**mg/kg**	Note 113	3	
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)	**4650**	**mg/kg**	Note 119	3	
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	**800**	**mg/kg**	Notes 113 & **161**	3	
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed products, excluding fermented soybean products of food category 12.10	**2250**	**mg/kg**	Note 113	3	
05.1.2	Cocoa mixes (syrups)	**1150**	**mg/kg**	Note 113	3	
05.1.3	Cocoa-based spreads, incl. fillings	**4550**	**mg/kg**	Notes 113 & **161**	3	
05.1.4	Cocoa and chocolate products	**2250**	**mg/kg**	Notes 113 & **161**	3	
05.1.5	Imitation chocolate, chocolate substitute products	**2250**	**mg/kg**	Notes 113 & **161**	3	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	**1150**	**mg/kg**	Note 113	3	
06.3	Breakfast cereals, including rolled oats	**1550**	**mg/kg**	Notes 119 & **161**	3	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	**800**	**mg/kg**	Notes 113 & **161**	3	
07.1	Bread and ordinary bakery wares	**2250**	**mg/kg**	Note 113	3	
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	**2250**	**mg/kg**	Notes 77 & 113	3	
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	450	mg/kg	Note 113	3	
09.4	Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans, and echinoderms	450	mg/kg	Note 113	3	
10.4	Egg-based desserts (e.g., custard)	**800**	**mg/kg**	Notes 113 & **161**	3	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	**2250**	**mg/kg**	Note 113	3	
11.6	Table-top sweeteners, including those containing high-intensity sweeteners		GMP	Note 113	3	
12.2.2	Seasonings and condiments	3100	mg/kg	Note 113	3	
12.3	Vinegars	**4550**	**mg/kg**	Note 113	3	
12.4	Mustards	**550**	**mg/kg**	Note 119	3	
12.5	Soups and broths	**250**	**mg/kg**	Notes 113 & **161**	3	
12.7	Salads (e.g., macaroni salad, potato salad), and sandwich spreads excluding coco-a dn nut-based spreads of food categories 04.2.2.5 and 05.1.3	**1550**	**mg/kg**	Notes 113 & **161**	3	
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	**1000**	**mg/kg**	Note 113	3	
13.4	Dietetic formulae for slimming purposes and weight reduction	**1000**	**mg/kg**	Note 113	3	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	**1000**	**mg/kg**	Note 113	3	
13.6	Food supplements	2000	mg/kg	Note 113	3	
14.1.2.2	Vegetable juice	**1350**	**mg/kg**	Note 113	3	
14.1.2.4	Concentrates for vegetable juice	**1350**	**mg/kg**	Notes 113 & **127**	3	
14.1.3.4	Concentrates for vegetable nectar	**1350**	**mg/kg**	Notes 113 & **127**	3	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	**950**	**mg/kg**	Notes 119 & **161**	3	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	**1350**	**mg/kg**	Note 119	3	
14.2.1	Beer and malt beverages	**800**	**mg/kg**	Notes 113 & **161**	3	

Recommendation 3 – Aspartame-Acesulfame, INS 962
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for aspartame-acesulfame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
14.2.2	Cider and perry	**800**	**mg/kg**	Note 113	3	
14.2.4	Wines (other than grape)	**1200**	**mg/kg**	Note 113	3	
14.2.7	Aromatized alcoholic beverrages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	**950**	**mg/kg**	Note 119	3	
15.0	Ready-to-eat savouries	**750**	**mg/kg**	Notes 113 & **161**	3	

Recommendation 4 – Aspartame-Acesulfame, INS 962
The eWG recommends that the 40th Codex Committee on Food Additives **further discuss** the following food additive provisions for aspartame-acesulfame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
05.3	Chewing gum	**4550**	**mg/kg**	Notes 113 & **161**	3	An ML of 11350 mg/kg expressed as Asp-Ace salt, is technologically justified, safe, does not affect exposure scenarios from last year's Codex, and does not need to be encapsulated to prolong sweetness

CYCLAMIC ACID, (AND Na, K, Ca SALTS) (INS 952)

50. The 26th JECFA (1982) assigned a group ADI of 11 mg/kg bw/d for calcium cyclamate, cyclohexylsulfamic acid, and sodium cyclamate all expressed as cyclamic acid

51. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function sweetener with cyclamic acid (and Na, K, Ca salts).

52. The Committee requested justification for the technological need for the draft (Step 6) provisions for cyclamic acid (and Na, K, Ca salts) (CL 2007/28-FA and ALINORM 07/30/12, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 – Cyclamic Acid, (and Na, K, Ca salts) INS 952
The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for cyclamates in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
14.1.4.3	Concentrates for fruit juice	1000	mg/kg			Cyclamate is used in drink concentrates in countries such as Australia and South Africa. ICBA proposes either adding the subcategory back or collapsing all proposed provisions into the main category 14.1.4 so that concentrates will be included with a proposed level of 1000 mg/kg.

Recommendation 2 – Cyclamic Acid, (and Na, K, Ca salts) INS 952
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for cyclamic acid in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)		GMP	Note 17	6	1) Discontinue for consistency wt Codex Standard for Fermented Milk 2) Clarification as to whether intense sweeteners will be allowed in this category? 3) Discontinue provided use of sweetener in "diet" fermented milks covered by food cat 1.7 or 01.1.2 – a ML of 80 mg/kg (replacing GMP) is needed to achieve tech effect. Need is based on requirement for lower energy value in "diet" then "regular" fermented milk products. Agrees with the IDF recommendation to modify the GSFA descriptions for "plain" food

Recommendation 2 – Cyclamic Acid, (and Na, K, Ca salts) INS 952 The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for cyclamic acid in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
						to be consistent with applicable Codex commodity standards 4) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Cyclamates are used in low cal products in this category. Cat. 1.2 includes sweetened yogurt; additives allowed in fermented milk std should be same as those in corresponding food cat.

Recommendation 3 – Cyclamic Acid, (and Na, K, Ca salts) INS 952 The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for cyclamates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
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	250	mg/kg	Notes 17 **and 161**	6	Some products of this category are sweet. Cyclamate allows for production of sweet vegetables with no added sugar. The tech need for using an intense sweetener in this category is justified. A ML of 250 mg/kg is needed to achieve the intended tech effect
12.6.1	Emulsified sauces (e.g., mayonnaise, salad dressing)	500	mg/kg	Note 17	6	1) For reasons of taste and microbial stability these products contain vinegar. To avoid growth of pathogenic bacteria the pH of these products is lowered to values around 4. This would result in a marked acid taste unless the acidity is mellowed by sweetening agents. Intense sweeteners such as cyclamates are not attacked by bacteria which may be found in these products and do not support their growth. In sweet-sour products with a high fat content it may even be necessary to use an intense sweetener as the solubility of sugar would not be sufficient to achieve the intended sweetness. The listed level is necessary as these products are often used in composite foods like delicatessen salads and have to provide a sweet-sour taste to the composite product. 2) The technological need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 500 mg/kg necessary to achieve tech effect to mellow vinegar taste
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	500	mg/kg	Note 17	6	1) Some vegetable salads falling in this category contain vinegar the taste of which has to be mellowed by adding intense sweeteners, such as cyclamate. 2) The technological need for using an intense sweetener in this category is justified, A ML of 500 mg/kg needed to achieve tech effect to mellow acidic taste

Recommendation 4 – Cyclamic Acid, (and Na, K, Ca salts) INS 952 The eWG recommends that the 40th CCFA **discuss further** the following food additive provisions for cyclamates in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
14.1.4.1	Carbonated water-based flavoured drinks	1500	mg/kg	Note 17	6	1) The eWG was informed that an ML of 250 mg/kg is not technologically feasible and would require significant product reformulations in many countries where cyclamate is permitted. 2) An ML of 1500 mg/kg is too high, ADI of 11 mg/kg bw/d will be exceeded by 60 kg adult drinking ½ liter soft drink 3) ML of 1500 mg/kg too high, ADI exceeded by child 15 kg bw drinking 150 ml 4) Supports listing in broader category 14.1.4. Restricting ML to 250 mg/kg would require reformulation in countries where cyclamates are permitted and the technical effect of cyclamate decreases below 400 ppm. The optimum sweetness in three component mixtures is reached at use levels of about 400-600, while two component mixtures with saccharin require higher use levels. 5) 1000 mg/kg - requests CCFA ask JECFA to conduct an intake assessment at of cyclamates at levels of 250 mg/kg. 400 (or 600 mg/kg) and 1000 mg/kg in 14.1.4. Cyclamates are used in beverages in many countries to provide a synergistic blend with saccharin where saccharin use is limited by regulation. This synergistic effect is reduced at levels < 400 mg/kg cyclamate. MLs of cyclamates vary by country due to consumption patterns, preference and a need for heat stable sweeteners in warm climates. Cyclamates are used in traditional drinks.
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	1500	mg/kg	Note 17	6	

SACCHARIN (INS 954)

53. The 41st JECFA (1993) assigned a group ADI of 5 mg/kg bw/d for calcium saccharin, potassium saccharin, sodium saccharin and saccharin.

54. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function sweetener with saccharin and its calcium, potassium and sodium salts.

55. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for saccharin (CL 2007/28-FA and ALINORM 07/30/12, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 – Saccharin, INS 954
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for saccharin in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.2.1	Fermented milks (plain)	200	mg/kg		6	1) For consistency wt Codex Standard for Fermented Milk 2) Clarification as to whether intense sweeteners will be allowed in this category? Adopt 200 mg/kg, like other intense sweeteners sucralose is used in the manufacture of "diet" fermented milk products to reduce the calories of "regular" fermented milk products. 3) Discontinue provided use of sweetener in "diet" fermented milks covered by food cat 1.7 or 01.1.2 – a ML of 200 mg is needed to achieve tech effect. Need is based on requirement for lower energy value in "diet" then "regular" fermented milk products. Agrees with the IDF recommendation to modify the GSFA descriptions for "plain" food to be consistent with applicable Codex commodity standards 4) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Sucralose is used in low cal products in this category Cat. 1.2 includes sweetened yogurt; additives allowed in fermented milk std should be same as those in corresponding food cat.
01.2.2	Renneted milk (plain)	100	mg/kg		6	1) Clarification as to whether intense sweeteners will be allowed in this category? Adopt 100 mg/kg, like other intense sweeteners sucralose is used in the manufacture of "diet" fermented milk products to reduce the calories of "regular" fermented milk products. 2) Needed in "diet" renneted milk products to significantly lower energy value than "regular" renneted milk products. ML of 100 mg/kg necessary to achieve tech effect 3) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Sucralose is used to manufacture lower energy renneted milk products resulting in significantly lower energy value that "regular" renneted milk products.
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	15	mg/kg		6	
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	1200	mg/kg		6	
09.3.3	Salmon substitutes, caviar, and other fish roe products	160	mg/kg		6	

Recommendation 2 - Saccharin, INS 954
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for saccharin in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.6.5	Cheese analogues	100	mg/kg		3	1) Saccharin allows for the manufacture of certain types of pre-sweetened unripened cheese analogues with no added carbohydrates, no added flavours and no other added foods. Carbohydrates may be degraded by lactic acid bacteria which results in loss of sweetness and increase in acidity while saccharin is not metabolised by these bacteria and remains inert. 2) ML of 100 mg/kg is needed to achieve intended tech effect
04.1.2.7	Candied fruit	**2000**	**mg/kg**	Note 161	3	1) Candied fruit requires a bulk sweetener to get its rather firm texture. Sugar substitutes used for sugar-free products are less sweet and require intense sweeteners like saccharin to bring the sweetness to the customary level. 2) The proposed ML is high. A 15 kg child would reach ADI of 5 mg/kg by consuming 15 g of candied fruit 3) The technological need for using an intense sweetener in this category is justified, as agreed a to by the 39th CCFA. An ML of 2000 mg/kg required to achieve tech effect
04.1.2.10	Fermented fruit products	160	mg/kg		3	New proposal added for consistency with the food additive provisions of the Draft Codex Standard for Pickled Fruits and Vegetables which were endorsed by the 39th CCFA. (Appendix V of ALINORM 07/30/12)
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	500	mg/kg		6	1) Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Saccharin is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2) ML of 500 mg/kg is needed to achieve tech effect
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	500	mg/kg		6	Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Saccharin is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. ML of 500 mg/kg is needed to achieve tech effect
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	**160**	**mg/kg**	**Note 144**	6	Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed saccharin level provides adequate sweetness. 2) Revise ML to 160 mg/kg; restrict use to sweet-wour preserves and energy reduced products only. 3) The technological need for using an intense sweetener in this category is justified, as

Recommendation 2 - Saccharin, INS 954
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for saccharin in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						agreed to by the 39th CCFA. A ML of 160 mg/kg required to achieve tech effect
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)	160	mg/kg		6	Some products of this category are sweet. Saccharin allows for production of sweet products with no added sugar. The tech need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 160 mg/kg required to achieve tech effect
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	200	mg/kg	Note 161	6	Some products of this category are sweet. Saccharin allows for production of sweetened vegetables, with no added sugar. The tech need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 200 mg/kg required to achieve tech effect
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	200	mg/kg	Note 161	6	Sweetening agents like saccharin can balance the acidity in these products and provide a balanced sweet-sour taste. The tech need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 200 mg/kg required to achieve tech effect
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	**160**	**mg/kg**	**Notes 144 & 161**	6	1) Sweetening agents can balance the acidity in these products and provide a balanced sweet-sour taste. Saccharin is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2) Revise ML to 160 mg/kg, restrict use to sweet-sour preserves and energy reduced products only 3) A ML of 500 mg/kg required to achieve tech effect
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	100	mg/kg	Note 97	3	New proposal added for consistency with CX-STAN 105-1981
06.3	Breakfast cereals, including rolled oats	100	mg/kg	Note 161	6	The technological need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 100 mg/kg required to achieve tech effect
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	500	mg/kg		6	Sweetener for calorie reduced products
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	500	mg/kg		6	Sweetener for calorie reduced products
09.2.4.1	Cooked fish and fish products	500	mg/kg		6	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	300	mg/kg	Note 159	6	1) Flavour enhancer / Sweetener for specific groups of products 2) Used in various pancake syrups not including maple syrup. 3) Intense sweeteners are widely used in these beverages (ready-to-drink as well as concentrates), owing to their relative stability in liquids. Sweeteners are already used in this category in Japan and several other countries in water and milk-based malted

Recommendation 2 - Saccharin, INS 954
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for saccharin in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						beverages. 4) The use of saccharin in products not based on sucrose or high fructose corn syrup or lower dry solids are less sweet and need sweeteners like saccharin to bring sweetness to standard level. The tech need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 300 mg/kg required to achieve tech effect
12.2.2	Seasonings and condiments	1500	mg/kg		6	1) Seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as Saccharin and other intense sweeteners. 2) A ML of 1500 mg/kg required to achieve tech effect
12.3	Vinegars	300	mg/kg		6	1) Vinegar is sometimes rounded and mellowed by addition of sweet-tasting, flavour-enhancing products. Saccharin balances acidity well. 2) A ML of 300 mg/kg required to achieve the intended technological effect
12.10.3	Fermented soybean paste (miso)	200	mg/kg		3	**S**weetness is an important characteristic of fermented soybean pastes. Saccharin is used to add sweet taste where sufficient sweet taste has not developed during the fermentation/aging process.
14.1.3.2	Vegetable nectars	80	mg/kg	Note 161	3	Saccharin is used in beverages of all types, including vegetable nectars, to produce a low calorie version of these sweetened drinks. The tech need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. A ML of 80 mg/kg required to achieve tech effect. requests that footnote 127 (as consumed) be included
14.1.4.1	Carbonated water-based flavoured drinks	**300**	**mg/kg**	**Note 161**	6	1) The eWG prior to the 39th CCFA could not reach consensus on an ML for use in these categories. That eWG recommended that the CCFA consider whether an ML of 500 mg/kg is acceptable in the broader category food category 14.1.4 with Note127. The 39th CCFA's eWG was informed that an ML of 80 mg/kg is not technologically feasible and would require significant product reformulations in many countries as well as significant financial impacts, especially to manufacturers in developing countries, There also would be increased ingredient cost, decreased stability (shorter shelf life in many cases), and in some cases lower consumer acceptability. 2) An ML of at least 300 mg/kg needed to achieve technological effect, ML of 80 mg/kg is not
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	**300**	**mg/kg**	**Note 161**	6	
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	**300**	**mg/kg**	**Notes 127 & 161**	6	

Recommendation 2 - Saccharin, INS 954 The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for saccharin in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
						technically feasible. The tech need for using an intense sweetener in this category is justified, as agreed to by the 39th CCFA. Saccharin is used in many fountain drinks due to its stability. 3) The additive is useful due to its stability, which is essential in providing consumer choice in many tropical developing countries.

SUCRALOSE (INS 955)

56. The 37th JECFA (1990) assigned a group ADI of 15 mg/kg bw/d for sucralose. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function sweetener with sucralose.

57. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for sucralose (CL 2007/28-FA and ALINORM 07/30/12, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 – Sucralose, INS 955 The eWG recommends that the 40th CCFA **include at Step 3** the following food additive provisions for sucralose in the GSFA.					
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Justification**
01.5.2	Milk and cream powder analogues	400	mg/kg		Include in the GSFA, as for the other sweeteners (Acesulfame K, Aspartame, and Neotame). The technological need for using an intense sweetener in category 01.5.2 is justified, as agreed to by the 39th CCFA (Aspartame) ML of 400 mg/kg represents the technological need.

Recommendation 2 – Sucralose, INS 955 The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for sucralose in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
01.2.1	Fermented milks (plain)	400	mg/kg		3	1) The Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks 2) Sucralose is necessary at 400 mg/kg as it is used in this food category in Japan 3) Clarification as to whether I intense sweeteners will be allowed in this category? Like other intense sweeteners sucralose is used in the manufacture of "diet" fermented milk products to reduce the calories of "regular" fermeneted milk products. 4) Discontinue provided use of sweetener in "diet" fermented milks covered by food cat 1.7 or 01.1.2 – a ML of 400 mg/kg is needed to achieve tech effect. Need is based on requirement for lower energy value in "diet" then "regular" fermented milk products. Agrees with the IDF recommendation to modify the GSFA descriptions for "plain" food to be consistent with applicable Codex commodity standards 5) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Sucralose is used in low cal products in this category Cat. 1.2 includes sweetened yogurt; additives allowed in fermented milk std should be same as those in corresponding food cat.
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	250	mg/kg		6	1) For consistency wt Codex Standard for Fermented Milk which does not allow the use of sweeteners in plain fermented mils 2) Clarification as to whether intense sweeteners will

Recommendation 2 – Sucralose, INS 955
The eWG recommends that the 40th CCFA **discontinue** further work on the following food additive provisions for sucralose in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						be allowed in this category. Adopt 250 mg/kg, like other intense sweeteners sucralose is used in the manufacture of "diet" fermented milk products to reduce the calories of "regular" fermeneted milk products. 3) Discontinue provided use of sweetener in "diet" fermented milks covered by food cat 1.7 or 01.1.2 – a ML of 250 mg is needed to achieve tech effect. Need is based on requirement for lower energy value in "diet" then "regular" fermented milk products. Agrees with the IDF recommendation to modify the GSFA descriptions for "plain" food to be consistent with applicable Codex commodity standards 4) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Sucralose is used in low cal products in this category Cat. 1.2 includes sweetened yogurt; additives allowed in fermented milk std should be same as those in corresponding food cat.
01.2.2	Renneted milk (plain)		GMP		6	1) Discontinue for consistency wt Codex Standard for Fermented Milk which does not allow the use of sweeteners in plain fermented milks 2) Clarification as to whether intense sweeteners will be allowed in this category? Adopt 250 mg/kg, like other intense sweeteners sucralose is used in the manufacture of "diet" fermented milk products to reduce the calories of "regular" fermeneted milk products. 3) Discontinue provided use of sweetener in "diet" fermented milks covered by food cat 1.7 or 01.1.2 – a ML of 250 mg is needed to achieve tech effect. Need is based on requirement for lower energy value in "diet" then "regular" fermented milk products. Agrees with the IDF recommendation to modify the GSFA descriptions for "plain" food to be consistent with applicable Codex commodity standards 4) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Sucralose is used to manufacture lower energy renneted milk products resulting in significantly lower energy value than "regular" renneted milk products.

Recommendation 3 - Sucralose, INS 955
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for sucralose in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.3.2	Beverage whiteners	580	mg/kg		3	1) Sucralose is used to replace sugar in low and reduce calorie plain dairy products. Intense sweeteners (e.g., sucralose) make pre-sweetened, no added sugar, beverage whiteners possible. 2) Sucralose is necessary at 580 mg/kg as it is used in this food category in Japan 3)1000 mg/kg necessary to achieve desired tech effect 4) Sucralose is used in this category for the manufacture of pre-sweetened beverage whiteners with no added carbohydrates, Beverage whiteners are produced for direct sale to consumers and are mostly used in coffee. Many people prefer sweet over unsweetened coffee and use table-top sweeteners included in beverage whiteners. Listing Sucralose for this use allows reduced calorie intake by specific groups of consumers, or for diabetics.
01.4	Cream (plain) and the like	580	mg/kg		3	1) Used for cream (plain) and the like. 2) Used as sweetener for the manufacture of low energy products under Food Category 01.4.4 (Cream analogues), which can be used for reduced calorie intake by specific groups of customers and/or diabetics so it should be included in the broader category of 01.4.

Recommendation 3 - Sucralose, INS 955
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for sucralose in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.6.5	Cheese analogues	**500**	**mg/kg**		6	Sucralose allows for the manufacture of certain types of pre-sweetened unripened cheese analogues with no added carbohydrates; no added flavours and no other added foods. Carbohydrates may be degraded by lactic acid bacteria which results in loss of sweetness and increase in acidity while Sucralose is not metabolised by these bacteria and remains inert. An ML of 500 mg/kg is technologically needed
04.1.2.1	Frozen fruit	400	mg/kg		3	1) Fruits are often frozen as such but sometimes also pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free products. The listed level for sucralose provides adequate sweetness.
04.1.2.2	Dried fruit	1500	mg/kg		3	1) Fruits are often dried as such but sometimes also pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free products. The listed level for sucralose provides adequate sweetness.
04.1.2.12	Cooked fruit	150	mg/kg		6	1) Intense sweeteners allow the production of pre-sweetened sugar-free products. The listed level for sucralose provides adequate sweetness. 2):150 mg/kg confirmed as tech. required by Canadian industry **3)** ML of 150 mg/kg is needed to achieve the technological effect. The tech need for using intense sweetener in this category was agreed to by the 39th CCFA.
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	150	mg/kg		6	1) Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Sucralose is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2) An ML of 150 mg/kg is needed to achieve the technological need
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	**500**	**mg/kg**		6	1) Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Sucralose is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability. 2) Used in food applications specifically used and enjoyed in Japan with some over the Codex max level. Therefore 580 mg/kg required. 3) 580 mg/kg necessary to achieve desired tech effect
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	**580**	**mg/kg**		6	1) Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed level for sucralose provides adequate sweetness. 2) Used in food applications specifically used and enjoyed in Japan with some over the Codex max level. Therefore 580 mg/kg required. 3) 580 mg/kg necessary to achieve desired tech effect
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	**580**	**mg/kg**		6	1) Sweetening agents can balance the acidity in these products and provide a balanced sweet-sour taste. Sucralose is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve their shelf stability. 2) Japan: used in food applications specifically used and enjoyed in Japan with some over the Codex max level. Therefore 580 mg/kg required. 3) 580 mg/kg necessary to achieve desired tech effect 4) The technological need for using an intense sweetener in category 4.1.2.12 is justified, as agreed to by the 39th CCFA (Neotame).

Recommendation 3 - Sucralose, INS 955
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for sucralose in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	150	mg/kg	**Note 144**	6	1) Sweetening agents can balance the acidity in these products and provide a balanced sweet-sour taste. Sucralose is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve their shelf stability 2) For use only in sweet-sour products 3) Necessary at 150 mg/kg as it is used in this food category in Japan 4) ML of 150 mg/kg is needed to achieve the technological need
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	**1800**	**mg/kg**	Note 161 & 164	3	1) Used in food applications specifically used and enjoyed in Japan with some over the Codex max level. Therefore 1800 mg/kg required. 2) Add footnote "for use in micro sweets and breath-freshening mints at 30,000 mg/kg." Sucralose provides enhanced stability at high processing temperatures, as well as enhanced stability in the presence of certain flavorings such as aldehydes and ketones. The high solubility of sucralose in water requires higher use levels to achieve the required sweetness. Thus, hard and soft candies require relatively high levels of sucralose. Sucralose has an emerging history of use in toppings/sweet sauces in the US at levels up to 100 ppm in hard & soft candies and 12,000 mg/kg in microsweets & breath mints sold in the US since 2003. Food category 5.4 is on the general list of categories for which the use of sweeteners is justified. 3) Add footnote "for use in micro sweets and breath-freshening mints at 30,000 mg/kg." ML of 1000 mg/kg in category 5.2 will not allow for the intended technological effect to be achieved in micro sweets and breath-freshening mints.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1000	mg/kg	**Note 161**	6	1) Sucralose is needed to sweeten sugar-free products of this category. 2) For use only in products with no added sugar 3) Sucralose has an emerging history of use in toppings and sweet sauces at levels up to 500 ppm in the US market since 2004. 4) Sucralose is needed to sweeten sugar-free products of this category. The technological need for using an intense sweetener in category 5.4 was agreed to by the 39th CCFA (Acesulfame K, Alitame, Aspartame, Cyclamates, Neotame, and Saccharin) ML of 1000 mg/kg represents the technological need.
06.3	Breakfast cereals, including rolled oats	1000	mg/kg	Note 161	6	1) A level of 1000 mg/kg has been assessed as technologically justified. 2)1000 mg/kg is technically justified and used in some products in various countries. Use at 500 mg/kg in Canada but levels vary dependent on country. 3) 1000 mg/kg as it is used in this food category in Japan 4) ML of 400 mg/kg is needed to achieve the technological effect. The technological need for using an intense sweetener in category 6.3 is justified, as agreed to by the 39th CCFA (Acesulfame K, Aspartame, Neotame)
07.1	Bread and ordinary bakery wares	650	mg/kg		6	1) To provide sweetness (other sweeteners are permitted) 2) Sucralose allows production of sweetened products without addition of soluble carbohydrates. Used in some breads to improve taste. 3) 650 mg/kg is used in this food category in Japan 4) ML of 250 mg/kg is needed to achieve the technological effect. Use of intense sweeteners such as sucralose allows production of sweetened products without addition of soluble carbohydrates or in combination with sugar alcohols. Sucralose is stable during baking.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	700	mg/kg	Note 165	6	1) Proposed new use in broader food category. Use of intense sweeteners allows production of sweetened products without addition of soluble carbohydrates or in combination with sugar alcohols. It is stable during baking. Fine bakery wares containing intense

Recommendation 3 - Sucralose, INS 955
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for sucralose in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						sweeteners are available. 2) An ML of 700 mg/kg is similar to the level considered technologically sufficient (650 mg/kg) for this food category in Canada. 3) 700 mg/kg is used in this food category in Japan 4) ML of 700mg/kg is needed to achieve the technological effect
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1500	mg/kg	Note 159	6	1) Flavour enhancer / Sweetener for specific groups of products 2) Products not based on sucrose or high-fructose corn syrup or having lower dry solids levels are less sweet than customary products. Stable sweeteners such as sucralose bring their sweetness to the standard level. Used in various pancake syrups not including maple syrup. 3) 1500 mg/kg is used in this food category in Japan 4) ML of 1500 mg/kg is needed to achieve the technological effect.
12.2.1	Herbs and spices	400	mg/kg		3	1) Flavour enhancer / Sweetener for specific groups of products Sugar like sweetness for low calorie products 2) Herbs and spices are often rounded by the addition of sweet-tasting substances such as intense sweeteners. ML of 400mg/kg is needed to achieve the technological effect.
12.2.2	Seasonings and condiments	700	mg/kg		6	1) Seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as sucralose or other intense sweeteners. 2)700 mg/kg is used in food applications specifically enjoyed and consumed in Japan in this food category. 3) ML of 700 mg/kg is needed to achieve the technological effect
12.3	Vinegars	**400**	**mg/kg**		3	1) Vinegar is sometimes rounded and mellowed by addition of sweet-tasting, flavour-enhancing products. Sucralose is stable in vinegar and balances its acidity well. An ML of 1000 mg/kg is necessary to achieve the intended sweetening effect. 2) Used in food applications specifically enjoyed and consumed in Japan in this food category therefore the Japanese usage standard of ML of 400 mg/kg is required. 3) 1000 mg/kg necessary to achieve desired tech effect
12.5	Soups and broths	600	mg/kg	Note 161	6	1) Used for soups and broths 2) Necessary at 600 mg/kg as it is used in this food category in Japan 3) 45 mg/kg for ER purposes only 4) The technological need for using an intense sweetener in category 12.5 was agreedto by the 39th CCFA (Acesulfame K, Alitame, Neotame, and Saccharin). ML of 600 mg/kg is needed to achieve the intended technological effect.
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)	700	mg/kg		6	1) Intense sweeteners are used to produce sugar-free beverages of this category. Owing to its good stability in liquids sucralose is used in beverages of all types. 2) 700 mg/kg is necessary as sucralose is used in food applications specifically enjoyed and consumed in Japan 3) The technological need for using an intense sweetener in category 14.2.7 was agreed to by the 39th CCFA for all other sweeteners (Acesulfame K, Aspartame, Cyclamates, Neotame, and Saccharin). Sucralose has the same technological need. ML of 700 mg/kg is needed to achieve the intended technological effect.
15.0	Ready-to-eat savouries	1000	mg/kg		6	1) Snacks may be salted, spicy, or sweetened. For sugar-free sweetened products intense sweeteners like sucralose have to be used. 2) 1000 mg/kg is necessary as sucralose is used in food applications specifically enjoyed and consumed in Japan 3) Discontinue, except for certain flavours and coated nuts at a ML of 200 mg/kg.

Recommendation 3 - Sucralose, INS 955 The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for sucralose in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
						4) The technological need for using an intense sweetener in category 15.0 was agreed to by the 39th CCFA (Acesulfame K, Neotame, and Saccharin) ML of 1000mg/kg represents the technological need for sucralose.

ALITAME (INS 956)

58. The 46th JECFA (1996) assigned an ADI of 1 mg/kg bw/d for alitame.

59. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical function sweetener with alitame.

60. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for alitame (CL 2007/28-FA and ALINORM 07/30/12, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 - Alitame, INS 956 The eWG recommends that the 40th CCFA **discontinue** work on the following food additive provisions for alitame in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	60	mg/kg		6	No sweeteners in a "plain" category
01.4.4	Cream analogues	100	mg/kg		3	No information provided
07.1	Bread and ordinary bakery wares	200	mg/kg		6	No information provided
12.2	Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	100	mg/kg		6	No information provided

NEOTAME (INS 961)

61. The 61st JECFA (2003) assigned an ADI of 2 mg/kg bw/d for neotame.

62. The Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) associates the technical functions flavour enhancer and sweetener with neotame.

63. The Committee requested justification for the technological need for the proposed draft (Step 3) and Draft (Step 6) provisions for neotame (CL 2007/28-FA and ALINORM 07/30/12, App. IX), with the understanding that if this information was not provided, the 40th CCFA would discontinue further consideration of these provisions in the GSFA.

Recommendation 1 – Neotame, INS 961 The eWG recommends that the 340h CCFA **discontinue** further work on the following food additive provisions for neotame in the GSFA.						
Food Cat No.	**Food Category**	**Max Level**		**Comments**	**Step**	**Justification provided to eWG**
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	65	mg/kg		3	1) For consistency wt Codex Standard for Fermented Milk 2) Clarification as to whether intense sweeteners will be allowed in this category? Adopt 65 mg/kg as intense sweeteners are used in "diet" fermented milk products to reduce the caloric value of "regular" fermented milk products. 3) If IDF's recommendations from the general comments are not accepted, then adopt in this food category @ proposed level. Neotame is used in low cal products in this category Cat. 1.2 includes sweetened yogurt; additives allowed in fermented milk std should be same as those in corresponding food cat.Technological need is questioned. 4) Like aspartame, acesulfame K and alitame, this artificial sweetener is used in the manufacture of "diet" fermented milk products. Technological need is based on the requirement for a significantly lower energy value than "regular" fermented milk products.

Recommendation 2 - Neotame, INS 961

The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for neotame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.3.2	Beverage whiteners	**65**	**mg/kg**		3	1) Neotame is used to replace sugars in the manufacture of pre-sweetened beverage whiteners with no added carbohydrates. An ML of 65 mg/kg is proposed in place of GMP, only 2) Neotame is used at 65 mg/kg in this category for the manufacture of pre-sweetened beverage whiteners with no added carbohydrates, Beverage whiteners are produced for direct sale to consumers and are mostly used in coffee. Many people prefer sweet over unsweetened coffee and use table-top sweeteners included in beverage whiteners. Listing Neotame for this use allows reduced calorie intake by specific groups of consumers, or for diabetics.
01.4.4	Cream analogues	33	mg/kg		3	Neotame is used to replace sugars for making low and reduced joule/calorie and no added sugar sweetened creams and related products, including cream analogues.
01.5.2	Milk and cream powder analogues	65	mg/kg		3	1) Neotame is used to replace sugars, for making low and reduced joule/calorie and no added sugar sweetened milk and cream powders and analogues. 2) Neotame should be added to food categories 01.5. However, if not neotame should be retained in this food category and 01.5.1 for consistency. Neotame is used in this category for the manufacture of pre-sweetened milk and cream powder analogues with no added carbohydrates. Neotame is inert but the addition of carbohydrates may result in browning reactions with impaired appearance of this product and impaired value of proteins.
01.6.5	Cheese analogues	33	mg/kg		3	Neotame at 33 mg/kg allows for the manufacture of certain types of pre-sweetened unripened cheese analogues with no added carbohydrates; no added flavours and no other added foods. Carbohydrates may be degraded by lactic acid bacteria which results in loss of sweetness and increase in acidity while intense sweeteners are not metabolised by these bacteria and remain inert.
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	10	mg/kg		3	Neotame at 10 mg/kg allows for the manufacture of pre-sweetened, flavoured products, as this category includes products with added flavours. They have the same technological requirements as their dairy-based counterparts.
04.1.2.1	Frozen fruit	100	mg/kg		3	Fruits are often frozen and pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free/low calorie products. The listed level provides adequate sweetness.
04.1.2.2	Dried fruit	100	mg/kg		3	Fruits are often frozen and pre-sweetened with sugar. Intense sweeteners allow production of pre-sweetened sugar-free/low calorie products. The listed level provides adequate sweetness.
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	33	mg/kg		3	Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Neotame is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability.
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	33	mg/kg		3	Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Neotame is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability.

Recommendation 2 - Neotame, INS 961
The eWG recommends that the 40th CCFA **adopt** the following food additive provisions for neotame in the GSFA.

Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
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	33	mg/kg		3	Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed neotame level provides adequate sweetness.
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)	33	mg/kg	**Note 161**	3	Some products in this category are sweetened. Neotame allows production of sweet products with no added sugar.
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	33	mg/kg		3	Sweetening agents can balance the acidity in these products and provide a balanced sweet-sour taste. Neotame is not degraded by lactic acid bacteria which may occur in brined products and can therefore improve shelf stability.
07.1	Bread and ordinary bakery wares	70	mg/kg		3	1)To provide sweetness (other sweeteners are permitted)ISA May be used to enhance the flavor of certain specialty breads 2) Used in some breads to improve taste.
07.2	Fine Bakery wares (sweet, salty, savoury) and mixes	80	mg/kg		3	
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	10	mg/kg		3	Marinated fish, crustaceans and molluscs are often sour-sweet. Intense sweeteners like neotame mellow the taste of vinegar and provide the desired sweetness. In products undergoing fermentation intense sweeteners are not degraded by micro-organisms. Technological need – same as for all sweeteners
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	10	mg/kg		3	Marinated fish, crustaceans and molluscs are often sour-sweet. Intense sweeteners like neotame mellow the taste of vinegar and provide the desired sweetness. In products undergoing fermentation intense sweeteners are not degraded by micro-organisms. Technological need – same as for all sweeteners
12.2	Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	**32**	**mg/kg**		3	Seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as Neotame and other intense sweeteners. An ML of 65 mg/kg is needed to achieve the intended technological effect
12.3	Vinegars	12	mg/kg		3	Vinegar is often rounded and mellowed by addition of sweet-tasting, flavour-enhancing products such as Neotame.