

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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Agenda Item 7 (a)

CX/FA 07/39/9 (Part 1)

January 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Thirty-ninth Session

Beijing, China, 24-28 April 2007

REPORT OF THE ELECTRONIC WORKING GROUP ON THE GSFA

PART 1¹

(prepared by United States of America with the assistance with the assistance of Australia, Brazil, Canada, European Community, Indonesia, Japan, Malaysia, Mexico, New Zealand, Norway, Republic of Korea, South Africa, Switzerland, Thailand, ELC, IADSA, ICBA, ICGA, ICGMA, IDF, IFAC, IFDI, IFU, ISA, ISDI, and NATCOL)

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 16 March 2007** 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 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) reestablished its electronic Working Group² (eWG) and requested it to provide a report with recommendations to the 39th Session of the Codex Committee on Food Additives (CCFA) on certain of the draft and proposed draft maximum levels for the food additives in the Codex General Standard for Food Additives (GSFA).

2. The Committee agreed that the eWG should take a horizontal approach to its discussion of the provisions for the use of sweeteners and colours.³

3. The Committee also agreed to request specific comments on particular Step 3 and Step 6 provisions with the understanding that if this information was not provided, the 39th CCFA would discontinue work on these food additive provisions.⁴ It was understood that comments submitted in response to the circular letter⁵ would be referred directly to the eWG and not be published.

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 United States (lead), with the assistance of Australia, Brazil, Canada, European Community, Indonesia, Japan, Malaysia, Mexico, New Zealand, Norway, Republic of Korea, South Africa, Switzerland, Thailand, ELC, IADSA, ICBA, ICGA, ICGMA, IDF, IFAC, IFDI, IFU, ISA, ISDI, and NATCOL.

³ ALINORM 06/29/12, para. 79

⁴ ALINORM 06/29/12, para. 80.

⁵ CL 2006/34-FAC – Comments submitted by Australia, Brazil, Canada, European Community, Japan, Malaysia, New Zealand, Norway, South Africa, Switzerland, CEFS, EFEMA, ELC, IADSA, ICBA, ICGA, IDF, IFAC, IFU, ISA, ISDI, OIV, and WSRO

4. 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. Individual members of the eWG reserve their right to provide additional comments and recommendations to the CCFA.

5. The CCFA's *ad hoc* 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 38th CCFAC agreed that, if additional information on specific food additive provisions was not provided, these provisions would be revoked (if Step 8) or discontinued (if Step 3 or 6).

INS No.	Additive	INS No.	Additive
210, 211, 212, 213	Benzoates	129	Allura Red AC
928	Benzoyl Peroxide	133	Brilliant Blue FCF
320	Butylated Hydroxyanisole (BHA)	161g	Canthaxanthin
321	Butylated Hydroxytoluene (BHT)	150c	Caramel Colour Class III
1503	Castor Oil	150d	Caramel Colour Class IV
472e	Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM)	120	Carmines
385, 386	EDTAs	160aii	Carotenes, Vegetable
900a	Polydimethylsiloxane	160ai,aii,e,f	Carotenoids
432,433, 434, 435, 436	Polysorbates	141i & 141ii	Chlorophyll, Copper Complexes
1203	Polyvinyl Alcohol	127	Erythrosine
477	Propylene Glycol Esters of Fatty Acids	143	Fast Green FCF
999	Quillaia Extract	163ii	Grape Skin Extract
220, 221, 222, 223, 224, 225, 227, 228, 539	Sulphites		
319	Tertiary Butylhydroxyquinone (TBHQ)	132	Indigotine
950	Acesulfame Potassium	172i, 172ii, 172iii	Iron Oxides
956	Alitame	124	Ponceau 4R
951	Aspartame	101i, 101ii	Riboflavins
	Aspartame-Acesulfame Salt	110	Sunset Yellow FCF
952	Cyclamic Acid (Sodium, Potassium, and Calcium Salts)		
961	Neotame		
954	Saccharin		
955	Sucralose		

6. Revisions to existing proposed draft (Step 3) or Draft (Step 6) food additive provisions proposed by the eWG are indicated in **bold** font in the following tables for each additive. Where appropriate, additional information provided, either in response to CL 2006/34-FAC or as part of the eWG deliberations, is included in the recommendations below.

PART I – MISCELLANEOUS FOOD ADDITIVES

BENZOATES (INS 210, 211, 212, 213)

7. The 29th CCFAC requested that JECFA perform intake assessments for benzoates based on the draft maximum use levels in the GSFA. Benzoates were identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to their intake exceeding their ADI. The 51st JECFA (1998) reviewed national intake data on benzoates.

8. JECFA has assigned a group ADI of 5 mg/kg bw for benzoates as benzoic acid, and has stated that there is no safety concern at current levels of intake when used as a flavoring agent.

Recommendation 1 - Benzoates, INS 210, 211, 212, 213						
The eWG recommends that the 39 th CCFA <u>discontinue</u> further work on the following food additive provisions for benzoates in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification Provided
04.1.2.5	jams, jellies and marmalades	1500	mg/kg	Note 13 ⁶	3	The heat treatment during the manufacture, the low water activity of this product and the natural preservation effect of the sugar does not justify the technological need at the proposed maximum levels. A carry over effect from the ingredients could be alleged.

BENZOYL PEROXIDE, INS 928

9. The 7th JECFA (1963) concluded that the use of benzoyl peroxide as a flour treatment agent at levels up to a treatment level of 40 ppm benzoyl peroxide was acceptable.

10. The 63rd JECFA (2004) stated that “Treatment of whey with benzoyl peroxide at a maximum concentration of 100 mg/kg does not pose a safety concern.”

Recommendation 1 – Benzoyl Peroxide, INS 928						
The eWG recommends that the 39 th CCFA <u>discontinue</u> further work on the following food additive provisions for benzoyl peroxide in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
01.6.2.1	ripened cheese, includes rind	1000	mg/kg	Note 55 ⁷	6	The use of bleaching agents has the potential to alter the nature of the raw material or the quality of foodstuff and in such a way that it could deceive the consumer. The proposed maximum level seems to be very high for achieving the intended technological need

Recommendation 2 - Benzoyl Peroxide, INS 928						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for benzoyl peroxide in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
01.8.1	liquid whey and whey products, excluding whey cheeses	100	mg/kg	Note A ⁸	6	The JECFA summary states: “Treatment of whey with benzoyl peroxide at a maximum concentration of 100 mg/kg does not pose a safety concern (JECFA, 2004)”.
06.2.1	flours	75	mg/kg		6	Bleaching agents are commonly used in flours to “age” the flour to ensure uniform consistency to meet consumer demands

BUTYLATED HYDROXYANISOLE (BHA) (INS 320)

11. The 28th CAC has endorsed several provisions in the GSFA for the use of BHA.

12. The 29th CCFAC requested that JECFA perform intake assessments for BHA based on the pending levels of maximum use in the GSFA. BHA was identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to their intake exceeding their ADI. The 51st JECFA (1998) reviewed national intake data on BHA.

13. The 51st JECFA’s exposure assessment identified the following food category for closer scrutiny by the CCFAC.

- 05.2 confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4

14. JECFA has assigned an ADI of 0-0.5 mg/kg bw for BHA.

15. Through CL 2006/34-FAC, the Committee requested information addressing intake by with the Step 6 provisions for BHA in food categories 05.2 and 05.4.

⁶ Note 13: As benzoic acid.

⁷ Note 55: Added level.

⁸ Note A: Excluding liquid whey and whey products used as an ingredient in infant formula

Recommendation 1 – Butylated Hydroxyanisole (BHA), INS 320						
The eWG recommends that the 39 th CCFA discontinue further work on the following food additive provisions for BHA in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
02.2.1.2	margarine and similar products	175	mg/kg	Notes 15 & 133 ⁹	6	Pending decision by CCFO on the draft standard for fat spreads and blends of fat spreads

Recommendation 2 - Butylated Hydroxyanisole (BHA), INS 320						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for BHA in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
01.3.2	beverage whiteners	100	mg/kg	Notes 15 ¹⁰ & 133	3	To prevent oxidation of vegetable fat component of these foods
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Notes 15 & 130	6	Exposure estimates provided by Canada and the United States of America (See Appendix I) indicate that exposure in children is well below the ADI for BHA.
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Notes 15 & 130	6	
07.0	bakery wares	200	mg/kg	Notes 15 & 130	6	To prevent oxidation of fat and oil component of these foods

BUTYLATED HYDROXYTOLUENE (BHT) (INS 321)

16. The 28th CAC has endorsed several provisions in the GSFA for the use of BHT.

17. The 29th CCFAC requested that JECFA perform intake assessments for BHT based on the pending levels of maximum use in the GSFA. BHT was identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to their intake exceeding their ADI. The 51st JECFA (1998) reviewed national intake data on BHT.

18. The 51st JECFA's exposure assessment identified the following for closer scrutiny by the CCFAC.

- 02.0 fats and oils, and fat emulsions (type water-in-oil)
- 05.3 chewing gum
- 09.2 Processed fish and fish products, including molluscs, crustaceans and echinoderms

19. JECFA has assigned an ADI of 0-0.3 mg/kg bw for BHT.

20. Through CL 2006/34-FAC, the Committee requested information addressing intake by with the Step 6 provisions for BHT in food categories 05.2 and 05.4 and information on whether it is appropriate to limit the use of BHT in categories 08.2 and 08.3 to dehydrated products only.

Recommendation 1 – Butylated Hydroxytoluene (BHT), INS 321						
The eWG recommends that the 39 th CCFA discontinue further work on the following food additive provisions for BHT in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
02.2.1.2	margarine and similar products	75	mg/kg	Notes 15 & 133 ¹¹	3	Pending decision by CCFO on the draft standard for fat spreads and blends of fat spreads. The maximum The use level of BHT at 75 mg/kg is insufficient to function as an antioxidant in foods covered by this food category.

⁹ **Note 133:** Any combination of Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at 200 mg/kg, provided that single use limits are not exceeded.

¹⁰ **Note 15:** Fat or oil basis.

¹¹ **Note 133:** Any combination of Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at 200 mg/kg, provided that single use limits are not exceeded.

Recommendation 2 - Butylated Hydroxytoluene (BHT), INS 321						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for BHT in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
01.3.2	beverage whiteners	100	mg/kg	Notes 15 ¹²	3	To prevent oxidation of vegetable fat component of these foods
02.2.1.2	margarine and similar products	200	mg/kg	Notes 15 & 130 ¹³	6	The use of BHT at a maximum level of 200 mg/kg is necessary to achieve its technological function as antioxidant to prohibit lipid oxidation.
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Notes 15 & 130	6	Exposure estimates provided by Canada and the United States of America (See Appendix I) indicate that exposure in children is well below the ADI for BHT.
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Notes 15 & 130	6	
07.0	bakery wares	200	mg/kg	Notes 15 & 130	6	
08.2	processed meat, poultry, and game products in whole pieces or cuts	100	mg/kg	Notes 15 & 130	6	Unsaturated fats are susceptible to oxidation which causes fat rancidity. In the case of dehydrated meat products the moisture content is reduced and the fat content is relatively high. The high fat content combined with lengthy storage at room-temperature makes these products more sensitive to fat oxidation. The addition of antioxidants is therefore necessary to retard oxidation.
08.3	processed comminuted meat, poultry, and game products	100	mg/kg	Notes 15 & 130 Note B ¹⁴	6	On the other hand for non-dehydrated products such as bacon, frozen raw or cooked meat, cooked meatballs or corned beef the use of the antioxidant would <u>not</u> be justified, as oxidation should be minimized by the appropriate handling of these products i.e. efficient transport, ideal storage conditions at low temperatures, canning and appropriate shelf life of the products. Used as anti oxidizing agents which prevents discolorization while meat is in a display cabinet. Also postpone the oxidation of certain fatty acids.

CASTOR OIL (INS 1503)

21. The 23rd JECFA (1983) assigned an ADI of 0.7 mg/kg bw/d for castor oil (1503).

Recommendation 1 – Castor Oil, INS 1503						
The eWG recommends that the 39 th CCFA discontinue further work on the following food additive provisions for castor oil in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
05.1	cocoa products and chocolate products including imitation and chocolate substitutes		GMP		6	1) There are no non-standardized foods in category 05.1.1 and the relevant commodity standards do not provide for the use of castor oil 2) Some sub-categories would not be expected to need a glazing agent.

¹² **Note 15:** Fat or oil basis.

¹³ **Note 130:** Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

¹⁴ **Note B:** For dehydrated products only

Recommendation 2 - Castor Oil, INS 1503						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for castor oil in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
05.1.4	Cocoa and chocolate products	350	mg/kg			Used as a glazing agent in panned chocolates to impart shiny appearance. The use of castor oil is not justified for food categories 05.1.1 <i>Cocoa mixes (powders) and cocoa mass/cake</i> , 05.1.2 <i>Cocoa mixes (syrops)</i> and 05.1.3 <i>Cocoa-based spreads, including fillings</i> and 05.1.5 <i>Imitation chocolate, chocolate substitute products</i> . Castor oil is a vehicle and carrier solvent used in confectionery, imitation chocolate and cocoa products.
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	500	mg/kg	6		Castor oil is a vehicle and carrier solvent used in confectionery, imitation chocolate and cocoa products.
05.3	chewing gum	2100	mg/kg	6		
13.6	food supplements	1000	mg/kg	6		1) The usage varies in quantity depending on the composition of the product formulation. From information supplied by supplement manufacturers, it would appear that all applications could be accommodated within a maximum level of 1000mg/kg of product. When considering this level it must be borne in mind that individual supplements are less than 2g in weight, with most being under 1.5g. 2) Castor oil is a vehicle and carrier solvent used in food supplements, chewing gum, confectionery, imitation chocolate and cocoa products. The following example shows daily intake using a typical coating system containing 7% castor oil, applied to a food supplement with a 4% weight gain assuming a daily food supplement consumption of 3 g. 3 g (food supplement) x 4.0% (coating) = 0.12 g coating 0.12 g coating x 1000 mg=120 mg coating 120 mg coating x 0.07 (Castor Oil) = 8.40 mg Castor Oil /Day

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

22. The 23rd CAC (1999) adopted the inclusion of tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f) in Table 3 of the GSFA.

23. The 57th JECFA (2001) withdrew the ADI for tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f) due to its specifications being combined with diacetyltartaric and fatty acid esters of glycerol (DATEM, INS 472e). As a result, the 34th CCFAC agreed that the listing for this additive (472f) in Table 3 should be deleted.

24. The 57th JECFA assigned a temporary grouped ADI of 0-50 mg/kg bw for both DATEM (INS 472e), and tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f).

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

26. The 34th CCFAC agreed to combine the provisions for INS 472e and 472f under "DATEM." The 37th CCFAC agreed to revoke the INS number for 472f, since it was no longer necessary.

Recommendation 1 – Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), INS 472e						
The eWG recommends that the 39 th CCFA discontinue further work on the following food additive provisions for DATEM in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
01.4	cream (plain) and the like	5000	mg/kg		6	Some sub-categories would not be

Recommendation 1 – Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), INS 472e						
The eWG recommends that the 39 th CCFA discontinue further work on the following food additive provisions for DATEM in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
						expected to need an emulsifier
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg	Note 16 ¹⁵	3	No additional information provided to support these provisions for DATEM
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg	Note 16	3	
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	5000	mg/kg		3	
13.1.1	infant formulae	5000	mg/kg		3	There are no non-standardized foods in these food categories and the relevant Codex commodity standard does not provide for the use of DATEM.
13.1.2	follow-up formulae	5000	mg/kg		3	

Recommendation 2 - Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), INS 472e						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for DATEM in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain	6000	mg/kg			1) Emulsifiers are essential in UHT creams to maintain emulsion stability and assist in whipping performance. Although other emulsifiers are available UHT cream manufacture is a difficult technology so it is preferable to retain as much scope in emulsifier selection as possible. 2) To achieve an enough emulsifying function in whip cream products. 3) Emulsifiers are essential in UHT creams and cream analogues (food category 01.4.4) to maintain emulsion stability and assist in whipping performance. Although other emulsifiers are available, UHT cream manufacture is a difficult technology so it is preferable to retain as much scope in emulsifier selection as possible. Also used as a stabilizer in cream that is cooked prior to packaging.
01.4.4	Cream analogues	6000	mg/kg			
06.2	flours and starches (including soybean powder)	3000	mg/kg		6	1) This additive 1) fortifies the net of gluten; 2) it increases the stability and the resistance of the mass; 3) it increases the tolerance to the variations of quality of the wheat flour, that is, it minimizes performance variations of different kinds of flours; 4) it raises the tolerance to process variations (mixture time, rest time, fermentation time, handling of the mass); 5) it enhances the volume of the bread and becomes it crusty; 6) it emulsifies the flour and the mass components; 7) it is important to long fermentation processes, in which the mass needs maximum tolerance, and to prevent process losses; and 9) it modifies the texture of bakery products,

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

Recommendation 2 - Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), INS 472e The eWG recommends that the 39 th CCFA adopt the following food additive provisions for DATEM in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
						becoming the bread crunchier, and also allows fat reduction (in cookies). 2) DATEM is used as an emulsifier to improve dough stability and volume in baked goods.
06.4.2	dried pastas and noodles and like products	5000	mg/kg		6	This additive 1) fortifies the net of gluten; 2) it increases the stability and the resistance of the mass; 3) it increases the tolerance to the variations of quality of the wheat flour, that is, it minimizes performance variations of different kinds of flours; 4) it raises the tolerance to process variations (mixture time, rest time, fermentation time, handling of the mass); 5) it enhances the volume of the bread and becomes it crusty; 6) it emulsifies the flour and the mass components; 7) it is important to long fermentation processes, in which the mass needs maximum tolerance, and to prevent process losses; and 9) it modifies the texture of bakery products, becoming the bread crunchier, and also allows fat reduction (in cookies).

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

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

28. 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.”

Recommendation - EDTAs, INS 385,386 The eWG recommends that the 39 th CCFA adopt the following food additive provisions for EDTAs in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	25	mg/kg	Note 21 ¹⁶	6	1) EDTA is acceptable for use in beer (Category 14.2.1). Category 14.2.7 includes aromatized beer, wine and spirituous cooler-type beverages. Therefore, it should also be acceptable for use in its aromatized equivalent and therefore the provision in this Category appears to be justified. 2) EDTA can help prevent the formation of benzene, therefore this use should be acceptable

POLYDIMETHYLSILOXANE (INS 900A)

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

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

Recommendation - Polydimethylsiloxane, INS 900a The eWG recommends that the 39 th CCFA adopt the following food additive provisions for polydimethylsiloxane in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
02.2.2	emulsions containing less than 80% fat	10	mg/kg	Note 152 ¹⁷	3	1) The proposed maximum use level of 10 mg/kg is justified to achieve the intended technical need as antifoaming

¹⁶ **Note 21:** As anhydrous calcium disodium EDTA.

Recommendation - Polydimethylsiloxane, INS 900a						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for polydimethylsiloxane in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
						agent in this food category
06.4.3	pre-cooked pastas and noodles and like products	50	mg/kg		3	For consistency with the Codex standard for instant noodles
12.9.1.3	other soybean products (including non-fermented soy sauce)	10	mg/kg		6	1) During production process of powdered soybean protein, being used as an antifoaming agent. 2) A maximum level of 10 mg/kg is justified to achieve the intended technical need as an antifoaming agent in this food category

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

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

32. 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.

Recommendation 1 – Polysorbates, INS 432, 433, 434, 435, 436						
The eWG recommends that the 39 th 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
01.4	cream (plain) and the like	10000	mg/kg		3	The use of an emulsifier in foods subject to some sub-categories would not be expected to need an emulsifier
07.1.1	Breads and rolls	3000	mg/kg		6	Replace with provision in broader food category 07.0 at 3000 mg/kg and Note 11
07.1.2	crackers, excluding sweet crackers	5000	mg/kg	Note 11 ¹⁸	6	
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	10000	mg/kg	Note 11	6	
07.1.4	bread-type products, including bread stuffing and bread crumbs	5000	mg/kg	Note 11	6	
07.1.5	steamed breads and buns	5000	mg/kg	Note 11	6	
07.1.6	mixes for breads and ordinary bakery wares	5000	mg/kg	Note 11	6	
07.2	fine bakery wares (sweet, salty, savoury) and mixes	5000	mg/kg		6	
14.1.4.1	carbonated water-based flavoured drinks	500	mg/kg		6	Replace with provision in broader food category 14.1.4 at 500 mg/kg and Note 127
14.1.4.2	non-carbonated water-based flavoured drinks, including punches and ades	500	mg/kg		6	
14.1.4.3	concentrates (liquid or solid) for water-based flavoured drinks	45000	mg/kg	Note 102 ¹⁹	6	

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436						
The eWG recommends that the 39 th 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	

¹⁷ **Note 152:** For frying purposes only.

¹⁸ **Note 11:** Flour basis.

¹⁹ **Note 102:** For use as a surfactant or wetting agent for colours in the food.

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for polysorbates in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
01.3.2	beverage whiteners	4000	mg/kg		6	
01.5.2	milk and cream powder analogues	4000	mg/kg		6	
01.6.1	unripened cheese	80	mg/kg	Note 38 ²⁰	6	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	3000	mg/kg	Note MM²¹	6	
02.1.2	vegetable oils and fats	5000	mg/kg	Note MM	6	
02.1.3	lard, tallow, fish oil, and other animal fats	5000	mg/kg	Note MM	6	
02.2.1.3	blends of butter and margarine	5000	mg/kg	Note MM	6	
02.2.2	emulsions containing less than 80% fat	5000	mg/kg	Note MM	6	
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	5000	mg/kg	Note MM	6	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	5000	mg/kg	Note MM	6	
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	5000	mg/kg		3	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	3000	mg/kg		6	
04.1.2.11	fruit fillings for pastries	3000	mg/kg		6	
04.2.2.3	vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine, or soy sauce	500	mg/kg		6	
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	Notes 7 ²² & 100 ²³	6	
04.2.2.6	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	3000	mg/kg		6	
05.1.2	cocoa mixes (syrups)	500	mg/kg		6	
05.1.3	cocoa-based spreads, including fillings	1000	mg/kg		6	
05.1.4	cocoa and chocolate products	5000	mg/kg	Note XX²⁴	6	Note added for consistency with relevant Codex commodity standard
05.1.5	imitation chocolate, chocolate substitute products	5000	mg/kg		6	

²⁰ **Note 38:** Level in creaming mixture.

²¹ **Note MM:** For use in fat emulsions for baking purposes only.

²² **Note 7:** Use level not in finished food.

²³ **Note 100:** For use as a dispersing agent in dill oil used in the final food.

²⁴ **Note XX;** Use level singly, not to exceed 15,000 mg/kg in combination

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for polysorbates in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	1000	mg/kg		6	
05.3	chewing gum	5000	mg/kg		6	
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	3000	mg/kg		6	
06.4.2	dried pastas and noodles and like products	5000	mg/kg		3	
06.4.3	pre-cooked pastas and noodles and like products	5000	mg/kg		3	
06.6	batters (e.g., for breading or batters for fish or poultry)	5000	mg/kg	Note 2 ²⁵	6	
07.0	Bakery wares	3000	mg/kg	Note 11²⁶	6	<p>1) Interaction with proteins: the arrangement of links between the chain of ethene 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 CO₂ 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.</p> <p>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.</p> <p>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.</p> <p>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 the enhance of the marrow soft in</p>

²⁵ **Note 2:** On dry ingredient, dry weight, dry mix or concentrate basis.

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for polysorbates in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
						bakery products.
08.2	processed meat, poultry, and game products in whole pieces or cuts	5000	mg/kg		6	
08.3	processed comminuted meat, poultry, and game products	5000	mg/kg		6	
08.4	edible casings (e.g., sausage casings)	1500	mg/kg		6	
10.4	egg-based desserts (e.g., custard)	3000	mg/kg		6	
12.2.1	herbs and spices	2000	mg/kg		6	
12.2.2	seasonings and condiments	5000	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	3000	mg/kg		6	
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	5000	mg/kg		6	
12.6.3	mixes for sauces and gravies	5000	mg/kg	Note 127²⁷	6	
12.6.4	clear sauces (e.g., fish sauce)	5000	mg/kg		6	
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	2000	mg/kg		6	
12.9.5	other protein products	4000	mg/kg	Note 15 ²⁸	6	
13.6	food supplements	25,000	mg/kg		6	<p>Polysorbates are used in food supplements, particularly in soft gelatin capsules. In capsules it is used to disperse and emulsify the active components (e.g. vitamins and minerals) in the paste formulations. This also has the beneficial effect of dispersing the contents of the capsule more rapidly in the digestive system. A second and important function of the polysorbates is as an edible surfactant in the capsule fill. They help to improve the delivery of odiferous and unpleasant tasting active components such as fish oils. The polysorbates disperse and emulsify the oil in the stomach and therefore reduce the impact of post-ingestion odour/reflux.</p> <p>All applications can be accommodated within a maximum level of 25000mg / kg. A daily intake of capsules would only deliver a maximum of 135mg polysorbates (JECFA ADI is 25mg / kg bw / d).</p> <p>Polysorbate 80 (INS 433) has two current technological applications in soft food supplement capsules:</p> <p>As an edible surfactant to improve the delivery of odiferous / unpleasant tasting substances such as fish and</p>

²⁶ **Note 11** Flour basis.

²⁷ **Note 127:** As served to the consumer

²⁸ **Note 15:** Fat or oil basis.

Recommendation 2 - Polysorbates, INS 432, 433, 434, 435, 436						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for polysorbates in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
						<p>fish-liver oils. The polysorbate 80 disperses and emulsifies the oil in the stomach and reduces post-ingestion odour / reflux.</p> <p>As an agent for dispersing and emulsifying the non oil-soluble micronutrients (vitamins and minerals) in some formulations containing high mineral levels.</p> <p>a) Usage Levels</p> <p>To achieve the required technological effects the polysorbate 80 has to be used at about 2.5% of the capsule fill. The fill represents a proportion of the total capsule weight with the shell making up the rest. Soft capsules are designed to be swallowed and thus there is a size limitation. This is related to a weight of about 1850 mg/capsule.</p> <p>The usage level of the polysorbate in the capsules is in the range 20 – 45 mg/capsule depending upon the formula. In the worse case of a larger capsule recommended to be taken three times a day the maximum daily intake of the polysorbate 80 is calculated as 135 mg/day. Most of the products deliver a much lower amount.</p> <p>When the above usage is calculated in terms of mg/kg product the levels currently in products fall within the range 6000 – 25000 mg/kg. However, it should be appreciated that one kg of product could represent many hundreds of daily doses. For example, even at the highest capsule weight 1 kg represents 540 capsules, or over a year's supply for one person.</p>
14.1.4	water-based flavoured drinks, including "sport," "energy" or "electrolyte" drinks and particulated drinks	500	mg/kg	Note 127 ²⁹	3	<p>1) Polysorbates are needed in these applications for emulsification and stabilisation:</p> <p>2) Based on information from our members, use levels generally do not exceed 500 mg/kg in ready-to-drink products. The inherent flavor of polysorbates limits their use levels in beverages.</p>
14.2.6	distilled spirituous beverages containing more than 15% alcohol	120	mg/kg		6	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	120	mg/kg		6	
16.0	composite foods - foods that could not be placed in categories 01 - 15	1000	mg/kg		6	

²⁹ **Note 127** As served to the consumer.

POLYVINYL ALCOHOL (INS 1203)

33. The 61st JECFA (2003) assigned an ADI of 50 mg/kg bw/d for polyvinyl alcohol.

Recommendation 1 - Polyvinyl Alcohol, INS 1203						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for polyvinyl alcohol in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
13.6	food supplements	45000	mg/kg		3	<p>1) Available information indicates that an ML of 20,000 mg/kg, rather than the higher 45,000 mg/kg for polyvinyl alcohol in food category 13.6 is adequate for film-coating formulations applied to dietary supplement products and is representative of GMP for such applications.</p> <p>2) Polyvinyl Alcohol is used in food supplements, mainly as a coating, sealing and surface finishing agent. It has specific properties that enable it to help with film-forming in aqueous film-coatings for food supplement tablets. Polyvinyl alcohol possesses good moisture and oxygen barrier properties which are essential in a film-coating to protect sensitive active ingredients such as vitamins and to ensure that the expected shelf life of the product can be met. All applications are likely to be met within a maximum level of 45000 mg/kg.</p>

Recommendation 2 - Polyvinyl Alcohol, INS 1203						
The eWG recommends that the 39 th CCFA <u>discontinue</u> on the following adopted food additive provisions for polyvinyl alcohol in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2000	mg/kg		3	The following justification was provided, but it was not supported by any Codex members.
05.1.4	cocoa and chocolate products	15000	mg/kg		3	The migration of moisture is an ongoing problem in maintaining high quality standards for various foods. An important need exists to develop new and improved coatings to be used as barriers to prevent moisture migration.
06.3	breakfast cereals, including rolled oats	5000	mg/kg		3	
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	15000	mg/kg		3	
						<p>PVA is used as a coating agent, surface finishing agent, polish finishing agent and film forming agent in food, food supplements and pharmaceutical products. It is an ideal glazing agent, especially in applications where moisture barrier/protection properties are required. PVA is being evaluated in various foods where individual components of the food require protection from moisture, in order to retain the overall, satisfactory taste, texture and quality of the food. The foods include high moisture foods such as ice creams and frozen yoghurt desserts with moisture-sensitive inclusions such as nuts, cookie pieces, and toffee bits, or in foods incorporating low to intermediate moisture components including ready-to-eat savouries such as nut and fruit mixes, as well as cereals and cereal products such as ready-to-eat breakfast cereals containing dried fruits or nuts. An improved coating is needed to protect these moisture sensitive inclusions added to foods. In addition multi-component chocolate bars, confectionery products (hard and soft candy) and chewing gum are also being evaluated for PVA use in order to preserve the integrity of the moisture-sensitive constituents.</p> <p>PVA is characterized by good film strength and adhesion qualities when used as a component of tablet coating formulations. PVA is currently commercially used on food supplement tablets.</p>

Recommendation 2 - Polyvinyl Alcohol, INS 1203						
The eWG recommends that the 39 th CCFA <u>discontinue</u> on the following adopted food additive provisions for polyvinyl alcohol in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
						PVA protects the active ingredients from moisture, oxygen and other environmental components, while simultaneously masking their taste and odour. It allows for easy handling of finished product and facilitates ingestion and swallowing. The viscosity of PVA allows for the application of the PVA containing film coating agents to tablets, capsules and other forms to which film coatings are typically applied at relatively high solids contents.

PROPYLENE GLYCOL ESTERS OF FATTY ACIDS (INS 477)

34. The 25th CAC has adopted at Step 8 several provisions for the use of propylene glycol esters of fatty acids.

35. The JECFA has assigned an ADI of 25 mg/kg bw for propylene glycol esters of fatty acids.

Recommendation - Propylene Glycol Esters of Fatty Acids, INS 477						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for propylene glycol esters of fatty acids in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
05.1.1	cocoa mixes (powders) and cocoa mass/cake	5000	mg/kg	Note 97 ³⁰	8	Add Note 97 for consistency with commodity standards. Food category 05.1.1 includes only standardized foods.
06.4.3	pre-cooked pastas and noodles and like products	5000	mg/kg	Note 2 ³¹	3	Identical provision is adopted in CX STAN 249

QUILLAIA EXTRACTS (INS 999)

36. The CAC has adopted at Step 8 provisions in the GSFA for the use of quillaia extracts. The only provision under consideration for inclusion in the GSFA is for use in food category 14.1.4.

37. Quillaia extracts were reviewed toxicologically by the 26th JECFA (1982). The available toxicological data included adequate lifetime studies in mice and rats, from which a NOEL was identified. However, in the absence of data, no specifications were prepared, and, hence, no ADI could be allocated. The 29th JECFA (1985) prepared new tentative specifications and established an ADI of 0–5mg/kg bw.

38. The 57th JECFA's (2001) evaluation of quillaia extracts was conducted in response to a request by the 32nd CCFAC that the JECFA re-evaluate all relevant information on the toxicity and, in particular, the intake of quillaia extracts. No new data were submitted to the 57th JECFA and therefore, the JECFA evaluated published reports on quillaia extracts or specific saponins that provided information relevant to a toxicological assessment of quillaia extracts. The 57th JECFA revised the tentative specifications for quillaia extract and maintained them as temporary.

39. The report of the 57th JECFA concluded that the use at a maximum level of 95–100mg/day (that reported by the manufacturers), as in the UK and the USA, appeared to be adequate for achieving the technological function as a foaming agent in soft drinks and did not appear to result in intakes that exceed the ADI. Young children are a possible exception, but, as the results of a short-term nutritional survey were used, the frequency or duration of their potential excursion above the ADI could not be determined.

40. The 57th JECFA recommended that the CCFAC review the use of quillaia extracts at 500 mg/kg as proposed in the draft GSFA.

41. The 61st JECFA (2003) assigned an ADI of 5 mg/kg bw for quillaia extracts with a saponin content of 20 - 26% (Quillaia Extract Type 1). The JECFA was unable to assign an ADI for quillaia extracts with a saponin content of 75 - 90% (Quillaia Extract Type 2) due to limited information on the qualitative and quantitative composition of quillaia extract type 2.

³⁰ **Note 97:** In the finished product/final cocoa and chocolate products.

³¹ **Note 2:** On dry ingredient, dry weight, dry mix, or concentrate basis.

42. The 63rd JECFA (2005) converted the ADI for Quillaia Extract Type 1 to an ADI based on saponin content using the lower end of the specified saponin range, and established as a group ADI of 5 mg/kg bw for quillaia extract type 1 and quillaia extract type 2.

43. An assessment of dietary exposure considered the additional use of quillaia extract type 1 in semi-frozen carbonated and non-carbonated beverages (up to 500 mg/kg product). Using a model diet approach, high-percentile consumption was estimated to lead to an exposure of 44 to 157% of the ADI, assuming the presence of quillaia extract type 1 at 295 mg/l in all water-based flavoured drinks. Using a probabilistic exposure assessment and assuming that the frequency and amount per eating occasion are independent variables, the estimated dietary exposure was below the ADI at the 90th percentile. Assuming 100% dependency between frequency and amount consumed, it is estimated that 100-700 individuals per million over the whole population could exceed the ADI under these conditions.

Recommendation 1 – Quillaia Extract, INS 999				
The eWG recommends that the 39 th CCFA revoke the following food additive provision for quillaia extract in the GSFA.				
Food Cat No.	Food Category	Max Level		Comments
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	100	mg/kg	

Recommendation 2 - Quillaia Extract, INS 999						
The eWG recommends that the 39 th CCFA adopt the following food additive provision for quillaia extract in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	50	mg/kg	Note 132 ³² , Note C ³³	6	The maximum level should be based on Quillaia Extract Type 1 [INS 999 (i)]. Therefore, the maximum level based on saponin basis can be derived from the specification of Quillaia Extract Type 1 ("Saponin content: not less than 20 % and not more than 26 % on the dried basis") by taking the upper level of the saponin content and multiplying that with the proposed maximum level resulting in a maximum level expressed on dried saponin basis:

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

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

45. 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).

46. 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.

47. 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

³² **Note 132:** Except for use at **130 mg/kg** (dried basis) in semi-frozen beverages.

³³ **Note C:** Quillaia Extract Type 1 (INS 999(i) only). Acceptable maximum use level is expressed on saponin basis

- 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

48. 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

Revise the GSFA listings for sulphites to associate the food additive functional classes of preservative, antioxidant, and bleaching agent to make the GSFA consistent with the Codex International Numbering System.

Recommendation 2 – Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539

The eWG recommends that the 39th CCFA **discontinue** further work on the following food additive provisions for sulphites in the GSFA.

Food Cat No.	Food Category	Max	Level	Comments	Step
04.1.2.4	canned or bottled (pasteurized) fruit	350	mg/kg	Note 44	6
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	50	mg/kg	Note 44	6
07.1.1	breads and rolls	50	mg/kg	Note 44	6
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	50	mg/kg	Note 44	6
07.1.4	bread-type products, including bread stuffing and bread crumbs	50	mg/kg	Note 44	6
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	500	mg/kg	Note 44	6
16.0	composite foods - foods that could not be placed in categories 01 - 15	350	mg/kg	Note 44	6

Recommendation 3 - Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539

The eWG recommends that the 39th CCFA **adopt** the following food additive provisions for sulphites in the GSFA.

Food Cat No.	Food Category	Max Level	Comments	Step	Justification
04.1.2.1	frozen fruit	500 mg/kg	Note 44 ³⁴	6	Sulfites act as an anti-browning agent in frozen sliced apples.
04.1.2.5	jams, jellies and marmelades	500 mg/kg	Note 44	6	1) Sulfites act as a preservative and antioxidant in these foods. 2) 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
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
09.2.4.2	cooked mollusks, crustaceans, and echinoderms	30 mg/kg	Note 44	6	1) Black spots (melanosis) form on crustaceans within a few hours after harvest without refrigeration. The reaction is an enzymatic process that involves the oxidation of phenols to quinones by polyphenol oxidase (PPO). Subsequently a non-enzymatic polymerization of the quinones occurs, leading to the formation of dark, high molecular weight pigments
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and	30 mg/kg	Note 44	6	The direct intervention of polyphenol oxidase

³⁴ **Note 44:** As residual SO₂.

Recommendation 3 - Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for sulphites in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
09.4	echinoderms fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg	Notes 44 & 140 ³⁵	6	<p>causes "melanosis" in the shell of the crustaceans during the period of post-capture which decreases the perceived quality of the shrimp by consumers and reduces its commercial value.</p> <p>The function of sulphites consists of reducing the formation of o-quinones, which are the precursory compounds of melanin, to maintain the product with its natural colour during the commercial distribution (4-5 days).</p> <p>Sodium metabisulphite is the principal product used in the prevention of "melanosis" in crustaceans and it's used in dusting or dipping. Residues in edible parts will depend on the quantity to be introduced into the muscle, influencing several factors as size of the pieces, physiological state, pH, temperature, etc. The product is applied at the moment of the capture and the time passed until the application is critical for the final quality of the product.</p> <p>In theory a considerable reduction of the SO₂ levels during the cooking process would be expected due to dilution in the cooking water. Nevertheless, in practice, the cooking results only in a limited reduction of the SO₂ levels from the fresh product in the cooked product. This is shown in a study performed in Spain in which 235 samples of prawns were examined in order to know the content in SO₂ before and after the cooking. It was found that the average factor between the cooked/crude level is 1.03, which confirms the absence of reduction of the SO₂ levels during this processing. Summarised results of the study are given in table 1 of the Annex.</p> <p>Therefore, the proposed level of SO₂ in food categories 09.2.4.2, should be aligned with the level for food category 09.1.2 <i>fresh mollusks, crustaceans, and echinoderms</i>. Consequently, <i>mollusks, crustaceans, and echinoderms</i> covered by categories 09.2.5 and 09.4 and produced from fresh products in category 09.1.2 could be expected to have a similar level of SO₂ as a result of a carry over.</p> <p>2) The sulphite level of 30 mg/kg for cooked product is justified to prevent higher levels of up to 100 mg/kg in the cooked product through the application of the carry over principle (For example by cooking fresh product with up to 300 mg/kg of sulphite).</p>
11.3	sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	70	mg/kg	Note 44	6	<p>1) Sulphites are necessary to preserve these products notably the molasses. The use of sulphites in such products at a maximum level of 70 mg/kg would not contribute significantly to the sulphite intake.</p> <p>2) Sodium Metabisulphite is used as a bleaching agent to decolourize syrups. The proposed maximum use level of 70 mg/kg is justified to achieve the intended technical need as a bleaching agent.</p> <p>3) 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</p> <p>4) This food category corresponds to a non-standardized and very heterogeneous group of products including molasses and other concentrated products whose contribution to the</p>

³⁵ **Note 140:** Except for use in canned abalone (PAUA) at 1000 mg/kg.

Recommendation 3 - Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for sulphites in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification
						sulphite intake is limited, particularly at a maximum level of 70 mg/kg. Sulphites can be used as an additive, in particular as a preservative, on these products and their use is authorized by the EU legislation, which sets a maximum level of 70 mg/kg. Suppressing the proposed level of 70 mg/kg may in addition, not serve the purpose of Codex to eliminate unnecessary trade barriers.
12.4	mustards	250	mg/kg	Notes 44 & 106 ³⁶	6	<p>1) The use of sulphites is essential in mustards in order to ensure the good preservation of the products, to guarantee their colour, their shelf life and their organoleptic quality. In the absence of sulphites, the product oxidises quickly, resulting in browning and formation of undesirable flavours. No other additive could show equivalent properties.</p> <p>It is imperative to maintain a maximum level of 250 mg/kg in mustards in general and of 500 mg/kg in more sensitive Dijon mustard. Moreover, sulphites are very volatile. For example for Dijon mustard, after processing (mixture, crushing etc), and taking into account the loss related to the conditions of temperature, the content of sulphites in the product at the time of the marketing would be only 300 mg/kg.</p> <p>In terms of sulphite intake, it must be pointed out that mustard in general and Dijon mustard in particular are strong products in taste which are consumed in very small quantities and in an irregular way.</p> <p>2) 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</p>
12.5	soups and broths	1000	mg/kg	Note 44	6	Complex mode of action by liberating sulphur dioxide; inhibits growth of micro organisms. Inhibits enzymes, anti-oxidant.
12.6	sauces and like products	300	mg/kg	Note 44	6	Complex mode of action by liberating sulphur dioxide; inhibits growth of micro organisms. Inhibits enzymes, anti-oxidant.
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	350	mg/kg	Note 44 & X ³⁷	6	<p>1) Aromatized alcoholic beverages are often relatively high in sugar but have lower alcohol levels compared with still wine there is increased potential for microbiological spoilage which can be controlled with adequate additions of sulphites.</p> <p>2) In wine, sulfiting agents are indispensable and perform several functions simultaneously. In the grape must, sulfur dioxide prevents enzymatic browning (particularly important for white wines), inhibits the growth of undesirable acetic or lactic acid bacteria and, by its selective antimicrobial effects, ensures that the required yeast dominates the fermentation. In the finished wine, sulfur dioxide stabilizes the colour, acts as an antimicrobial agent and antioxidant on storage and serves to trap acetaldehyde. In beer brewing, sulfur dioxide has some other important functions in addition to its selective antimicrobial activity. Addition of sulfur dioxide during malting increases the extractability of the malt; this additive is also used in the drying of hops and in reducing the formation of nitrosamines during kilning of the malt. In the finished beer, sulfur dioxide functions as an antioxidant in stabilizing the</p>

³⁶ **Note 106:** Except for use in Dijon mustard at 500 mg/kg.

³⁷ **Note X:** Acceptable maximum level based on combined state of total sulphites, this is equivalent to 70 mg/kg in the free state.

Recommendation 3 - Sulphites, INS 220, 221, 222, 223, 224, 225, 227, 228, 539						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for sulphites in the GSFA.						
Food Cat No.	Food Category	Max Level	Comments	Step	Justification	
					flavor. 3) The level of 350 mg/kg of sulphites (<u>in the combined state</u>) applies in the Canadian standard for wine (70 mg/kg of sulphites in the free state). These levels were recently confirmed with the Canadian Vintners Association and they would also apply in aromatized wines. (It may be helpful to provide a note explaining the combined state of sulphites.) Aromatized wines are alcoholic products obtained from wines to which alcohol has been added along with flavouring substances, including aromatic herbs. Sulfites exert the same antimicrobial and antioxidant function in aromatized wines as in standardized wines and will be present in aromatized wines at the same level. 4): Used as an antioxidant in aromatized alcoholic beverages.	

TERTIARY BUTYLHYDROXYQUINONE (TBHQ) (INS 319)

49. The 28th CAC has adopted several provisions in the GSFA for the use of TBHQ.

50. The 29th CCFAC requested that JECFA perform intake assessments for TBHQ based on the pending levels of maximum use in the GSFA.. TBHQ was identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to their intake exceeding their ADI. The 51st JECFA (1998) reviewed national intake data on TBHQ.

51. The 51st JECFA's exposure assessment identified the following for closer scrutiny by the CCFAC.

- 02.0 Fats and oils, and fat emulsions (type water-in-oil)
- 09.2 Processed fish and fish products, including molluscs, crustaceans and echinoderms
- 14.1.4 Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks

52. JECFA has assigned an ADI of 0-0.7 mg/kg bw for TBHQ.

Recommendation - Tertiary Butylhydroxyquinone (TBHQ), INS 319						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for TBHQ in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
01.3.2	beverage whiteners	100	mg/kg	Notes 15 ³⁸ & 130 ³⁹	3	To prevent oxidation of vegetable fat component of these foods
08.2	processed meat, poultry, and game products in whole pieces or cuts	100	mg/kg	Notes 15 & 130, Note B	6	1) Unsaturated fats are susceptible to oxidation which causes fat rancidity. In the case of dehydrated meat products the moisture content is reduced and the fat content is relatively high. The high fat content combined with lengthy storage at room-temperature makes these products more sensitive to fat oxidation. The addition of antioxidants is therefore necessary to retard oxidation. On the other hand for non-dehydrated products such as bacon, frozen raw or cooked meat, cooked meatballs or corned beef the use of the antioxidant would <u>not</u> be justified, as oxidation should be minimized by the appropriate handling of these products i.e. efficient
08.3	processed comminuted meat, poultry, and game products	100	mg/kg	Notes 15 & 130, Note B ⁴⁰	6	

³⁸ **Note 15:** Fat or oil basis.

³⁹ **Note 130:** Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

Recommendation - Tertiary Butylhydroxyquinone (TBHQ), INS 319						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for TBHQ in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification
						transport, ideal storage conditions at low temperatures, canning and appropriate shelf life of the products. 2) Used as anti oxidizing agents which prevent discolorization while meat is in a display cabinet. Also postpone the oxidation of certain fatty acids.

PART II - SWEETENERS

53. The 38th CCFAC agreed that the eWG should take a “horizontal” approach to its discussion of the GSFA provisions for sweeteners. The eWG 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 II). The CCFA may wish to consider this list of food categories as work on the GSFA progresses.

54. Some members of the eWG proposed including additional Notes (e.g., 138,⁴¹ 144,⁴² 145⁴³) to a number of the draft (Step 6) and proposed draft (Step 3) provisions for food additive sweeteners to reduce the potential for misleading consumers, when foods are promoted as “energy reduced” or contain high intensity sweeteners. Other members of the eWG did not support adding such notes because Codex has not defined the term “energy reduced” for labeling/claims purposes. In addition, it was questioned whether such additional restrictions were necessary since the use of high intensity sweeteners to replace all or part of the sugar in full-calorie or full-sugar counterpart will result in a product that is reduced in both calories and sugar content. Moreover, some members considered these notes too specific in the context of a world-wide standard. Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet.

Recommendation 1 - Sweeteners

The eWG recommends that the 39th CCFA discuss the list of food categories for which the use of food additive sweeteners is justified (Appendix II), with a view toward reaching consensus and using the list as a working document in its future discussion of food additive sweeteners.

Recommendation 2 – Sweeteners

The eWG recommends that the 39th CCFA consider whether additional notes restricting the use of food additive sweeteners to energy reduced products etc (i.e., Notes 68,⁴⁴138⁴⁵. 144⁴⁶, 145⁴⁷, , D⁴⁸, E⁴⁹, F⁵⁰, G⁵¹, H⁵², J⁵³, K⁵⁴, L⁵⁵, M⁵⁶, N⁵⁷) should be included in the GSFA.

⁴⁰ **Note B:** For dehydrated products only

⁴¹ **Note 138:** For use in energy-reduced products only.

⁴² **Note 144:** For use in sweet and sour products only.

⁴³ **Note 145:** Products are energy reduced or with no added sugar.

⁴⁴ **Note 68** For use in products with no added sugar only.

⁴⁵ **Note 138:** For use in energy-reduced products only.

⁴⁶ **Note 144:** For use in sweet and sour products only.

⁴⁷ **Note 145:** Products are energy reduced or with no added sugar.

⁴⁸ **Note D:** For use in products for special nutritional purposes only.

⁴⁹ **Note E:** For use in products in liquid form; 500 mg/kg for use in products in solid form.

⁵⁰ **Note F:** For milk-based sandwich spreads only.

⁵¹ **Note G:** For use in products in liquid form; 2000 mg/kg for products in solid form.

⁵² **Note H:** For use in energy-reduced or alcohol-free beer only

⁵³ **Note J:** For use in products in liquid form; 500 mg/kg for products in solid form.

⁵⁴ **Note K:** For use in syrup-type or chewable products; 500 mg/kg for in products in solid form; 80 mg/kg in products in liquid form.

⁵⁵ **Note L:** Fat-based sandwich spreads

⁵⁶ **Note M:** 240 mg/kg for liquid forms, 800 mg/kg for solid forms, 2400 mg/kg for syrup-type or chewable forms

⁵⁷ **Note N:** For use in breakfast cereals with a fibre content of more than 15% and containing at least 20% bran only.

ACESULFAME POTASSIUM (INS 950)

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

Recommendation 1 – Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks
01.4	cream (plain) and the like	1000	mg/kg		3	See recommendation 3. Foods in some food sub-categories would not be expected to contain added sweeteners.
01.5	milk powder and cream powder and powder analogues (plain)	3000	mg/kg		3	
01.5.1	milk powder and cream powder (plain)		GMP		6	The use of food additive sweeteners is not justified in these food categories
01.6.1	unripened cheese	500	mg/kg		3	
05.1.1	cocoa mixes (powders) and cocoa mass/cake	2500	mg/kg		6	Category 05.1.1 contains only standardized foods and the commodity standards permit only 350 mg/kg
06.1	whole, broken, or flaked grain, including rice	300	mg/kg		3	
06.4.3	pre-cooked pastas and noodles and like products	200	mg/kg		3	
07.2.1	cakes, cookies and pies (e.g., fruit-filled or custard types)	1000	mg/kg		6	Combined under category 07.2 (see recommendation 2)
07.2.2	other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	2000	mg/kg		6	
07.2.3	mixes for fine bakery wares (e.g., cakes, pancakes)	1000	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	1000	mg/kg		6	Combined under category 12.6 (see recommendation 2)
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	500	mg/kg		6	
12.6.3	mixes for sauces and gravies	1000	mg/kg		6	
12.6.4	clear sauces (e.g., fish sauce)	500	mg/kg		6	
13.1.3	formulae for special medical purposes for infants	450	mg/kg		3	There are no non-standardized foods in this category. For consistency with the Draft revised Codex standard for infant formula
14.2.3	grape wines	500	mg/kg		3	
14.2.5	mead	500	mg/kg		3	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	350	mg/kg		3	
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	1000	mg/kg		6	Combined under category 15.0 (see recommendation 2)
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	1000	mg/kg		6	
15.3	snacks - fish based	350	mg/kg		6	

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th 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

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th 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
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	350	mg/kg	[Note 145 ⁵⁸]	6	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	350	mg/kg	[Note 145]	6	An ML of 500 mg/kg is needed to achieve the intended technical effect
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	350	mg/kg	[Note 145]	6	An ML of 500 mg/kg is needed to achieve the intended technical effect
03.0	edible ices, including sherbet and sorbet	800	mg/kg	[Note 145]	6	
04.1.2.3	fruit in vinegar, oil, or brine	200	mg/kg	[Note 145]	6	
04.1.2.4	canned or bottled (pasteurized) fruit	350	mg/kg	[Note 145]	6	
04.1.2.5	jams, jellies and marmelades	1000	mg/kg	[Note 138 ⁵⁹]	6	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	1000	mg/kg	[Note 138]	6	
04.1.2.7	candied fruit	500	mg/kg	[Note 145]	6	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 acesulfame K to bring the sweetness to the customary level.
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	350	mg/kg	[Note 138]	6	An ML of 500 mg/kg is needed to achieve the intended technical effect
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	350	mg/kg	[Note 138]	6	An ML of 500 mg/kg is needed to achieve the intended technical effect
04.1.2.10	fermented fruit products	350	mg/kg	[Note 138]	3	
04.1.2.11	fruit fillings for pastries	350	mg/kg	[Note 138]	6	An ML of 500 mg/kg is needed to achieve the intended technical effect
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	200	mg/kg	[Note 144 ⁶⁰]	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	350	mg/kg	[Note 138]	6	Intense sweeteners allow production of sweet sugar-free products. Acesulfame K was found to withstand the sterilisation conditions used for the common types of canned vegetables. The listed acesulfame K level is not sufficient to provide adequate sweetness. It is proposed to align it with the level proposed for category 04.2.2.5 (1000 mg/kg).
05.1.1	cocoa mixes (powders) and cocoa mass/cake	350	mg/kg	Note 97 ⁶¹	6	1) For consistency with Codex commodity standards. There are no non-standardized foods in this category. This category includes products for the

⁵⁸ **Note 145:** Products are energy reduced or with no added sugar.

⁵⁹ **Note 138:** For use in energy-reduced products only.

⁶⁰ **Note 144:** For use in sweet and sour products only

⁶¹ **Note 97:** In the finished product/final cocoa and chocolate products

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for acesulfame potassium in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
						preparation of cocoa-based beverages. For sugar-free products intense sweeteners can be the only source of sweetness. The listed level is necessary as the dilution to prepare a cocoa beverage can be 10 fold and even higher. A 10 fold dilution results in 250 mg/L in the beverage. 2) An ML of 2500 mg/kg is needed to achieve the intended technical effect
05.1.2	cocoa mixes (syrups)	350	mg/kg	[Note 145] Note 97	6	1) For sugar-free products intense sweeteners can be the only source of sweetness. The level listed for this category is too low to achieve the intended technological need. 2500 mg/kg is technologically needed. 2) An ML of 2500 mg/kg is needed to achieve the intended technical effect
05.1.3	cocoa-based spreads, including fillings	1000	mg/kg	[Note 145]	6	An ML of 2000 mg/kg is needed to achieve the intended technical effect
05.1.4	cocoa and chocolate products	500	mg/kg		3	A n MLof 1000 mg/kg is technologically needed
05.1.5	imitation chocolate, chocolate substitute products	500	mg/kg	[Note 145]	6	A n MLof 1000 mg/kg is technologically needed
05.2.1	hard candy	500	mg/kg	[Note 145]	6	A maximum level of 2500 mg/kg is necessary for microsweets and breath-freshening mints. Sugar-free hard 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 represents the case of need for hard candy.
05.2.2	soft candy	1000	mg/kg	[Note 145]	6	A maximum level of 2000 mg/kg is necessary for microsweets and breath-freshening mints. 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 represents the case of

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th 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
						need for soft candy.
05.2.3	nougats and marzipans	1000	mg/kg	[Note 145]	6	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 products. Use of intense sweeteners in these products is common in many countries. An ML of 2000 mg/kg represents the case of need for nougats and marzipan
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	500	mg/kg	[Note 145]	6	
06.3	breakfast cereals, including rolled oats	1200	mg/kg	[Note 145] & Note N ⁶²	6	
06.4.2	dried pastas and noodles and like products	200	mg/kg		3	1) To provide sweetness (other sweeteners are permitted) 2) Flavour enhancer / Sweetener for specific groups of products
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	350	mg/kg	[Note 145]	6	An ML of 500 mg/kg is technologically needed.
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 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.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	1000	mg/kg	[Note D ⁶³]	6	
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	[Note 144]	6	
09.4	fully preserved, including canned or	200	mg/kg	[Note 144]	3	

⁶² **Note N:** For use in breakfast cereals with a fibre content of more than 15% and containing at least 20% bran only.

⁶³ **Note D:** For use in products for special nutritional purposes only.

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th 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
	fermented fish and fish products, including mollusks, crustaceans, and echinoderms					
10.4	egg-based desserts (e.g., custard)	350	mg/kg	[Note 145]	6	An ML of 500 mg/kg is technologically needed.
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000	mg/kg		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 like acesulfame K bring their sweetness to the standard level.
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP		3	
12.4	mustards	350	mg/kg		6	
12.5	soups and broths	110	mg/kg	[Note 138]	6	
12.6	sauces and like products	1000	mg/kg			1)Used for emulsified and non-emulsified sauces 2) Flavour enhancer / Sweetener for specific groups of products. 3)Heat resistant, non-nutritive sweetener for low calorie products
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	[Note 145]	6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	500	mg/kg		6	1) Flavour enhancer / Sweetener for specific groups of products 2) These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.
13.4	dietetic formulae for slimming purposes and weight reduction	450	mg/kg		6	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	450	mg/kg		3	
13.6	food supplements	350	mg/kg	[Note E ⁶⁴]	6	1) Acesulfame Potassium is used in food supplements as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink. Usage levels depend on the application and the level of sweetness required to mask

⁶⁴ **Note E:** For use in products in liquid form; 500 mg/kg for use in products in solid form.

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for acesulfame potassium in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
						<p>unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 2000mg / kg.</p> <p>It is noted that the previous eWG recommendation only gave the maximum level of use of this sweetener in food supplements in liquid form and referred to Note 155 for the maximum level of the solid form. However, Note 155 failed to include the maximum level of use of this sweetener in food supplements supplied in a syrup-type or chewable form.</p> <p>2) Proposed Note E is confusing and incomplete because it fails to account for syrup-type or chewable forms of dietary supplements. An ML of 2000 mg/kg acesulfame potassium is needed for such products. The use of sweeteners in food supplements is very low when compared to other product categories due to the unit-dose form of supplements and their low individual weight. The highest level should be retained level determined for each sweetener for food supplements and remove the footnotes.</p>
14.1.2.2	vegetable juice	350	mg/kg	[Note 145]	6	Owing to its good stability in liquids acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. The level should be aligned with 14.1.2.1 Fruit juice. As carbohydrates from juice provide some sweetness a lower level than for water-based beverages is sufficient
14.1.2.4	concentrates for vegetable juice	350	mg/kg	Note 127, [145]	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. Allocation of a numerical level for concentrates is, however, not in line with the carry-over provisions of the preamble of the standard. It is therefore proposed to list the same level as for the ready-to drink beverages
14.1.3.4	concentrates for vegetable nectar	350	mg/kg	Note, 127, [145]	3	Owing to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages

Recommendation 2 - Acesulfame Potassium, INS 950						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for acesulfame potassium in the GSFA.						
Food Cat No.	Food Category	Max	Level	Comments	Step	Justification provided to eWG
						of all types, ready-to-drink as well as concentrates. Allocation of a numerical level for concentrates is, however, not in line with the carry-over provisions of the preamble of the standard. It is therefore proposed to list the same level as for the ready-to drink beverages.
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	350	mg/kg	[Note 145]	6	1) Acesulfame K is widely used in water-based flavoured drinks We request removal of Footnote 147 since it is unnecessary and the term "energy-reduced" is not defined by Codex. 2) 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. 3) An ML of 600 mg/kg is technologically needed.
14.2.1	beer and malt beverages	350	mg/kg		6	1) In EU permitted for use in energy-reduced or alcohol-free beer only. 2) Owing to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, including sweet types of beer. In products bottled with micro-organisms, intense sweeteners are not degraded by these.
14.2.2	cider and perry	350	mg/kg		6	Owing to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, including cider and perry.
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	350	mg/kg		3	1) Intense sweeteners are used to produce sugar-free beverages of this category. Owing to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types. 2) An ML of 500 mg/kg is technologically needed.
15.0	Ready-to-eat savouries	350	mg/kg		6	

Recommendation 3 - Acesulfame Potassium, INS 950						
Comments are requested 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
01.3.2	beverage whiteners	2000	mg/kg		3	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

Recommendation 3 - Acesulfame Potassium, INS 950						
Comments are requested 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
						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.
01.4.4	Cream analogues	1000	mg/kg		3	1) Reassigned to subcategory. 2) 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.
01.5.2	Milk and cream powder analogues	1000	mg/kg		3	1) Reassigned to subcategory. 2) 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.
01.6.5	cheese analogues	350	mg/kg		3	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. Carbohydrates may be degraded by 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

Recommendation 3 - Acesulfame Potassium, INS 950						
Comments are requested 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
						sugar-free products. The listed acesulfame K level provides adequate sweetness.
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)	2500	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.
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.
05.3	chewing gum	5000	mg/kg		6	1) 3500 mg/kg is technologically justified. 2) Acesulfame K is technologically needed at levels up to 5.000 mg per kilogram of chewing gum. Although the literature notes its solubility in water of 27 grams in 100 ml, acesulfame K does not dissolve rapidly in the mouth and, therefore, requires this level to compensate for this delayed sensory perception 3) There is trade in chewing gum containing 5000 mg/kg. For example, India, Kenya, South Korea, Malaysia, Japan, Philippines, Hong Kong, and Vietnam have set an ML of 5000 mg/kg. In addition, Mexico, Taiwan, Singapore and the USA have established a GMP limit.
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	[Note 144]		Proposed new use.
12.2	herbs, spices, seasoning, 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.

Recommendation 3 - Acesulfame Potassium, INS 950						
Comments are requested 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
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 145]		1) Proposed new use 2) 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. 3) An ML of 500 mg/kg is technologically needed without note 145
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	600	mg/kg		3	1) Acesulfame potassium is widely use in canned coffees 2) 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.
14.2.4	wines (other than grape)	500	mg/kg		3	Owing to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, including cider and perry
16.0	composite foods - foods that could not be placed in categories 01 - 15	350	mg/kg		3	Permitted in jelly and dairy and fat based desserts, dips and snacks

ALITAME (INS 956)

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

Recommendation 1 - Alitame, INS 956						
The eWG recommends that the 39 th 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks
01.4	cream (plain) and the like	100	mg/kg		6	No technological need identified
05.0	confectionery	300	mg/kg		6	There are no non-standardized foods in food category 05.1.1 and the relevant Codex commodity standards do not provide for the use of alitame
07.0	bakery wares	200	mg/kg		6	Limited to subcategory 07.1 (see recommendation 2)

Recommendation 2 - Alitame, INS 956						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for alitame 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)	100	mg/kg	[Note 145]	6	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured	100	mg/kg	[Note 145]	6	

Recommendation 2 - Alitame, INS 956						
The eWG recommends that the 39 th CCFA adopt the following food additive provisions for alitame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
	yoghurt)					
03.0	edible ices, including sherbet and sorbet	100	mg/kg	[Note 145]	6	
04.1.2.5	jams, jellies and marmelades	100	mg/kg	[Note 138]	6	
05.1.2	cocoa mixes (syrops)	300	mg/kg		6	Alitame is technologically needed at up to 300 mg/kg of chewing gum. It has 2000 times the sweetness of sucrose and provides a very clean sugary sweet taste with no aftertaste. Alitame also provides the following additional benefits: It is a significantly more potent sweetener than aspartame, acesulfame K, saccharin, cyclamates and sucralose, so less is required for a given level of sweetness. It has a much better taste quality and is more thermally and hydrolytically stable than some of the other high intensity sweeteners, giving the chewing gum a longer shelf life.
05.1.3	cocoa-based spreads, including fillings	300	mg/kg		6	
05.1.4	cocoa and chocolate products	300	mg/kg		6	
05.1.5	imitation chocolate, chocolate substitute products	300	mg/kg		6	
05.2	confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	300	mg/kg		6	
05.3	chewing gum	300	mg/kg		6	
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces	300	mg/kg		6	
07.1	Bread and ordinary bakery wares	200	mg/kg		6	Approved for Biscuits, cakes and pastries
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	200	mg/kg		6	1) Flavour enhancer / Sweetener for specific groups of products 2) Alitame improves the sweetness and flavor profile of these products and provides hydrolytic stability. 3) Improves sweetness and flavour profile. 4) Products not based on sucrose or high-fructose corn syrup or having lower dry solids levels are less sweet than customary products. Stable sweeteners like alitame bring their sweetness to the standard level. Alitame improves sweetness and flavour profile.
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP		6	
12.5	soups and broths	40	mg/kg	[Note 145]	6	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	300	mg/kg		6	
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	40	mg/kg	[Note 145]	6	

Recommendation 3 - Alitame, INS 956						
Comments are requested on the following food additive provisions for alitame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.4.4	Cream analogues	100	mg/kg			1) Proposed new use 2) Alitame allows for the manufacture of pre-sweetened cream analogues with no added carbohydrates, no added flavours and no added other foods.

Recommendation 3 - Alitame, INS 956						
Comments are requested on the following food additive provisions for alitame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	100	mg/kg		6	Herbs, spices, seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as alitame and other intense sweeteners.

ASPARTAME, INS 951

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

Recommendation 1 – Aspartame, INS 951						
The eWG recommends that the 39 th 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks
01.4.1	pasteurized cream (plain)	6000	mg/kg		3	
01.4.3	clotted cream (plain)	6000	mg/kg		3	
10.2.3	dried and/or heat coagulated egg products	1000	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	500	mg/kg		6	Combined ML in category 12.6 (see recommendation 2)
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	350	mg/kg		6	
12.6.3	mixes for sauces and gravies	350	mg/kg		6	
12.6.4	clear sauces (e.g., fish sauce)	350	mg/kg		6	
13.1.3	formulae for special medical purposes for infants	800	mg/kg	Note 84 ⁶⁵	3	There are no non-standardized foods in this category. For consistency with the Draft revised Codex standard for infant formula

Recommendation 2 - Aspartame, INS 951						
The eWG recommends that the 39 th 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
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	600	mg/kg	[Note 145]	6	
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	6000	mg/kg		3	1) Approved for Cream, reduced cream and light cream) 2) It used at a level of 1000 mg/kg for whipping cream as an artificial sweetener when significantly lower energy values are needed for lower calorie products.
01.5.2	milk and cream powder analogues	2000	mg/kg		6	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 milk and cream powders with no added carbohydrates, no added flavours and no other added foods.
01.7	dairy-based desserts (e.g.,	1000	mg/kg	[Note 145]	6	

⁶⁵ **Note 84:** For infants over 1 year of age only.

Recommendation 2 - Aspartame, INS 951						
The eWG recommends that the 39 th 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
	pudding, fruit or flavoured yoghurt)					
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	1000	mg/kg	[Note 145]	6	
03.0	edible ices, including sherbet and sorbet	1000	mg/kg	[Note 145]	6	
04.1.2.3	fruit in vinegar, oil, or brine	300	mg/kg	[Note 144]	6	
04.1.2.4	canned or bottled (pasteurized) fruit	1000	mg/kg	[Note 145]	6	Fruits are often sterilised in the presence of sugar. Intense sweeteners allow production of sweet sugar-free products. The listed level provides adequate sweetness.
04.1.2.5	jams, jellies and marmelades	1000	mg/kg	[Note 138]	6	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	1000	mg/kg	[Note 138]	6	1) There are fruit spreads on the Canadian market which contain amounts of aspartame at this level of use. 2) For these products, considerations as for jams, jellies and marmalades apply. The listed level provides adequate sweetness.
04.1.2.7	candied fruit	2000	mg/kg	[Note 145]	6	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 to bring the sweetness to the customary level.
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	1000	mg/kg	[Note 138]	6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	1000	mg/kg	[Note 145]	6	
04.1.2.10	fermented fruit products	1000	mg/kg	[Note 138]	6	
04.1.2.11	fruit fillings for pastries	1000	mg/kg	[Note 138]	6	
04.1.2.12	cooked fruit	1000	mg/kg	[Note 145]	6	
04.2.2.3	vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine, or soy sauce	300	mg/kg	[Note 144]	3	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.
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 138]	6	
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	1000	mg/kg	[Note 138]	6	
05.1.1	cocoa mixes (powders) and	3000	mg/kg	Note 97	6	1) For consistency with Codex

Recommendation 2 - Aspartame, INS 951						
The eWG recommends that the 39 th 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
	cocoa mass/cake					commodity standards. There are no non-standardized foods in this category. 2) This category includes products for the preparation of cocoa-based beverages. For sugar-free products intense sweeteners can be the only source of sweetness. The listed level is necessary as the dilution to prepare a cocoa beverage can be 10 fold and even higher.
05.1.2	cocoa mixes (syrups)	1000	mg/kg	[Note 145]	6	This category includes products for the preparation of cocoa-based beverages. For sugar-free products intense sweeteners can be the only source of sweetness. The listed level is necessary as the dilution to prepare a cocoa beverage can be 10 fold and even higher.
05.3	chewing gum	10000	mg/kg	[Note 68 ⁶⁶]	6	1) 10,000 mg/kg of aspartame (provision under the Canadian Regulations) corresponds to the level of this sweetener in chewing gums on the Canadian market. 2) Aspartame is technologically needed at levels up to 10,000 mg per kilogram of chewing gum. Aspartame provides a very clean sweet taste with no after-taste. Aspartame is much less soluble than sucrose and requires a higher use level to achieve a sweetness impact compared to a sucrose-sweetened product. Its benefit over the Saccharin product is its clean after-taste. 3) Aspartame is technologically needed at levels up to 10000 mg/kg. Aspartame provides a very clean sweet taste with no after-taste. Aspartame is much less soluble than sucrose and requires a higher use level to achieve a sweetness impact compared to a sucrose-sweetened product. The sweetener is released progressively as the gum is chewed.
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1000	mg/kg	[Note 145]	6	
06.3	breakfast cereals, including rolled oats	1000	mg/kg	[Note 145, & N ⁶⁷]	6	
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	1000	mg/kg	[Note 145]	6	
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.

⁶⁶ **Note 68** For use in products with no added sugar only.

⁶⁷ **Note N:** For use in breakfast cereals with a fibre content of more than 15% and containing at least 20% bran only

Recommendation 2 - Aspartame, INS 951						
The eWG recommends that the 39 th 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
						<p>2) To provide sweetness (other sweeteners are permitted)</p> <p>3) Used in some breads to improve taste.</p> <p>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.</p>
07.2	fine bakery wares (sweet, salty, savoury) and mixes	1700	mg/kg	[Note D]	6	
09.2	processed fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg	[Note 144]	6	
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg	[Note 144]	6	
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg	[Note 144]	3	
10.4	egg-based desserts (e.g., custard)	1000	mg/kg	[Note 145]	6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	3000	mg/kg		6	<p>1) Used for syrups.</p> <p>2) Used in various pancake syrups not including maple syrup</p> <p>3) Flavour enhancer / Sweetener for specific groups of products</p>
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP		6	
12.4	mustards	350	mg/kg		6	
12.6	Sauces and like products	350	mg/kg		6	
12.7	salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	350	mg/kg	[Note 145, F⁶⁸]	6	Some vegetable salads falling in this category contain some vinegar, the taste of which has to be mellowed as discussed for category 12.3 vinegar.
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	1000	mg/kg		6	<p>1) Flavour enhancer / Sweetener for specific groups of products</p> <p>2) Aspartame is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance</p>

⁶⁸ **Note F:** For milk-based sandwich spreads only.

Recommendation 2 - Aspartame, INS 951						
The eWG recommends that the 39 th 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
						with an otherwise very restricted diet.
13.4	dietetic formulae for slimming purposes and weight reduction	800	mg/kg		6	
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		6	
13.6	food supplements	600	mg/kg	[Note G ⁶⁹]	6	<p>1) Aspartame is used in food supplements (category 13.6) as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink. Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 5500mg / kg.</p> <p>2) Proposed Note G is confusing and incomplete as it fails to account for the use of aspartame in syrup-type or chewable forms of dietary supplements. An ML of 5500 mg/kg aspartame is needed in these types of products.. The use of sweeteners in food supplements is very low when compared to other product categories due to the unit-dose form of supplements and their low individual weight. The highest level should be retained level determined for each sweetener for food supplements and remove the footnotes.</p> <p>3) An ML of 5500 mg/kg is needed to achieve the intended technical effect.</p>
14.1.2.2	vegetable juice	600	mg/kg	[Note 145]	6	Aspartame is widely used in beverages of all types, ready-to-drink as well as concentrates.
14.1.2.4	concentrates for vegetable juice	600	mg/kg	Note 127, [Note 145]	6	
14.1.3.2	vegetable nectar	600	mg/kg	[Note 145]	6	
14.1.3.4	concentrates for vegetable nectar	600	mg/kg	Note 127, [Note 145]	6	
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	600	mg/kg	[Note 145]	6	
14.2.1	beer and malt beverages	600	mg/kg	[Note H ⁷⁰]	6	
14.2.2	cider and perry	600	mg/kg		6	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic	600	mg/kg		6	

⁶⁹ **Note G:** For use in products in liquid form; 2000 mg/kg for products in solid form.

⁷⁰ **Note H:** For use in energy-reduced or alcohol-free beer only

Recommendation 2 - Aspartame, INS 951						
The eWG recommends that the 39 th 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
	refreshers)					

Recommendation 3 - Aspartame, INS 951						
Comments are requested on the following food additive provisions for aspartame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.3.2	beverage whiteners	6000	mg/kg		3	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.
01.4.4	cream analogues	1000	mg/kg		6	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.
01.5.1	milk powder and cream powder (plain)	5000	mg/kg		3	Approved for Dried milk, milk powder, cream powder
01.6.1	unripened cheese	1000	mg/kg		3	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.
01.6.5	cheese analogues	1000	mg/kg		6	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.
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1000	mg/kg		3	Aspartame 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	2000	mg/kg		3	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.
04.1.2.2	dried fruit	3000	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 level provides adequate sweetness.
04.2.2.1	frozen vegetables (including	1000	mg/kg		6	Sweetening agents can balance the acidity of vinegar used in these

Recommendation 3 - Aspartame, INS 951						
Comments are requested on the following food additive provisions for aspartame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
	mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds					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.
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	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.
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	Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed aspartame 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)	3000	mg/kg		6	Some products of this category are sweet. Aspartame 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	1000	mg/kg		6	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.
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.
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.
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.
05.2.1	hard candy	10000	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 hard 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 10,000 mg/kg represents the case of need for hard candy.
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

Recommendation 3 - Aspartame, INS 951						
Comments are requested on the following food additive provisions for aspartame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						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.
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 level of sugar-based 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
08.2	processed meat, poultry, and game products in whole pieces or cuts	300	mg/kg		6	Flavour enhancer / Sweetener for specific groups of products, e.g. low calorie products. Heat resistant
08.3	processed comminuted meat, poultry, and game products	300	mg/kg		6	Flavour enhancer / Sweetener for specific groups of products, e.g. low calorie products. Heat resistant
12.2.2	seasonings and condiments	2000	mg/kg		6	Seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as aspartame and other intense sweeteners.
12.3	vinegars		GMP		3	1) Numeric ML of 2000 mg/kg is proposed. 2) Vinegar is sometimes rounded and mellowed by addition of sweet-tasting, flavour-enhancing products. Aspartame is stable in vinegar and balances its acidity well.
12.5	soups and broths	600	mg/kg		6	1) An ML of 110 mg/kg with Note 138 is technologically justified. 2) An ML of 600 mg/kg is technologically justified.
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	5000	mg/kg		3	1) ICBA members produce canned coffees that are served hot but no use of aspartame has been reported in these products 2) Owing to its good stability in liquids aspartame is widely used in beverages of all types, ready-to-drink as well as concentrates.
14.2.4	wines (other than grape)	700	mg/kg		6	Intense sweeteners are widely used in these beverages, including cider and perry.
14.2.5	mead	700	mg/kg		6	Technological need is questioned
14.2.6	distilled spirituous beverages containing more than 15% alcohol	700	mg/kg		6	To provide sweetness (other sweeteners are permitted)
15.0	ready-to-eat savouries	500	mg/kg		6	1) Products should be placed into appropriate categories. 2) Snacks may be salted, spicy, or

Recommendation 3 - Aspartame, INS 951						
Comments are requested on the following food additive provisions for aspartame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						sweetened. For sugar-free sweetened products intense sweeteners like Aspartame have to be used.

ASPARTAME-ACESULFAME, (INS 962)

58. 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).

59. 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 recommends 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 113⁷¹ and 119⁷² 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).

60. 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.

⁷¹ **Note 113:** Use level reported as acesulfame potassium equivalents.

⁷² **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 39 th 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks
01.4.1	pasteurized cream (plain)	2270	mg/kg	Note 113	3	
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	2270	mg/kg	Note 113	3	
01.4.3	clotted cream (plain)	2270	mg/kg	Note 113	3	
01.5.1	milk powder and cream powder (plain)	6820	mg/kg	Note 113	3	
01.6.1	unripened cheese	1130	mg/kg	Note 113	3	
05.1.1	cocoa mixes (powders) and cocoa mass/cake	4660	mg/kg	Note 119	3	There are no non-standardized foods in this category and the relevant Codex standards (105 & 141) do not provide for the use of this food additive.
05.2.1	hard candy	5680	mg/kg	Notes 113 & 145	3	Combined ML in category 05.2 (see recommendation 2)
05.2.2	soft candy	4540	mg/kg	Notes 113 & 145	3	
05.2.3	nougats and marzipans	2270	mg/kg	Notes 113 & 145	3	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	770	mg/kg	Note 119	3	Combined ML in category 12.6 (see recommendation 2)
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	540	mg/kg	Note 119	3	
12.6.3	mixes for sauces and gravies	540	mg/kg	Note 119	3	
12.6.4	clear sauces (e.g., fish sauce)	540	mg/kg	Note 119	3	
13.1.3	formulae for special medical purposes for infants	1020	mg/kg	Note 113	3	There are no non-standardized foods in this category. For consistency with the Draft revised Codex standard for infant formula
14.2.5	mead	1080	mg/kg	Note 113	3	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	790	mg/kg	Note 113	3	

Recommendation 3 – Aspartame-Acesulfame, INS 962						
The eWG recommends that the 39 th CCFA <u>adopt</u> 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 ⁷³ & 145 ⁷⁴	3	
01.3.2	beverage whiteners	4545	mg/kg	Note 113	3	
01.4.4	cream analogues	1550	mg/kg	Note 119 ⁷⁵	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 & 145	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 & 145	3	
03.0	edible ices, including sherbet and sorbet	1550	mg/kg	Notes 119 & 145	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 & 144 ⁷⁶	3	
04.1.2.4	canned or bottled (pasteurized) fruit	450	mg/kg	Notes 113 & 145	3	
04.1.2.5	jams, jellies and marmelades	550	mg/kg	Notes 119 & 138 ⁷⁷	3	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	2250	mg/kg	Notes 113 & 138	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 & 138	3	
04.1.2.9	fruit-based desserts, incl. fruit-flavoured water-based desserts	800	mg/kg	Notes 113 & 145	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 & 144	3	
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	

⁷³ **Note 113:** Use level reported as acesulfame potassium equivalents.

⁷⁴ **Note 145:** Products are energy reduced or with no added sugar.

⁷⁵ **Note 119:** Use level reported as aspartame equivalents.

⁷⁶ **Note 144:** For use in sweet and sour products only

⁷⁷ **Note 138:** For use in energy-reduced products only.

Recommendation 3 – Aspartame-Acesulfame, INS 962						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for aspartame-acesulfame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
04.2.2.5	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 & 145	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 & 145	3	
05.1.4	cocoa and chocolate products	2250	mg/kg	Notes 113 & 145	3	
05.1.5	cocoa and chocolate products	2250	mg/kg	Notes 113 & 145	3	
05.2	Confectionery	5700	mg/kg	Notes 113 & 145	3	Combined ML evel from all subcategories
05.3	chewing gum	4550	mg/kg	Notes 68 & 113	3	Aspartame-acesulfame salt is approximately 350 times sweeter than sugar. Aspartame-acesulfame salt has several advantages compared with a physical mixture of the individual sweeteners aspartame and acesulfame-K. In chewing gum it is highly important, that during chewing the taste is preserved as long as possible. A longer lasting sweetness is an essential condition for this. When using mixtures of aspartame and acesulfame-K the duration of the sweetness can be extended by encapsulating the sweeteners, thereby gradually releasing the sweetness during chewing. Aspartame-acesulfame salt does not have to be encapsulated, but already leads to a prolonged sweetness by itself. On top of that, use of the aspartame-acesulfame salt results in an extra sweetness boost after a few minutes of chewing, which leads to better tasting chewing gum for the consumer.
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	1550	mg/kg	Notes 119 &	3	

Recommendation 3 – Aspartame-Acesulfame, INS 962						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for aspartame-acesulfame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
	rolled oats			145		
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	800	mg/kg	Notes 113 & 145	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 ⁷⁸ & 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 mollusks, crustaceans, and echinoderms	450	mg/kg	Note 113	3	
10.4	egg-based desserts (e.g., custard)	800	mg/kg	Notes 113 & 145	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 & 138	3	
12.6	saucers and like products	750	mg/kg	Note 119		
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 & 145	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	1150	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 ⁷⁹	3	
14.1.3.2	Vegetable nectar	1350	mg/kg	Note 113		Proposed new use for consistency with use in category 14.1.3.4
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	950	mg/kg	Notes 119 & 145	3	

⁷⁸ **Note 77:** For special nutritional uses only.

⁷⁹ **Note 127:** As served to the consumer

Recommendation 3 – Aspartame-Acesulfame, INS 962						
The eWG recommends that the 39 th CCFA <u>adopt</u> the following food additive provisions for aspartame-acesulfame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
	particulated drinks					
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	1350	mg/kg	Note 113	3	
14.2.1	beer and malt beverages	800	mg/kg	Notes 113 & 138	3	
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 beverages (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 & 144	3	

CYCLAMATES (INS 952)

61. 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

Recommendation 1 – Cyclamates, INS 952						
The eWG recommends that the 39 th CCFA <u>discontinue</u> further work on the following food additive provisions for cyclamates 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks
04.1.2.7	candied fruit	500	mg/kg	Note 17	6	
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	Note 17	6	
05.1	cocoa products and chocolate products including imitations and chocolate substitutes	500	mg/kg	Note 17	6	Subcategory 05.1.1 contains no non-standardized foods. CX STANs 105 & 141 do not contain any provisions for the use of cyclamates.
05.2.1	hard candy	2500	mg/kg	Note 17	6	Combined ML under category 05.2 (see recommendation 2)
05.2.2	soft candy	500	mg/kg	Note 17	6	
05.2.3	nougats and marzipans	500	mg/kg	Note 17	6	
07.2.1	cakes, cookies and pies (e.g., fruit-filled or custard types)	1600	mg/kg	Note 17	6	Combined ML under category 07.2 (see recommendation 2)
07.2.2	other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	2000	mg/kg	Note 17	6	
07.2.3	mixes for fine bakery wares (e.g., cakes, pancakes)	1600	mg/kg	Note 17	6	

Recommendation 2 - Cyclamates, INS 952						
The eWG recommends that the 39 th 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
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	250	mg/kg	Note 17 ⁸⁰ [Note 145] ⁸¹	6	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	250	mg/kg	Note 17 [Note 145]	6	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	250	mg/kg	Note 17 [Note 145]	6	
03.0	edible ices, including sherbet and sorbet	250	mg/kg	Note 17 [Note 145]	6	
04.1.2.4	canned or bottled (pasteurized) fruit	1000	mg/kg	Note 17 [Note 145]	6	
04.1.2.5	jams, jellies and marmelades	1000	mg/kg	Note 17 [Note 145]	6	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	2000	mg/kg	Note 17 [Note 145]	6	
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	250	mg/kg	Note 17 [Note 138]	6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	250	mg/kg	Note 17 [Note 138]	6	
05.1.2	Cocoa mixes (syrops)	250	mg/kg	Note 17 127 ⁸² [Note145]	6	
05.1.3	Cocoa-based spreads, incl. fillings	500	mg/kg	Note 17 [Note145]	6	
05.1.4	Cocoa and chocolate products	500	mg/kg	Note 17	6	
05.1.5	Imitation chocolate, chocolate substitute products	500	mg/kg	Note 17 [Note145]	6	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	500	mg/kg	Note 17 [Note145]	6	
05.3	chewing gum	3000	mg/kg	Note 17 [Note 138]	6	Cyclamate is approximately 30 times sweeter than sucrose. This sweetener is suitable for use in chewing gum as it has both a high sweetening power and a "pure" taste without the bitter aftertaste of saccharin. Cyclamate is technologically needed at levels up to 3.000 mg per kilogram of chewing gum. At this level, cyclamate is released gradually and is available to sweeten the product during the whole chewing period. With the requested level of 3.000 mg of cyclamate per kilogram of chewing gum, due regard has also been paid to the sweetener's ADI value.
05.4	decorations (e.g., for fine	500	mg/kg	Note 17	6	

⁸⁰ **Note 17:** As cyclamic acid.

⁸¹ **Note 145:** For use only in energy-reduced products or products with no added sugar.

⁸² **Note 127:** As served to the consumer

Recommendation 2 - Cyclamates, INS 952						
The eWG recommends that the 39 th 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
	bakery wares), toppings (non-fruit) and sweet sauces			[Note 145]		
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	250	mg/kg	Note 17 [Note 145]	6	
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	1600	mg/kg	Note 17 [Note D⁸³]	6	
10.4	egg-based desserts (e.g., custard)	250	mg/kg	Note 17 [Note 145]	6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	500	mg/kg	Note 17	6	
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP	Note 17	6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400	mg/kg	Note 17	6	
13.4	dietetic formulae for slimming purposes and weight reduction	400	mg/kg	Note 17	6	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	400	mg/kg	Note 17	3	
13.6	food supplements	400	mg/kg	Note 17 [Note J ⁸⁴]	6	<p>Cyclamates are used in food supplements (category 13.6) as an intense sweetener. They are specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.</p> <p>Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 1250mg / kg.</p> <p>2) Proposed Note J is confusing and incomplete because it fails to account for the use of cyclamates in syrup-type or chewable forms. An ML of 1250 m/kg cyclamates is needed in such foods.. The use of sweeteners in food supplements is very low when compared to other product categories due to the unit-dose form of supplements and their low individual weight. The highest level should be retained level determined for each sweetener for food supplements and remove the footnotes.</p>
14.1.3.2	vegetable nectar	250	mg/kg	Note 17 [Note 145]	3	
14.1.3.4	concentrates for vegetable nectar	250	mg/kg	Notes 17 & 127 ⁸⁵ [Note 145]	3	

⁸³ **Note D:** For use in products for special nutritional purposes only.

⁸⁴ **Note J:** For use in products in liquid form; 500 mg/kg for products in solid form.

Recommendation 2 - Cyclamates, INS 952						
The eWG recommends that the 39 th 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
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	250	mg/kg	Note 17	6	

Recommendation 3 - Cyclamates, INS 952						
Comments are requested on the following food additive provisions for cyclamates in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	500	mg/kg	Note 17	6	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.
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	Some vegetable salads falling in this category contain vinegar the taste of which has to be mellowed by adding intense sweeteners, such as cyclamate.
14.1.4.1	carbonated water-based flavoured drinks	1500	mg/kg	Note 17	6	The eWG could not reach consensus on ML for use in these categories. The eWG recommends that the CCFA consider whether an ML of 800 mg/kg is acceptable in the broader category food category 14.1.4 with notes 17, 127 & [145].
14.1.4.2	non-carbonated water-based flavoured drinks, including punches and ades	1500	mg/kg	Note 17	6	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. Cyclamate is an effective and stable sweetener with a good taste profile. At levels low levels (<<400 ppm), the improvement of taste quality by cyclamate becomes negligible and the synergistic effects are substantially reduced. The optimum sweetness in three component mixtures is reached at use level about 600-700 while two component mixtures with saccharin require higher use levels.

⁸⁵ **Note 127:** As served to the consumer.

NEOTAME (INS 961)

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

Recommendation 1 – Neotame, INS 961						
The eWG recommends that the 39 th 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
01.4.1	pasteurized cream (plain)		GMP		3	
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)		GMP		3	
01.4.3	clotted cream (plain)		GMP		3	
01.5.1	milk powder and cream powder (plain)		GMP		3	
01.6.1	unripened cheese	33	mg/kg		3	
05.1.1	cocoa mixes (powders) and cocoa mass/cake	100	mg/kg		3	Subcategory 05.1.1 contains no non-standardized foods. CX STANs 105 & 141 do not contain any provisions for the use of neotame.
08.2	processed meat, poultry, and game products in whole pieces or cuts	10	mg/kg		3	
08.3	processed comminuted meat, poultry, and game products	10	mg/kg		3	
09.2	processed fish and fish products, including mollusks, crustaceans, and echinoderms	10	mg/kg		3	
10.2.3	dried and/or heat coagulated egg products	33	mg/kg		3	
13.1.3	formulae for special medical purposes for infants	25	mg/kg		3	There are no non-standardized foods in this category. For consistency with the Draft revised Codex standard for infant formula

Recommendation 2 - Neotame, INS 961						
The eWG recommends that the 39 th 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
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	20	mg/kg	[Note 145]	3	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	100	mg/kg	[Note 145]	3	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	100	mg/kg	[Note 145]	3	
03.0	edible ices, including sherbet and sorbet	100	mg/kg	[Note 145]	3	
04.1.2.3	fruit in vinegar, oil, or brine	100	mg/kg	[Note 138]	3	
04.1.2.4	canned or bottled (pasteurized) fruit	33	mg/kg	[Note 145]	3	
04.1.2.5	jams, jellies and marmelades	70	mg/kg	[Note 138]	3	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	70	mg/kg	[Note 138]	3	
04.1.2.7	candied fruit	65	mg/kg	[Note 145]	3	
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	100	mg/kg	[Note 138]	3	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based	100	mg/kg	[Note 145]	3	

Recommendation 2 - Neotame, INS 961						
The eWG recommends that the 39 th 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
	desserts					
04.1.2.10	fermented fruit products	65	mg/kg	[Note 138]	3	
04.1.2.11	fruit fillings for pastries	100	mg/kg	[Note 138]	3	
04.1.2.12	cooked fruit	65	mg/kg	[Note 138]	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	10	mg/kg	[Note 144]	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	33	mg/kg	[Note 138]	3	
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	33	mg/kg	[Note 138]	3	
05.1.2	cocoa mixes (syrups)	33	mg/kg	Note 97 ⁸⁶ [Note 145]	3	
05.1.3	cocoa-based spreads, including fillings	100	mg/kg	[Note 145]	3	
05.1.4	cocoa and chocolate products	80	mg/kg	[Note 145]	3	
05.1.5	imitation chocolate, chocolate substitute products	100	mg/kg	[Note 145]	3	
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	1000	mg/kg	[Note 145]	3	
05.3	chewing gum	1000	mg/kg	[Note 145]	3	Neotame is an intense sweetener derived from aspartame. It is 7.000 – 13.000 times as sweet as sugar and 30-60 times as sweet as aspartame. Neotame is technologically needed at levels up to 1.000 mg/kg of chewing gum. It provides zero calories and has a clean, sweet, sugar-like taste with no undesirable taste characteristics like the ones of many other high intensity sweeteners. It can be used alone or blended with other high intensity or carbohydrate sweeteners. It is stable under dry conditions and more stable than aspartame in neutral pH conditions.
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	100	mg/kg		3	
06.3	breakfast cereals, including rolled oats	160	mg/kg	[Note 145 & Note N ⁸⁷	3	
06.5	cereal and starch based	33	mg/kg	[Note 145]	3	

⁸⁶ **Note 97:** In the finished product/final cocoa and chocolate products

⁸⁷ **Note N** For use in breakfast cereals with a fibre content of more than 15% and containing at least 20% bran only.

Recommendation 2 - Neotame, INS 961						
The eWG recommends that the 39 th 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
	desserts (e.g., rice pudding, tapioca pudding)					
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	130	mg/kg	[Note D ⁸⁸]		
10.4	egg-based desserts (e.g., custard)	100	mg/kg	[Note 145]	3	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	70	mg/kg		3	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 bring their sweetness to the standard level.
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP		3	
12.4	mustards	12	mg/kg		3	
12.5	soups and broths	20	mg/kg	[Note 138]	3	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	65	mg/kg		3	1) To provide sweetness (other sweeteners are permitted) 2) Flavour enhancer / Sweetener for specific groups of products
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	70	mg/kg		3	1) To provide sweetness (other sweeteners are permitted) 2) Flavour enhancer / Sweetener for specific groups of products
12.6.3	mixes for sauces and gravies	12	mg/kg		3	1) To provide sweetness (other sweeteners are permitted) 2) Flavour enhancer/ sweetener for specific groups of products
12.6.4	clear sauces (e.g., fish sauce)	12	mg/kg		3	To provide sweetness (other sweeteners are 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	33	mg/kg	[Note 145 & F ⁸⁹]	3	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	33	mg/kg		3	Flavour enhancer / Sweetener for specific groups of products
13.4	dietetic formulae for slimming purposes and weight reduction	33	mg/kg		3	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	65	mg/kg		3	
13.6	food supplements	90	mg/kg		3	Neotame is used in food supplements (category 13.6) as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that

⁸⁸ **Note D** For use in products for special nutritional purposes only

⁸⁹ **Note F:** For milk-based sandwich spreads only.

Recommendation 2 - Neotame, INS 961						
The eWG recommends that the 39 th 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
						dissolve in water to make a drink. Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 90mg / kg.
14.1.2.2	vegetable juice	65	mg/kg	[Note 145]	3	Neotame is widely used in fruit and vegetable juices and nectars including concentrates, to replace sucrose.
14.1.2.4	concentrates for vegetable juice	65	mg/kg	[Note 145] [Note 127]	3	
14.1.3.2	vegetable nectar	65	mg/kg	[Note 145]	3	
14.1.3.4	concentrates for vegetable nectar	65	mg/kg	[Note 145] [Note 127]	3	
14.1.4	water-based flavoured drinks, including "sport," "energy" or "electrolyte" drinks and particulated drinks	33	mg/kg	[Note 145]	3	
14.2.1	beer and malt beverages	20	mg/kg	[Note H ⁹⁰]	3	
14.2.2	cider and perry	20	mg/kg		3	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	33	mg/kg		3	
15.0	ready-to-eat savouries	32	mg/kg		3	

Recommendation 3 - Neotame, INS 961						
Comments are requested 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) Technological need is questioned. 2) 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.
01.3.2	beverage whiteners		GMP		3	1) Technological need is questioned. 2) 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
01.4.4	cream analogues	33	mg/kg		3	1) Technological need is questioned. 2) 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) Technological need is questioned. 2) Neotame is used to replace sugars, for making low and reduced joule/calorie and no

⁹⁰ **Note H:** For use in energy-reduced or alcohol free beer only

Recommendation 3 - Neotame, INS 961						
Comments are requested on the following food additive provisions for neotame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						added sugar sweetened milk and cream powders and analogues.
01.6.5	cheese analogues	33	mg/kg		3	1) Technological need is questioned. 2) 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	1) Technological need is questioned. 2) 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	Technological need
04.1.2.2	dried fruit	100	mg/kg		3	Technological need
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	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	33	mg/kg		3	Technological need
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	Technological need
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		3	Technological need
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	Technological need
07.2	fine bakery wares (sweet, salty, savoury) and mixes	80	mg/kg		3	1) Low calorie versions of this product can be made with the addition of intense sweetener such as Neotame, to replace sugar. An ML of 130 mg/kg is needed. 2) An ML of 80 mg/kg is needed to achieve the intended technological effect

Recommendation 3 - Neotame, INS 961						
Comments are requested on the following food additive provisions for neotame in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	10	mg/kg		3	Technological need
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	10	mg/kg		3	Technological need
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	65	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.
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	50	mg/kg		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 beverages.
14.2.4	wines (other than grape)	23	mg/kg		3	Intense sweeteners are widely used beverages of this type, including cider and perry.
14.2.5	mead	23	mg/kg		3	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	23	mg/kg		3	To provide sweetness (other sweeteners are permitted)

SACCHARIN (INS 954)

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

Recommendation 1 – Saccharin, INS 954						
The eWG recommends that the 39 th 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners is plain fermented milks
01.2.2	renneted milk (plain)	100	mg/kg		6	No technological need identified
01.6.1	unripened cheese	100	mg/kg		6	No technological need identified
05.1	cocoa products and chocolate products including imitations and chocolate substitutes	500	mg/kg		6	There are no non-standardized foods in this category and the relevant standards (105 & 141) do not contain any provision for the use of saccharin
05.2.1	hard candy	3000	mg/kg		6	Combined ML under category 05.2 (see recommendation 2)
05.2.2	soft candy	500	mg/kg		6	
05.2.3	nougats and marzipans	500	mg/kg		6	
08.2.1.1	cured (including salted) non-heat treated processed meat, poultry, and game products in whole pieces or cuts	2000	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	500	mg/kg		6	Combined ML under category 12.6 (see recommendation 2)
12.6.2	non-emulsified sauces (e.g.,	160	mg/kg		6	

Recommendation 1 – Saccharin, INS 954						
The eWG recommends that the 39 th 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
	ketchup, cheese sauce, cream sauce, brown gravy)					
12.6.3	mixes for sauces and gravies	300	mg/kg		6	
12.6.4	clear sauces (e.g., fish sauce)	160	mg/kg		6	
12.9.1.3	other soybean products (including non-fermented soy sauce)	500	mg/kg		6	
13.1.3	formulae for special medical purposes for infants	200	mg/kg		3	There are no non-standardized foods in this category. For consistency with the Draft revised Codex standard for infant formula
16.0	composite foods - foods that could not be placed in categories 01 - 15	200	mg/kg		6	

Recommendation 2 - Saccharin, INS 954						
The eWG recommends that the 39 th 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
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	80	mg/kg	[Note 145] ⁹¹	6	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	100	mg/kg	[Note 145]	6	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	100	mg/kg	[Note 145]	6	
03.0	edible ices, including sherbet and sorbet	100	mg/kg	[Note 145]	6	
04.1.2.3	fruit in vinegar, oil, or brine	160	mg/kg	[Note 144] ⁹²	6	
04.1.2.4	canned or bottled (pasteurized) fruit	200	mg/kg	[Note 145]	6	
04.1.2.5	jams, jellies and marmelades	200	mg/kg	[Note 138] ⁹³	6	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	200	mg/kg	[Note 138]	6	
04.1.2.7	candied fruit	5000	mg/kg	[Note 138]	3	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.
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	200	mg/kg	[Note 138]	6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	100	mg/kg	[Note 138]	6	
04.2.2.3	vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine,	160	mg/kg	[Note 144]	6	

⁹¹ **Note 145:** For use only in energy reduced products or products with no added sugar

⁹² **Note 144:** For use in sweet and sour products only

⁹³ **Note 138:** For use only in energy reduced products or products

Recommendation 2 - Saccharin, INS 954						
The eWG recommends that the 39 th 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
	or soy sauce					
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 138]	6	
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	200	mg/kg	[Note 138]	6	
05.1.2	Cocoa mixes (syrops)	80	mg/kg	[Note 145]		
05.1.3	Cocoa-based spreads, incl. fillings	200	mg/kg	[Note 145]		
05.1.4	Cocoa and chocolate products	500	mg/kg			For consistency with CX STAN 87
05.1.5	Imitation chocolate, chocolate substitute products	500	mg/kg	[Note 145]		
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	500	mg/kg	[Note 145]		
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	500	mg/kg		6	Saccharin is used to sweeten sugar-free products of this category.
06.3	breakfast cereals, including rolled oats	100	mg/kg	[Notes 145 & N ⁹⁴	6	
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	100	mg/kg	[Note 145]	6	
07.2	fine bakery wares (sweet, salty, savoury) and mixes	170	mg/kg	[Note D] ⁹⁵	6	
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	160	mg/kg	[Note 144] ⁹⁶	6	Marinated fish, crustaceans and molluscs are often sour-sweet. Intense sweeteners like saccharin mellow the taste of vinegar and provide the desired sweetness. In products undergoing fermentation intense sweeteners are not degraded by micro-organisms.
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	160	mg/kg	[Note 144]	6	
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	160	mg/kg	[Note 144]		
09.4	fully preserved, including canned or fermented fish and	200	mg/kg	[Note 144]	6	

⁹⁴ **Note N** For use in breakfast cereals with a fibre content of more than 15% and containing at least 20% bran only.

⁹⁵ **Note D:** For use in products for special nutritional purposes only.

⁹⁶ **Note 144:** For use in sweet and sour products only.

Recommendation 2 - Saccharin, INS 954						
The eWG recommends that the 39 th 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
	fish products, including mollusks, crustaceans, and echinoderms					
10.4	egg-based desserts (e.g., custard)	100	mg/kg	[Note 144]	6	
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP		6	
12.4	mustards	320	mg/kg		6	
12.5	soups and broths	110	mg/kg	[Note 138]	6	
12.6	sauces and like products	160	mg/kg		6	
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	200	mg/kg	[Note 145, F ⁹⁷]	6	Some vegetable salads falling in this category contain some vinegar the taste of which has to be mellowed as discussed for category 12.3 vinegar.
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	200	mg/kg		6	1) Flavour enhancer / Sweetener for specific groups of products 2) These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise restricted diet.
13.4	dietetic formulae for slimming purposes and weight reduction	300	mg/kg		6	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	200	mg/kg		6	
13.6	food supplements	1200	mg/kg	[Note K ⁹⁸]	6	The use of sweeteners in food supplements is very low when compared to other product categories due to the unit-dose form of supplements and their low individual weight. The highest level should be retained level determined for each sweetener for food supplements and remove the footnotes.
14.1.2.2	vegetable juice	80	mg/kg	[Note 145]		Saccharin is used in beverages of all types, ready-to-drink as well as concentrates.
14.1.2.4	concentrates for vegetable juice	80	mg/kg	Note 127 [Note 145]	6	
14.1.3.4	concentrates for vegetable nectar	300	mg/kg	Note 127 & [Note 145 ⁹⁹]	6	
14.2.1	beer and malt beverages	80	mg/kg	[Note H ¹⁰⁰]	6	Saccharin is widely used in beverages of all types, including sweet types of beer. In products bottled with micro-organisms, saccharin is not degraded by these.
14.2.2	cider and perry	80	mg/kg		6	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	80	mg/kg		6	
15.0	ready-to-eat savouries	100	mg/kg		6	Snacks may be salted, spicy, or

⁹⁷ **Note F:** For milk-based sandwich spreads only.

⁹⁸ **Note K:** For use in syrup-type or chewable products; 500 mg/kg for in products in solid form; 80 mg/kg in products in liquid form.

⁹⁹ **Note 145:** For use only in energy reduced products or products with no added sugar

¹⁰⁰ **Note H:** For use in energy-reduced or alcohol-free beer only

Recommendation 2 - Saccharin, INS 954						
The eWG recommends that the 39 th 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
						sweetened. For sugar-free sweetened products intense sweeteners like saccharin have to be used.

Recommendation 3 - Saccharin, INS 954						
Comments are requested on the following food additive provisions for saccharin in the GSFA						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.6.5	Cheese analogues	100	mg/kg			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.
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	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.
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	
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	500	mg/kg		6	Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed saccharin 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)	160	mg/kg		6	Technological need
04.2.2.8	cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	500	mg/kg		6	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.
05.3	chewing gum	3000	mg/kg		6	1) An ML of 1200 mg/kg with Note 68 s technologically needed. 2) Saccharin is technologically needed up to levels of 3.000 mg/kg of chewing gum. Saccharin's low solubility in water requires, as for aspartame, higher use levels to get the required sweetness. We believe that the small contribution of chewing gum products to the overall intake of saccharin justifies such level. Moreover, saccharin limits itself by its unpleasant aftertaste if used at levels

Recommendation 3 - Saccharin, INS 954						
Comments are requested on the following food additive provisions for saccharin in the GSFA						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						too high. The salts of saccharin have their own benefit in that they provide the fastest impact of flavour, due to their very high solubility in water. For consistency reasons with other intense sweeteners Note 168 should not be included. The safety at this level has been documented There is trade in chewing gums containing more than 1200 mg/kg saccharin Just by way of example, South Africa currently authorizes saccharin at 2500 mg/kg in chewing gum
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	15	mg/kg		6	Technological need
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	Technological need
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	1200	mg/kg		6	Technological need
09.3.3	salmon substitutes, caviar, and other fish roe products	160	mg/kg		6	Technological need
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	300	mg/kg		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 beverages.
12.2.2	Seasonings and condiments	1500	mg/kg			Seasoning and condiments are sometimes rounded by the addition of sweet-tasting and flavour-enhancing products such as Saccharin and other intense sweeteners.
12.3	vinegars	300	mg/kg		6	Vinegar is sometimes rounded and mellowed by addition of sweet-tasting, flavour-enhancing products. Saccharin balances acidity well.
14.1.4.1	carbonated water-based flavoured drinks	500	mg/kg		6	The eWG could not reach consensus on an ML for use in these categories. The eWG recommends that the CCFA consider whether an ML of 500 mg/kg is of acceptable in the broader category food category 14.1.4 with note 127 & [145]. The 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
14.1.4.2	non-carbonated water-based flavoured drinks, including punches and ades	500	mg/kg		6	
14.1.4.3	concentrates (liquid or solid) for water-based flavoured drinks	2000	mg/kg		6	

Recommendation 3 - Saccharin, INS 954						
Comments are requested on the following food additive provisions for saccharin in the GSFA						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						increased ingredient cost, decreased stability (shorter shelf life in many cases), and in some cases lower consumer acceptability.
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	200	mg/kg		6	1) Our members produce canned Ready to drink coffees that are served hot but there is no reported use of saccharin in these products that are common in Japan. 2) Saccharin is widely used in beverages of all types, ready-to-drink as well as concentrates.

SUCRALOSE, INS 955

64. The 37th JECFA (1990) assigned a group ADI of 15 mg/kg bw/d for sucralose.

Recommendation 1 – Sucralose, INS 955						
The eWG recommends that the 39 th CCFA <u>discontinue</u> 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	Codex draft Standard for Fermented Milk does not contain any provisions for sweeteners in plain fermented milks
01.2.1.2	fermented milks (plain), heat-treated after fermentation	250	mg/kg		6	
01.2.2	renneted milk (plain)		GMP		6	No Technological Need Identified
01.3.1	condensed milk (plain)		GMP		6	No Technological Need Identified
01.5	milk powder and cream powder and powder analogues (plain)		GMP		6	No Technological Need Identified
01.6.1	unripened cheese		GMP		6	No Technological Need Identified
01.6.2	ripened cheese		GMP		6	No Technological Need Identified
01.6.4	processed cheese		GMP		6	No Technological Need Identified
01.8.1	liquid whey and whey products, excluding whey cheeses		GMP		6	
06.6	batters (e.g., for breading or batters for fish or poultry)	600	mg/kg		6	
07.2.1	cakes, cookies and pies (e.g., fruit-filled or custard types)	750	mg/kg		6	See Recommendation 3 to combine under category 07.2
07.2.2	other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	800	mg/kg		6	
07.2.3	mixes for fine bakery wares (e.g., cakes, pancakes)	750	mg/kg		6	
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	450	mg/kg		6	Combined ML under category 09.3 (see recommendation 2)
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	450	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	450	mg/kg		6	Combined ML under category 12.6 (see recommendation 2)
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	450	mg/kg		6	
12.6.3	mixes for sauces and gravies	450	mg/kg	Note 127	6	
12.6.4	clear sauces (e.g., fish sauce)	450	mg/kg		6	
13.1.3	formulae for special medical purposes for infants	400	mg/kg		3	There are no non-standardized foods in this category. For consistency with the Draft revised

Recommendation 1 – Sucralose, INS 955						
The eWG recommends that the 39 th 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
						Codex standard for infant formula
14.1.4.1	carbonated water-based flavoured drinks	600	mg/kg		6	Combined ML under category 14.1.4 (see recommendation 2)
14.1.4.2	non-carbonated water-based flavoured drinks, including punches and ades	600	mg/kg		6	
14.1.4.3	concentrates (liquid or solid) for water-based flavoured drinks	1500	mg/kg		3	

Recommendation 2 - Sucralose, INS 955						
The eWG recommends that the 39 th 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
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	300	mg/kg	[Note 145]	6	
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	400	mg/kg	[Note 145]	6	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	400	mg/kg	[Note 145]	3	
03.0	edible ices, including sherbet and sorbet	320	mg/kg	[Note 145]	6	
04.1.2.3	fruit in vinegar, oil, or brine	180	mg/kg	[Note 144]	3	
04.1.2.4	canned or bottled (pasteurized) fruit	400	mg/kg	[Note 145]	6	
04.1.2.5	jams, jellies and marmelades	400	mg/kg	[Note 138]	3	
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	400	mg/kg	[Note 145]	6	
04.1.2.7	candied fruit	800	mg/kg	[Note 145]	6	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 to bring the sweetness to the customary level.
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	400	mg/kg	[Note 145]	6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	400	mg/kg	[Note 145]	6	
04.1.2.10	fermented fruit products	150	mg/kg	[Note 138]	6	
04.1.2.11	fruit fillings for pastries	400	mg/kg	[Note 138]	3	
04.2.2.3	vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil,	400	mg/kg		6	

Recommendation 2 - Sucralose, INS 955						
The eWG recommends that the 39 th 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
	brine, or soy sauce					
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)	400	mg/kg	[Note 145, L¹⁰¹]	6	Some products of this category are sweet. Sucralose allows production of sweet products with no added sugar.
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	400	mg/kg	[Note 145]	6	
05.1.1	cocoa mixes (powders) and cocoa mass/cake	580	mg/kg	Note 97¹⁰²	6	Category 05.1.1 does not contain any non-standardized foods. ML and note are consistent with the relevant CX STANs 105 & 141
05.1.2	cocoa mixes (syrups)	400	mg/kg	Note 97 [Note 145]	6	This category includes products for the preparation of cocoa-based beverages. For sugar-free products intense sweeteners can be the only source of sweetness. An ML of 1000 mg/kg is necessary as the dilution to prepare a cocoa beverage can be 10 fold and even higher.
05.1.3	cocoa-based spreads, including fillings	400	mg/kg	[Note 145, L]	6	An ML of 700 mg/kg is necessary to achieve the intended technical effect.
05.1.4	cocoa and chocolate products	800	mg/kg	[Note 145]	6	
05.1.5	imitation chocolate, chocolate substitute products	800	mg/kg	[Note 145]	6	
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	1000	mg/kg	[Note 68]	3	
06.3	breakfast cereals, including rolled oats	1000	mg/kg	[Note 145, N¹⁰³]	6	A level of 1000 mg/kg has been assessed as technologically justified.
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	400	mg/kg	[Note 145]	6	
06.7	pre-cooked or processed rice products, including rice cakes (Oriental type only)	200	mg/kg	Note 72	6	
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.
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	120	mg/kg	[Note 144]	3	

¹⁰¹ **Note L:** Fat-based sandwich spreads only

¹⁰² **Note 97:** In the finished product/final cocoa and chocolate products.

¹⁰³ **Note N:** For use in breakfast cereals with a fibre content of more than 15% and containing at least 20% bran only.

Recommendation 2 - Sucralose, INS 955						
The eWG recommends that the 39 th 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
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans and echinoderms	120	mg/kg	[Note 144]	3	
10.4	egg-based desserts (e.g., custard)	400	mg/kg	[Note 145]	3	
11.6	table-top sweeteners, including those containing high-intensity sweeteners		GMP		3	
12.4	mustards	140	mg/kg		6	
12.5	soups and broths	600	mg/kg	[Note 138]	6	Used for soups and broths
12.6	Sauces and like products	450	mg/kg	Note 127	6	Proposed use level in broader food category. 1) To provide sweetness (other sweeteners are permitted) 2) Flavour enhancer / Sweetener for specific groups of products Sugar like sweetness for low calorie products
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	1250	mg/kg	[Note 138, L]	6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400	mg/kg		6	1) Used as a sweetener for dietetic foods intended for special medical purposes. 2) Flavour enhancer / Sweetener for specific groups of products 3) These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.
13.4	dietetic formulae for slimming purposes and weight reduction	320	mg/kg		6	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	400	mg/kg		6	
13.6	food supplements	2400	mg/kg	[Note M ¹⁰⁴]	3	1) Sucralose is used in food supplements as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink. Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 2400mg / kg. 2) The use of sweeteners in food supplements is very low when

¹⁰⁴ **Note M:** 240 mg/kg for liquid forms, 800 mg/kg for solid forms, 2400 mg/kg for syrup-type or chewable forms

Recommendation 2 - Sucralose, INS 955						
The eWG recommends that the 39 th 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
						compared to other product categories due to the unit-dose form of supplements and their low individual weight. The highest level should be retained level determined for each sweetener for food supplements and remove the footnotes.
14.1.3.2	vegetable nectar	300	mg/kg	[Note 145]	3	Sucralose is used in beverages of all types, including vegetable juices, concentrates and nectars.
14.1.3.4	concentrates for vegetable nectar	300	mg/kg	Note 127 [Note 145]	3	Sucralose is used in beverages of all types, including vegetable juices, concentrates and nectars.
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	300	mg/kg	Note 127 [Note 145]		Proposed new use in broader food category
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	300	mg/kg	[Note 145]	3	1) Only allow in water or milk-based malted beverages such as Ovaltine and Horlicks 2) Sucralose is used as a sweetener in canned coffee products that are served hot. The permitted level in Japan where these products are common is 400 mg/kg but we can accept 300 mg/kg. 3)Owing to its stability in liquids, sucralose is widely used in beverages of all types, ready-to-drink as well as concentrate 4) 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 beverages.
15.0	ready-to-eat savouries	1000	mg/kg		6	Snacks may be salted, spicy, or sweetened. For sugar-free sweetened products intense sweeteners like sucralose have to be used.

Recommendation 3 - Sucralose, INS 955						
Comments are requested on the following food additive provisions for sucralose in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
01.3.2	beverage whiteners	580	mg/kg		3	
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 products under Food Category 01.4.4(Cream analogues), so it should be included in the broader category of 01.4.
01.6.5	cheese analogues		GMP		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

Recommendation 3 - Sucralose, INS 955						
Comments are requested on the following food additive provisions for sucralose in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						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	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	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	Intense sweeteners allow the production of pre-sweetened sugar-free products. The listed level for sucralose 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	150	mg/kg		6	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.
04.2.2.2	dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	150	mg/kg		6	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.
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	150	mg/kg		6	Some of these products are sweetened. Intense sweeteners allow production of sweetened sugar-free products. The listed level for sucralose provides adequate sweetness.
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	150	mg/kg		6	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
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		6	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
05.3	chewing gum	5000	mg/kg		6	1) An ML of 3000 mg/kg is justified. 2) Note 68 should be added. 3) An ML of 5000 mg/kg is needed based on the following.

Recommendation 3 - Sucralose, INS 955						
Comments are requested on the following food additive provisions for sucralose in the GSFA.						
Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						<p>Sucralose may be used as a sugar substitute in sugar free chewing gum and is technologically needed up to levels of 5,000 mg/kg either singly or in combination with other permitted sweeteners. Sucralose provides benefits over the other intense sweeteners such as Aspartame, by demonstrating enhanced stability at high processing temperatures, as well as enhanced stability in the presence of certain flavourings such as aldehydes and ketones. Sucralose also imparts a more sugary clean aftertaste than other intense sweeteners such as Acesulfame-K or Saccharin. Sucralose's high solubility in water requires higher use levels to get the required sweetness. Chewing gum also requires relatively high percentage levels of Sucralose because the sweetener must be released slowly over the course of a 20 or 30 minutes chewing period. The safety at this level has been documented. There is trade in chewing gum containing sucralose at this level. For example, Russia is authorizing sucralose at 5000 mg/kg in chewing gum</p>
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1000	mg/kg		6	Sucralose is needed to sweeten sugar-free products of this category.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	700	mg/kg	[Note D]		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 sweeteners are available.
11.3	sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	1500	mg/kg		6	Flavour enhancer / Sweetener for specific groups of products
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1500	mg/kg		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.
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
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

Recommendation 3 - Sucralose, INS 955						
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Food Cat No.	Food Category	Max Level		Comments	Step	Justification provided to eWG
						as sucralose or other intense sweeteners.
12.3	vinegars		GMP		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.
14.1.2.2	vegetable juice	300	mg/kg		3	1) Sucralose is used in beverages of all types, including vegetable juices, concentrates and nectars.
14.1.2.4	concentrates for vegetable juice	1500	mg/kg		3	2) Sucralose is used in beverages of all types, including vegetable juices, concentrates and nectars.
14.2	alcoholic beverages, including alcohol-free and low-alcoholic counterparts	700	mg/kg		6	A variety of alcoholic beverages containing intense sweeteners such as sucralose are already available on the market.
14.2.1	Beer and malt beverages	250	mg/kg			1) New proposal 2) Owing to its good stability in liquids and during pasteurisation sucralose is widely used in beverages of all types, including sweet types of beer. In products bottled with micro-organisms is not degraded by these.
14.2.2	Cider and perry	50	mg/kg			1) New proposal 2) Owing to its good stability in liquids and during pasteurisation sucralose is used in beverages of all types, including cider and perry.
14.2.4	Concentrates for vegetable juice	700	mg/kg			1) New proposal 2) An ML of 700 mg/kg is necessary to achieve the intended technical effect.
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)	700	mg/kg			1) New proposal 2) 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.