

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 6 (c)

CX/FAC 05/37/10
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

FOOD ADDITIVES PROVISIONS OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

PROPOSED DRAFT FOOD ADDITIVE PROVISIONS AT STEP 3 AND PROPOSALS FOR NEW USES

- COMMENTS (IN RESPONSE TO CL 2004/44-FAC)

The following comments have been received from: Brazil, Chile, European Community, Indonesia, United States of America, Venezuela, AAC, AMFEP, CEFS, ELC, IFAC, ISA, and OIV

BRAZIL:

I) Food Additive Provisions:

- Brazil supports advancing the provisions included in Table 3 (INS 457, 468 and 1451) to Step 5.
- Brazil does not support the advancing to Step 5 of the procedure for provisions listed below:

INS/ Additive	Food Category	Brazil comments
950 – Acesulfame Potassium	1.3.2	Brazil requests justify the technological function on these food categories as well the proposed maximum levels. Those levels (2000, 2500, 3000mg/kg) are too high as a flavour enhancer or sweetener. In dietetic food the maximum level is 1000mg/kg. In Brazil and UE the limits is 350mg/kg, which is adequate for technological need.
	1.5	
	2.3	
	5.1.4	
	6.4	
	12.2	
129 – Allura Red AC	12.3	
	1.6.3	Brazil requests justify the use as a surface treatment in whey cheese.
	2.1.3	Brazil requests justify the technological function on these food categories
	2.2.1.2	
14.2.1		

	10.1	Brazil propose exclude "Note 3" from this category
523 - Aluminium Ammonium Sulphate	7.1.2 7.1.3 7.1.4 7.1.5 7.2	Brazil requests specify reporting basis to which compound the limit apply (Note 29). Is it sulphate or aluminium?
	12.9.2 12.10.2 12.10.3	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
510 – Ammonium chloride	4.2.2.7 8.1 9.2 12.1.2 12.2.1 14.1.5	Having regard functional class for this additive is flour treatment agent, what is the proposal of adding it to food categories that do not contain flour such as fermented vegetable, fresh meat, processed fish, salt, herbs and coffee?
160b – Annatto extracts	6.4.2	Brazil requests add "Note 8" in these categories.
	7.1 9.3 11.3 11.4 13.6 14.2.3 14.2.3.3	On food category 6.4.2, Brazil requests the limit of 100 mg/kg. The limit of 24mg/kg is not sufficient to achieve the effect level.
304 – Ascorbyl esters	13.3	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
951 – Aspartame	1.3.2 1.4.1 1.4.2 1.4.3 1.5.1	Usual levels of use of aspartame in beverages are up to 1000mg/kg as a sweetener. Brazil requests justify the proposed level of 5000 to 6000mg/kg for these categories.
	9.4 12.3	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
162 – Beet red	12.1.1	Brazil does not support the provision for use colours in salt. What is the technological need for this?
210-213 – Benzoates	8.3.2	Brazil does not support the use of preservatives in heat-treated processed comminuted meat, poultry and game products.
320 – BHA	1.3.1	Brazil requests clarify which ingredient is responsible for carry over in this food.
321 – BHT	1.3.1	Brazil requests clarify which ingredient is responsible for carry over in this food.

133 – Brilliant blue FCF	1.6.3	Brazil requests justify the use as a surface treatment in whey cheese.
	2.1.3 2.2.1.2 14.2.1	Brazil requests justify the technological function on these food categories
	10.1	Brazil propose exclude “Note 3” from this category
404, 302, 170i, 509, 333, 526, 327, 282, 634, 516 – Calcium Salts	All entries	Express the limit of calcium salts at the same basis. Eg: calcium carbonate – Note 58: as calcium but calcium propionate does not have a Note.
160aii – carotenes, vegetable	7.1.6	In response CL 2002/44-FAC and CL 2003/13, Brazil already requests to include this additive for the category 7.1.6 – Mixes for bread and ordinary bakery wares.
407 – Carrageenan	9.1	Brazil requests justify the technological need in fresh products.
952 – Cyclamates	13.5	Brazil requests to check if the correct figure is 1600 instead of 16000.
472e – Diacetyltartaric and fatty acid esters of glycerol	8.1.2	Brazil requests add “Note 16” for this category
968 - Erythritol	All entries	Use levels of 200000 to 600000 (20% and 60%) represent the use of the substance as a ingredient instead of additive. Brazil does not support those levels and requests clarify the use of sweetener in salt and herbs.
127 - Erythrosine	2.1.3 2.2.1.2 14.2.1	Brazil requests justify the technological function on these food categories
	10.1	Brazil propose exclude “Note 3” from this category
310 – Gallate, propyl	6.4.2	Brazil requests add “Note 15”
	6.4.3	
575 – Glucono delta-lactone	9.1	Brazil requests justify the technological need in fresh products.
132 – Indigotine	1.6.3	Brazil requests justify the use as a surface treatment in whey cheese.
	2.1.3 2.2.1.2 14.2.1	Brazil requests justify the technological function on these food categories
	10.1	Brazil propose exclude “Note 3” from this category
953 - Isomalt	All entries	Proposed levels of 50000 to 300000 mg/kg do not have laxative effect?
966 – Lactitol	8.1	Brazil requests justify the technological need.
965 – Maltitol	9.1	
421- Mannitol	12.1.2	
961 – Neotame	1.3.2	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
	1.4.1	
	1.4.2.	

	1.5.1	
234 – Nisin	1.0	Brazil requests specify the food categories because it is not necessary in all categories.
	8.0	Question: is the level for the preparation or pure nisin?
124 – Ponceau 4R	10.1	Brazil requests exclude “Note 3”
101i -101ii – Riboflavines	2.0	Brazil requests specify the food categories because it is not necessary in all categories.
	7.0	
954 – Saccharin	4.1.2.7	Brazil does not support the level of 5000mg/kg.
541i – Sodium aluminium phosphates	05.2	Brazil requests specify reporting basis to which compound the limit apply (Note 29). Is it sulphate or aluminium?
500i – Sodium carbonate	8.1	Brazil requests justify the technological need.
262ii – Sodium diacetate	5.1.3	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
	5.1.5	
220-227 and 539 – Sulphites	11.2	Brazil requests justify the technological need.
	12.2.2	There is a provision for 12.2
110 – Sunset yellow FCF	15.1	Brazil requests clarify the high level.
334-337 - Tartrates	13.3	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
	13.4	
	13.6	
102 - Tartrazine	1.6.3	Brazil requests justify the use as a surface treatment in whey cheese.
	2.1.3	Brazil requests justify the technological function on these food categories
	2.2.1.2	
	14.2.1	
	10.1	Brazil propose exclude “Note 3” from this category
	14.2.1	Brazil requests justify the technological need.
319 – TBHQ	1.1.2	Brazil requests add “Note 15”
	1.3.1	Brazil requests clarify which ingredient is responsible for carry over in this food.
306-307 – Tocopherols	All entries	Brazil requests add “Note 15”
	6.4.2	Brazil requests clarify the technological need of the limit (2000) which is 10 times more than the other categories.
	13.3	Brazil requests that additives having numerical ADI with GMP entries should have numerical maximum level.
	13.4	
	13.6	

CHILE:

Additive	INS	Food Cat N°	Max Level Codex	COMMENTS BY CHILE
ACESULFAMO POTASSIUM	950	All categories indicated	All levels indicated	OK
ACETIC ACID, GLACIAL	260	04.2.2.7	GMP	OK
		09.2	GMP	OK
		11.1.3	330 mg/kg	No opinion
		13.1.3	GMP	OK
		14.1.5	GMP	OK
		14.2.5	500 mg/kg	OK
ACETIC AND FATTY ACID ESTERS OF GLYCEROL	472a	13.1.3	5000 mg/kg	OK
ACETYLATED DISTARCH ADIPATE	1422	01.2	GMP	OK
		13.1.1	GMP	OK
		13.1.3	6000 mg/kg	5000 mg/kg in the Codex standard for food elaborated with processed cereal foods for infants and young children
ACETYLATED DISTARCH PHOSPHATE	1414	01.2	GMP	OK
		13.1.3	6000 mg/kg	5000 mg/kg in the Codex standard for food elaborated with processed cereal foods for infants and young children
ACID TREATED STARCH	1401	All categories indicated	All levels indicated	OK
ADIPATES		01.2.1	1500 mg/kg	No opinion
ADIPIC ACID	355	04.2.7	50000 mg/kg	No opinion
SODIUM ADIPATE	356			
POTASSIUM ADIPATE	357			
AMMONIUM ADIPATE	359			
AGAR	406	06.4.1	GMP	OK
ALGINIC ACID	400	04.2.2.7	GMP	OK

		06.4.1	GMP	OK
		09.2	GMP	OK
		12.1.2	GMP	OK
		12.1.1	GMP	OK
		13.1.3	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		14.1.5	GMP	OK

ALKALINE TREATED STARCH	1402	All categories indicated	All levels indicated	OK
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ALLURA RED AC	129	All categories indicated	All levels indicated	OK
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ALPHA.AMYLASE(BACILLUS SUBTILIS)	1100	06.2.2	GMP	OK
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ALPHA.AMYLASE(BACILLUS LICHENIFORMIS)	1100	06.2.2	GMP	OK
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ALUMINIUM AMMONIUM SULPHATE	523	All categories indicated	All levels indicated	No opinion, not included in the Chilean regulations
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ALUMINIUM SILICATE	559	12.2.1	GMP	OK
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AMARANTH	123	All categories indicated	All levels indicated	Not permitted according to the Chilean regulations
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AMMONIUM CHLORIDE	510	All categories indicated	All levels indicated	OK
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ANNATTO EXTRACTS	160b	All categories indicated, except for the following categories	All levels indicated	OK
		14.2.3.	10 mg/kg	No opinion
		14.2.3.3	15 mg/kg	No opinion
ASCORBIC ACID	300	All categories indicated	All levels indicated	GMP is proposed for all of them

ASCORBYL PALMITATE	304	13.1.1	10 mg/kg	It should be verified whether this is in agreement with the Codex standard relating to this food category and it should be stated as fatty material
		13.1.2	50 mg/kg	It should be verified whether this is in agreement with the Codex standard relating to this food category and it should be stated as fatty material
		13.1.3	100 mg/kg	It should be verified whether this is in agreement with the Codex standard relating to this food category and it should be stated as fatty material
		13.3	GMP	OK
		13.4	500 mg/kg	It should be verified whether this is in agreement with the Codex standard relating to this food category and it should be stated as fatty material
		13.5	500 mg/kg	It should be verified whether this is in agreement with the Codex standard relating to this food category and it should be stated as fatty material

ASPARTAME	951	01.3.2	6000 mg/kg	OK
		01.4.1	6000 mg/kg	OK
		01.4.2	6000 mg/kg	OK
		01.4.3	6000 mg/kg	OK
		01.5.1	5000 mg/kg	OK
		01.6.1	1000 mg/kg	OK
		02.3	1000 mg/kg	OK
		04.2.2.3	2500 mg/kg	OK
		09.4	GMP	OK
		12.3	GMP	OK
		13.1.3	800 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		14.1.5	5000 mg/kg	OK

AZORUBINE	122	All categories indicated	All levels indicated	OK
BEET RED	162	12.1.1	GMP	OK
		13.1.3	20 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
BENZOATES		04.1.2.5	1500 mg/kg	No opinion
BENZOIC ACID	210	08.3.2	1000 mg/kg	OK
SODIUM BENZOATE	211	12.9.1.3	1000 mg/kg	OK
POTASSIUM BENZOATE	212			
CALCIUM BENZOATE	213			
BENZOYL PEROXIDE	928	01.8.2	100 mg/kg	No opinion
BHA	320	01.1.2	200 mg/kg	OK
		01.3.1	200 mg/kg	OK
		06.4.3	200 mg/kg	OK
		12.5.2	300 mg/kg	OK as it is, but it should be specified whether the product is ready for consumption
BHT	321	01.1.2	200 mg/kg	100 mg/kg in the Chilean regulations. Verificar evaluación toxicológica
		01.3.1	200 mg/kg	100 mg/kg in the Chilean regulations. Verificar evaluación toxicológica
BLEACHED STARCH	1403	All categories indicated	All levels indicated	OK
BRILLANT BLUE FCF	133	All categories indicated	All levels indicated	OK
CALCIUM ALGINATE	404	13.1.3	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
CALCIUM ASCORBATE	302	06.4.1	200 mg/kg	GMP is proposed

		06.4.2	200 mg/kg	GMP is proposed
		13.1.3	3000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		14.1.2.2	GMP	OK
		14.1.2.4	GMP	OK
		14.1.3.2	GMP	OK
		14.1.3.4	GMP	OK

CALCIUM CARBONATE	170i	All categories indicated	All levels indicated	GMP is proposed for all of them
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CALCIUM CHLORIDE	509	All categories indicated	All levels indicated	GMP is proposed
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CALCIUM CITRATES	333	13.1.3	GMP	OK
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CALCIUM HYDROXIDE	526	13.1.3	GMP	OK
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CALCIUM LACTATE	327	All categories indicated	All levels indicated	GMP is proposed for all of them
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CALCIUM PROPIONATE	282	All categories indicated	All levels indicated	1000 mg/kg is proposed
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CALCIUM RIBONUCLEOTIDES, 5'	634	All categories indicated	All levels indicated	OK
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CALCIUM SULPHATE	516	All categories indicated	All levels indicated	OK
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CANTHAXANTIN	161	06.3	50 mg/kg	No opinion
		14.2.7	5 mg/kg	No opinion

CARAMEL COLOUR, CLASS I	150a	All categories indicated	All levels indicated	No opinion
CARAMEL COLOUR, CLASS II	150b	All categories indicated	All levels indicated	No opinion

CARAMEL COLOUR, CLASS III	150c	All categories indicated	All levels indicated	Account should be taken of the limit for the 2-acetyl-4(5)-tetrahydroxybutylimidazole (THI) content
CARAMEL COLOUR, CLASS IV	150d	All categories indicated	All levels indicated	Account should be taken of the limit for the 4-methylimidazole (4-MeI) content
CARBON DIOXIDE	290	All categories indicated	All levels indicated	OK
CARMINES	120	All categories indicated	All levels indicated	OK, expressed as carminic acid
CARNAUBA WAX	903	All categories indicated	All levels indicated	No opinion
CAROB BEAN GUM	410	01.2	GMP	OK
		06.4.1	GMP	OK
		13.1.3	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
CAROTENES, VEGETABLES	160aii			No opinion
CAROTENOIDS		All categories indicated	All levels indicated	No opinion
Beta-Carotene (Synthetic)	160ai			
Beta-Carotene (Blakeslea trispora)	160aii			
Beta-Apo-8'-Carotenal	160e			
Beta-Apo-8'-Carotenoic Acid, Methyl or Ethyl Ester	160f			
CARRAGEENAN	407	04.2.2.7	GMP	OK
		06.4.1	GMP	OK
		09.1	GMP	OK

		13.1.2	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	300 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

CHLOROPHYLLS	140	13.1.3	20 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.6	25000 mg/kg	No opinion

CHLOROPHYLLS, COPPER COMPLEXES	141i	All categories indicated	All levels indicated	No opinion
	141ii	All categories indicated	All levels indicated	No opinion

CITRIC ACID	330	04.2.2.7	GMP	OK
		06.4.1	GMP	OK
		06.4.2	GMP	OK
		09.2	GMP	OK
		09.2.2	GMP	OK
		13.1.3	GMP	OK
		14.1.2.2	3000 mg/kg	No opinion
		14.1.2.4	3000 mg/kg	No opinion
		14.1.3.2	5000 mg/kg	No opinion
		14.1.3.4	5000 mg/kg	No opinion
		14.1.5	GMP	OK
		14.2.3	4000 mg/kg	No opinion

CITRIC AND FATTY ACID ESTERS OF GLYCEROL	472c	04.2.2.7	GMP	OK
		13.1.1	9000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	7500 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

		13.1.3	9000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
CURCUMIN	100i	All categories indicated	All levels indicated	OK
CURDLAN	424	06.4.1	GMP	No opinion
CYCLAMATES	952	13.5	16000 mg/kg	OK
DEXTRINS, WHITE AND YELLOW, ROASTED STRACH	1400	All categories indicated	GMP	OK
DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLICEROL	472e	All categories indicated except for the following three categories	All levels indicated	GMP is proposed
		13.1.1	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.3	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
DISODIUM GUANYLATE, 5'	627	All categories indicated	GMP	OK
DISODIUM INOSINATE, 5'	631	All categories indicated	GMP	OK
DISODIUM RIBONUCLEOTIDES, 5'	635	All categories indicated	GMP	OK
DISTARCH PHOSPHATE	1412	01.2	GMP	OK
		06.4.1	200 mg/kg	
		06.4.2	200 mg/kg	

		13.1.3	60000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
ENZYME TREATED STARCH	1405	All categories indicated	GMP	OK
ERYTHORBIC ACID	315	14.2.3	250 mg/kg	No opinion
ERYTHRITOL	968	All categories indicated	All levels indicated	No opinion
ERYTHOSINE	127	All categories indicated	All levels indicated	Not permitted according to the Chilean regulations, except in cherry preserves, fruit cocktail and maraschino
FAST GREEN FCF	143	All categories indicated	All levels indicated	OK
FUMARIC ACID	297	All categories indicated except for the following category	GMP	OK
		06.4.2	200 mg/kg	No opinion
GALLATE PROPYL	310	06.4.2	200 mg/kg	100 mg/kg in the Chilean regulations, in the fatty material
		06.4.3	200 mg/kg	100 mg/kg in the Chilean regulations, in the fatty material
GELLAM GUM	418	06.4.1	GMP	OK
GLUCONO DELTA-LACTONE	575	06.4.1	GMP	OK
		09.1	100 mg/kg	No opinion
		13.1.3	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

		13.2	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
GLUCOSE OXIDASE (ASPERGILLUS NIGER VAR.)	1102	06.2.1	780 mg/kg	OK
GLYCEROL	422	All categories indicated	GMP	OK
GLYCEROL ESTER OF ROSIN	445	All categories indicated	5 mg/kg	No opinion
GRAPE SKIN EXTRACT	163ii	All categories indicated except for the following category	All levels indicated	No opinion
		13.1.3	20 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
GUAIAC RESIN	314	All categories indicated	All levels indicated	No opinion
GUAR GUM	412	All categories indicated except for the following category	GMP	OK
		13.1.3	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
GUAR GUM	414	06.4.1	GMP	OK
		13.1.3	20000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

HYDROCHLORIC ACID	507	13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
HYDROGENATED POLY-1-DECENE	507	All categories indicated	All levels indicated	No opinion
HYDROXIBENZOATES, p-				
Ethyl- p-Hydroxybenzoate	214			
Methyl- p-Hydroxybenzoate	218			
Propyl- p-Hydroxybenzoate	216			
		11.6	1500 mg/kg	1000 mg/kg in the Chilean regulations
		13.6	2000 mg/kg	1000 mg/kg in the Chilean regulations
		15.1	1000 mg/kg	OK
HYDROXYPROPYL DISTARCH PHOSPHATE	1442	All categories indicated	GMP	OK
HYDROXYPROPYL STARCH	1440	All categories indicated	GMP	OK
INDIGOTINE	132	All categories indicated	All levels indicated	OK
INVERTASE (SACCHAROMYCES CEREVISIAE)	1103	All categories indicated	GMP	OK
IRON OXIDES				
Iron Oxide, Black	172i			
Iron Oxide, Red	172ii			
Iron Oxide, yellow	172iii			
		All categories indicated	All levels indicated	No opinion
ISOMALT	953	All categories indicated	All levels indicated	GMP is proposed
KARAYA GUM	416	06.4.1	GMP	OK

KONJAC FLOUR	425	All categories indicated	GMP	Not permitted according to the Chilean regulations
LACTIC ACID (L-,D-DI-)	425	All categories indicated	GMP	OK
LACTIC AND FATTY ACID ESTERS OF GLYCEROL	472a	13.1.3	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
LACTITOL	966	All categories indicated	All levels indicated	GMP is proposed for all of them
LECITHIN	322	All categories indicated	GMP	OK
MAGNESIUM CARBONATE	504i	All categories indicated	All levels indicated	GMP is proposed
MALIC ACID (DL-)	296	All categories indicated	All levels indicated	GMP is proposed for all of them
MALTITOL and MALTYTOL SYRUP	965	All categories indicated	All levels indicated	GMP is proposed for all of them
MANNITOL	421	All categories indicated	All levels indicated	GMP is proposed for all of them
MICROCRYSTALLINE CELLULOSE	460i	All categories indicated	GMP	OK
MONO- AND DIGLYCERIDES	471	06.4.1	GMP	OK
		13.1.3	5000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
MONOSODIUM GLUTAMATE, L-	621	All categories indicated	GMP	OK
MONOSTARCH PHOSPHATE	1410	01.2	GMP	OK

		13.1.1	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	50000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

NEOTAME	961	All categories indicated	All levels indicated	No opinion
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NISIN	234	All categories indicated	All levels indicated	No opinion
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NITRITES	249	09.2.4.1	100 mg/kg	OK
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NITROGEN	941	All categories indicated	GMP	No opinion
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OXIDIZED STARCH	1404	01.2	GMP	OK
		13.1.1	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	50000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

PECTIN (AMIDATED AND NON-AMIDATED)	440	All categories indicated	All levels indicated	No opinion
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PHOSPHATED DISTARCH PHOSPHATE	1413	All categories indicated	All levels indicated	OK
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PHOSPHATES		All categories indicated	All levels indicated	Should be expressed as P ₂ O ₅ and should be considered as phosphor inherent in the foodstuff
POLYDIMETHYLSILOXANE	900a	12.2.2	50 mg/kg	No opinion
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	All categories indicated	All levels indicated	GMP is proposed for all of them
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	476	05.1.1	5000 mg/kg	No opinion
POLYSORBATES		All categories indicated	All levels indicated	10000 mg/kg is proposed for all of them
POLYVINYL ALCOHOL	1203	All categories indicated	All levels indicated	No opinion
PONCEUA 4R	124	All categories indicated	All levels indicated	OK
POTASSIUM ACETATES	261	13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
POTASSIUM ALGINATES	402	13.1.3	500 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
POTASSIUM ASCORBATE	303	All categories indicated	GMP	OK
POTASSIUM CARBONATE	501i	All categories indicated	GMP	OK
POTASSIUM CHLORIDE	508	All categories indicated, excepto la siguiente	GMP	OK
		12.1.1	350 mg/kg	No opinion

POTASSIUM DIHYDROGEN CITRATE	332i	All categories indicated except for the following category	All levels indicated	It should be verified whether this is in agreement with the Codex Standard for this food category
POTASSIUM HYDROGEN CARBONATE	501ii	13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
POTASSIUM HYDROXIDE	525	13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
POTASSIUM LACTATE	326	13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
PROCESSED EUCHEUMA SEAWEED	407a	All categories indicated	GMP	No opinion
PROPYLENE GLYCOL	1520	All categories indicated	All levels indicated	No opinion
PROPYLENE GLYCOL ALGINATE	405	All categories indicated except for the following categories	All levels indicated	GMP is proposed
		13.1.1	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.2	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

PROPYLENE GLYCOL ESTERS OF FATTY ACIDS	477	02.2.1.3	10000 mg/kg	GMP is proposed
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RIBOFLAVINS		All categories indicated	All levels indicated	OK
Riboflavin 5'-Phosphate, Sodium	101i			
Riboflavin 5'-Phosphate	101ii			

SACCHARIN	954	04.1.2.7	5000 mg/kg	No opinion
		13.1.3	200 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

SILICON DIOXIDE (AMORPHOUS)	551	All categories indicated	All levels indicated	GMP is proposed for all of them
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SODIUM ACETATE	262i	All categories indicated	GMP	OK
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SODIUM ALGINATE	401	All categories indicated except for the following category	GMP	OK
		13.1.3	1000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

SODIUM ALUMINIUM PHOSPHATES		All categories indicated	All levels indicated	No opinion
Sodium Aluminium Phosphate-Acidic	541i			
Sodium Aluminium Phosphate-Basic	541ii			

SODIUM ASCORBATE	301	All categories indicated except for the following categories	All levels indicated	GMP is proposed for all of them
		13.1.1.	75 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

		13.1.3	3000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
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SODIUM ASCORBATE	500i	All categories indicated except for the following category	GMP	OK
		13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category

SODIUM CARBOXYMETHYL CELLULOSE	466	All categories indicated except for the following category	All levels indicated	GMP is proposed for all of them
		13.1.1	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	10000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.2	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category

SODIUM DIACETATE	262i	All categories indicated	GMP	OK
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SODIUM DIHYDROGEN CITRATE	331i	All categories indicated	All levels indicated	It should be verified whether this is in agreement with the Codex Standard for this food category
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SODIUM ERYTHORBATE	316	04.2.2.7	GMP	OK
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SODIUM FUMARATE	365	All categories indicated	GMP	OK
SODIUM GLUCONATE	576	All categories indicated	GMP	OK
SODIUM HYDROGEN CARBONATE	500ii	All categories indicated	GMP	OK
SODIUM HYDROXIDE	524	13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
SODIUM LACTATE	325	All categories indicated	All levels indicated	GMP is proposed for all of them
SODIUM MALATE	350ii	All categories indicated	GMP	OK
SORBITAN ESTERS OF FATTY ACIDS		All categories indicated	All levels indicated	No opinion
SORBITOL (INCLUDING SORBITOL SYRUP)	420	All categories indicated	All levels indicated	GMP is proposed for all of them
STARCH ACETATE		01.2	GMP	OK
Starch Acetate Esterified with Acetic Anhydride	1420	13.1.1	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
Starch Acetate Esterified with Vinyl Acetate	1421	13.1.2	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	50000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
STARCH SODIUM OCTENYL SUCCINATE	1450	01.2	GMP	OK

		13.1.1	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.2	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	20000 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category

STEAROYL-2-LACTYLATES		All categories indicated	All levels indicated	GMP is proposed for all of them
Sodium Stearoyl Lactylate	481i			
Calcium Stearoyl Lactylate	482i			

SUCRALOSE	955	All categories indicated	All levels indicated	No opinion
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SUCROGLYCERIDES	474	03.0	10000 mg/kg	No opinion
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SUCROSE ESTERS OF FATTY ACIDS	473	All categories indicated	All levels indicated	No opinion
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SULPHITES		All categories indicated	All levels indicated	No opinion
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SUNSET YELLOW FCF	110	All categories indicated	All levels indicated	OK
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TARTARIC, ACETIC & FATTY ACID ESTERS OF GLYCEROL (MIXED)	472f	All categories indicated	All levels indicated	GMP is proposed
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TARTRATES		All categories indicated	All levels indicated	GMP is proposed
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TARTRAZINE	102	All categories indicated	All levels indicated	OK
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TBHQ	319	All categories indicated	All levels indicated	OK, expressed as fat basis
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THAUMATIN	957	All categories indicated	GMP	No opinion
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TOCOPHEROLS		All categories indicated	GMP	GMP is proposed for all of them
Mixed Tocopherols Concentrate	306			
Alpha-Tocopherol	307			

TRAGACANTH GUM	413	0.4.1	GMP	OK
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TRIPOTASSIUM CITRATE	332ii	13.1.1	2 mg/kg	It should be verified whether this is in agreement with the Codex Standard for this food category
		13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category

TRISODIUM CITRATE	331iii	04.2.2.7	GMP	OK
		06.2	GMP	OK
		13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category

XANTHAN GUM	415	All categories indicated except for the following category	All levels indicated	GMP is proposed
		13.1.3	GMP	It should be verified whether this is in agreement with the Codex Standard for this food category

XYLITOL	967	All categories indicated except for the following category	All levels indicated	GMP is proposed for all of them
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Note: Note "It should be verified whether this is in agreement with the Codex Standard relating to this food category" is reiterated, as the additives and/or the limits for the same as stated in the standards laid down by the Committee on Foods for Special Diets do not agree.

EUROPEAN COMMUNITY:

The European Community appreciates the opportunity to comment on the proposed food additive provisions at Step 3 as contained in the circular letter 2004/44-FAC. The EC would like to make the following comments:

Circular letter 2004/44-FAC lists the food additive provisions that remain at Step 3. These include proposals to replace the GMP level by numerical level, proposals to change the previously proposed level to a higher one, proposals to permit the additive in a new food category, proposals due to changes in food category system and proposals for additive provisions at Step 3 that were contained in Appendix I of the circular letter CL 2002/44-FAC.

The European Community would like to note that it would be more beneficial to comment on the proposals for provisions for food additives for which a numerical ADI has been allocated if it was done in conjunction with the comments that are already at Step 6 or Step 5/8. This is due to the fact that the safe use of a food additive requires the understanding of the overall usage of the additive in question.

PART I Food Additive Provisions at Step 3

1) Comments on proposed use of food additives in foods for infants and young children

JECFA has expressed the opinion that children should not be exposed to food additives before the age of 12 weeks, and that the ADI does not apply to children below the age of 12 weeks¹. The EC Scientific Committee on Food (SCF) has endorsed the principle that technological additives should not be used in food for infants and young children², although exceptional technological circumstances may justify the use of an additive. Therefore, the SCF has always performed a new risk assessment on the evaluated food additives when the proposed use is for foods intended for infants and young children.

Infant formulae and follow-on formulae may satisfy all or most of the nutritional requirements of infants. Infant formulae may even be the only food for infants during their first months of life. For this reason it is imperative that this food only contains additives that are technologically justified or even indispensable. If considered necessary the authorised level of use should be the minimal amounts necessary to obtain the desired effect.

For the above reasons, the European Community

- supports the following proposals:
 - carob bean gum (INS 410), guar gum (INS 412), mono- and diglycerides (INS 471), pectins (INS 440), sodium alginate (INS 401) and xanthan gum (INS 415) in category 13.1.3
 - citric and fatty acid esters of glycerol (INS 472c) in categories 13.1.1, 13.1.2 and 13.1.3
 - carbon dioxide (INS 290) and nitrogen (INS 941) in categories 13.1.1, 13.1.2 and 13.2
 - ascorbyl esters (INS 304) in categories 13.1.1, 13.1.2 and 13.1.1, but only at the level of 10 mg/kg as proposed for category 13.1.1.
 - gum arabic (INS 414) and silicon dioxide (INS 551) in category 13.1.3 but only as a carry over from nutrient preparation. The level of gum arabic in the product ready for consumption should not be more than 10 mg/kg.
 - sodium ascorbate (INS 301) in categories 3.1, but only as a carry over from nutrient preparation. The level of sodium ascorbate in the product ready for consumption should not be more than 75 mg/kg.
 - lactic acid (L-, D- and D1-) (INS 270) in category 13.1.3, but only in L+-form.

¹ WHO (1978). Evaluation of certain food additives. Twenty-first report of the Joint FAO/WHO Expert Committee on food additives. World Health Organisation, Geneva, Technical Report series no 617.

² Opinion of the Scientific Committee on Food on the applicability of the ADI (Acceptable Daily Intake) for food additives to infants (expressed on 17/09/1998)

- potassium dihydrogen citrate (INS 332i) and tripotassium citrates (INS 332ii) in category 13.1, but at level of 2000 mg/kg and not at 2 mg/kg or GMP.
- sodium dihydrogen citrate (INS 331i) and trisodium citrate (INS 331ii) in categories 13.1 and 13.2. The level for category 13.1.3 should be the same as for 13.1.1 and 13.1.2 (2000 mg/kg).
- sodium carboxymethyl cellulose (INS 466), but only in category 13.1.3.
- starch sodium octenyl succinate (INS 1450) in category 13.1.3 and in categories 13.1.1 and 13.1.2, but in these two categories only as a carry over from nutrient preparations.
- does not support the following proposals:
 - acesulfame K (INS 950), acetic acid, glacial (INS 260), acetic and fatty acid esters of glycerol (INS 472a), acetylated distarch phosphate (INS 1414), alginic acid (INS 400), aspartame (INS 951), beet red (INS 162), calcium alginate (INS 404), calcium ascorbate (INS 302), calcium carbonate (INS 170), calcium citrates (INS 333), calcium hydroxide (INS 526), calcium lactate (INS 327), carotenes, vegetable (INS 160aii), chlorophylls (INS 140), chlorophylls, copper complexes (INS 141i), citric acid (INS 330), distarch phosphate (INS 1412), glucono delta-lactone (INS 575), grape skin extract (INS 163ii), hydrochloric acid (INS 507), lactic and fatty acids esters of glycerol (INS 472b), malic acid (DL-) (INS 296), mannitol (INS 421), neotame (INS 961), phosphated distarch phosphate (INS 1413), potassium acetates (INS 261), potassium alginate (INS 303), potassium hydrogen carbonate (INS 501ii), potassium hydroxide (INS 525), potassium lactate (INS 326), saccharin (INS 954), sodium acetate (INS 262i), sodium carbonate (INS 500i), sodium hydrogen carbonate (INS 500ii), sodium hydroxide (INS 524), sodium lactate (INS 325), sucralose (INS 955), tartrates (INS 334-337) and xylitol (INS 967) in category 13.1.3.
 - acid treated starch (INS 1401), alkaline treated starch (INS 1402) and bleached starch (INS 1403), dextrans (INS 1400), enzyme treated starch (INS 1405) and tartaric, acetic & fatty acid esters of glycerol (mixed) (INS 472f) in category 13.1.1.
 - diacetyltartaric and fatty acid esters of glycerol (INS 472e) and hydroxypropyl distarch phosphate (INS 1442) in categories 13.1.1 and 13.1.2.
 - acetylated distarch adipate (INS 1422) in categories 13.1.1 and 13.1.3.
 - monostarch phosphate (INS 1410), oxidize starch (INS 1404), potassium carbonate (INS 501i), starch acetate in categories 13.1.1, 13.1.2 and 13.1.3.
 - carrageenan (INS 407) and hydroxypropyl starch (INS 1440) in categories 13.1.2 and 13.1.3.
 - isomalt (INS 953) and propylene glycol alginate (INS 405) in categories 13.1.1, 13.1.2 and 13.2.
 - processed eucheama seaweed (INS 407a) and thaumatin (INS 957) in category 13.2.

It should be noted the CCNFSDU is currently revising the food additive provisions contained in Draft Revised Codex Standards for Infant Formulae and for Formulae for Special Medical Purposes Intended for Infants. Also the Committee has referred the food additive provisions contained in the Draft Revised Codex Standard for Processed Cereal-based Foods for Infants and Young Children for endorsement of 37th CCFAC. It is imperative that the food additive provision for categories 13.1 and 13.2 in the GSFA are in line with the provisions in corresponding standards. Therefore, the best approach might be to postpone any discussion within the GSFA on additives in these categories and to wait the outcome of the new revisions and endorsement of additives for processed cereal-based foods.

2) Comments on proposed use of food additives in pastas and noodles and like products

In the 34th session of CCFAC, the Committee agreed that food category 06.4 “Pasta and Noodles and like products” would be revised by creating three subcategories as follows:

06.4.1 Fresh pastas and noodles and like products, 06.4.2 Dried pastas and noodles and like products and 06.4.3 Pre-cooked pastas and noodles and like products. This was agreed with the understanding that there

would be few, if any, additives needed in the dried pastas and noodles category (paragraph 55 of ALINORM 03/12).

Now, however, the circular letter contains numerous proposals for the use of food additives in dried pastas and noodles and like products, for example acesulfame potassium, annatto extracts, ascorbic acid, calcium ascorbate, calcium carbonate, calcium propionate, calcium ribonucleotides, caramel colours (class II, III, IV), carmines, carotenes (vegetable), citric acid, disodium guanylate, disodium inosinate, disodium ribonucleotides, distarch phosphate, propyl gallate, lactic acid, malic acid, monosodium glutamate, phosphated distarch phosphate, polysorbates, potassium chloride, propylene glycol alginate, riboflavins, silicon dioxide, sodium ascorbate, sodium carboxymethyl cellulose, sodium gluconate, sodium hydrogen carbonate, sodium lactate, sorbitan esters of fatty acids, stearyl-2-lactates and xanthan gum.

In the view of the European Community, this is incompatible with the understanding on the agreement of CCFAC on the need for food additives in dried pastas and noodles and, therefore, these proposals cannot be supported.

3) Comments on specific food additives

ACESULFAME POTASSIUM (INS 950)

Acesulfame K is proposed for use in many categories where technological justification should be provided e.g. cream (plain) and the like (01.4), milk powder and cream powder and powder analogues (01.5), unripened cheese (01.6.1), whole, broken or flaked grain (06.1), bread and ordinary bakery wares (07.1) and grape wines (14.2.3).

ACETIC ACID, GLACIAL (INS 260)

The proposal to use acetic acid in soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup and raw cane sugar (11.1.3) is in contradiction with the Codex Standard for Sugars. Therefore, the European Community does not support this entry.

ALLURA RED AC (INS 129)

The use of allura red in lard, tallow, fish oil and other animal fats (02.1.3), margarine and similar products (02.2.1.2) and beer and malt beverages (14.2.1) should be technologically justified and at the same time it should be demonstrated that the consumer is not misled.

Consequently the EC does not support these proposals.

ALUMINIUM AMMONIUM SULPHATE (INS 523)

Many new uses are proposed for this food additive. The European Community would like to hear the technological justification for these uses. Furthermore, numerical use levels should be proposed instead of GMP, as this additive is included in the provisional tolerable weekly intake for aluminium from all sources (7 mg/kg b.w.).

ANNATO EXTRACTS (INS 160)

At its 61st meeting, JECFA examined 6 Annatto extracts (B to G). For 4 of these extracts, temporary ADIs were established. For the two remaining extracts, no ADI could be established since no data on toxicity were available. The Committee requested additional information to clarify the role that the non-pigment components play in the expression of the differences in toxicity of the extracts. In addition the Committee requested data on reproductive toxicity of an extract that contains norbixin.

Therefore, the European Community would like to suggest that the discussion on the proposed uses for Annatto extracts are postponed until a full characterization and evaluation of the whole group of Annatto extracts is available.

ASPARTAME (INS 951)

Aspartame K is proposed for use in many categories where technological justification should be provided e.g. pasteurised cream (plain) (01.4.1), sterilised and UHT creams (plain) (01.4.2), milk powder and cream powder (plain) (01.5.1), and unripened cheese (01.6.1).

BEET RED (INS 162)

The use of beet red in salt (12.1.2) should be technologically justified and at the same time it should be demonstrated that the consumer is not misled.

Consequently the EC does not support this proposal.

BENZOATES (INS 210, 211, 212, 213)

The European Community supports the use of benzoates in 04.1.2.4 jams, jellies and marmalades at level of 500 mg/kg, but only if they are energy-reduced.

BRILLIANT BLUE FCF (INS 133)

Generally the use of brilliant blue FCF is proposed for a too large variety of products. It should be considered that colours could also deceive the consumer.

For instance the use of brilliant blue FCF in lard, tallow, fish oil (02.1.3) and margarine (02.2.1.2) has a bleaching effect on the natural yellow colour of these foodstuffs. The resulting white colour serves no purpose in enhancing the safety or nutritional value of the foodstuffs. Consequently, these uses cannot be supported.

Moreover the use in cocoa products and chocolate products (05.1) and in beer and malt beverages (14.2.1) can be questioned. Consequently the EC considers it necessary to thoroughly review this listing, especially in relation to technological need.

CANTHAXANTHIN (INS 161g)

Due to the low ADI (0-0.03 mg/kg) of canthaxanthin and the high consumption of breakfast cereals, the European Community does not support the use in category 06.3.

CARAMEL COLOUR CLASS II, III AND IV (INS 150 b,c,d)

Caramel colours are being proposed for almost all food categories listed in the food category system. Considering the use of colours may mislead the consumer careful consideration should be given to those foods where the use of colour is desirable. The European Community considers that the use of colours is not necessary in the following proposed categories: dried pastas and noodles and like products (06.4.2), pre-cooked pastas and noodles and like products (06.4.3), bakery wares (07.0), meat and meat products (08.0), fresh fish and fish products (09.1), egg products (10.2), powdered sugar and other sugars (11.1.2 and 11.4) and vegetable juice and nectar (14.1.2.2, 14.1.2.4, 14.1.3.2, 14.1.3.4).

CARMINES (INS 120)

JECFA has set ADI for carmines of 0-5 mg/kg bodyweight. In view of this ADI the use of carmines is proposed for too many products. The use of carmines in the following products should be technologically justified at the same time it should be demonstrated that the consumer is not misled: fats and oils (2.1), fat emulsions mainly of type water-in-oil (2.2), pre-cooked pastas and noodles and like products (06.4.3), beer and malt beverages (14.2.1).

Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

CAROTENES, VEGETABLE (INS 160a ii, E 160a)

Generally the use of carotenes is proposed for too many products. It should be considered that colours could also deceive the consumer. Especially the proposed use in canned or bottled (pasteurised) fruit and vegetable juices and nectars (14.1.2.1 – 14.1.3.4) should be justified. The use in many other products e.g. cocoa and chocolate products (05.1.4), bread-type products (07.1.4), fresh eggs (10.1), beer and malt beverages (14.2.1) or wine in general (14.2.3) seems to be not only unjustified but rather intended to deceive the consumer. Consequently the EC considers it necessary to thoroughly review the listings for carotenes and to especially question the necessity for use.

CYCLAMATES (INS 952)

The level proposed for dietetic foods (13.5) is very high for a sweetener that is 30 times sweeter than sucrose. The European Community does not support this entry.

ERYTHROSINE (INS 127)

Due to the low ADI (0-0.1 mg/kg) of erythrosine the use of this red colour should be limited. Therefore, the European Community does not support the use in lard, tallow, fish oil and other animal fats (02.1.3), fermented vegetables (04.2.2.7), edible casings (08.4) and fully preserved fish and fish products (09.4).

GRAPE SKIN EXTRACT (INS 163ii)

Generally the use of colours should be carefully considered as colours could also deceive the consumer. The use in many products e.g. bakery wares (07.0), fresh meat, poultry and game, whole pieces or cuts (08.1.1), vegetable nectars (14.1.3.2, 14.1.3.4) and beer and malt beverages (14.2.1) seems to be unjustified. Consequently the EC considers it necessary to thoroughly review this listing and to especially question the necessity.

HYDROXYBENZOATES, p-

Ethyl p-hydroxybenzoate (INS 214), Propyl p-hydroxybenzoate (INS 216), Methyl p-hydroxybenzoate (INS 218)

The European Food Safety Authority (EFSA) has recently assessed the information on the safety of p-hydroxybenzoates and expressed its opinion on 13 July 2004³. EFSA established a full-group acceptable daily intake (ADI) of 0-10 mg/kg bw for the sum of methyl and ethyl parabens and their sodium salts. EFSA considered that propyl paraben should not be included in this group ADI because propyl paraben, contrary to methyl and ethyl paraben, had effects on sex hormones and the male reproductive organs in juvenile rats. Therefore, EFSA was unable to recommend an ADI for propyl paraben because of the lack of clear no-observed-adverse-effect-level (NOAEL).

JECFA has last evaluated parabens in 1973. The European Community would like to propose that CCFAC request JECFA to re-evaluate the safety of propyl paraben.

INDIGOTINE (INS 132)

The use of indigotine in lard, tallow, fish oil and other animal fats (02.1.3) and margarine and similar products (02.2.1.2) should be technologically justified and at the same time it should be demonstrated that the consumer is not misled.

Consequently the EC does not support these proposals.

ISOMALT (INS 953)

The proposed use in coffee etc (14.1.5), especially as proposed at level of 300 000 mg/kg, can give rise to problems due to the laxative effect of polyols. Therefore, the EC does not support this entry.

LACTITOL (INS 966)

The use of lactitol is proposed in unprocessed foods such as fresh meat (08.1) and fresh fish (09.1). The European Community questions the technological need of these uses and, therefore, does not support these entries. Furthermore, the proposed use in coffee etc (14.1.5), especially at proposed level of 30 000 mg/kg, can give rise to problems due to the laxative effect of polyols. Therefore, the EC does not support this entry.

MICROCRYSTALLINE CELLULOSE (INS 460i)

The European Community questions the need of microcrystalline cellulose in refined and raw sugars (11.1), which are mainly solid sugars. Furthermore, the Codex Standard for Sugars does not contain this food additive.

NISIN (INS 234)

In the European Community there is generally a cautious use of this preservative in foodstuffs. For this reason the technological need for nisin is recognised only in very few foodstuffs, e.g ripened cheese (01.6.1) and processed cheese (01.6.4).

³ Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a Request from the Commission related to para hydroxybenzoates (E 214-219), The EFSA Journal (2004) 83, 1-26.

The EC questions the new entries proposed at step 3 for dairy products (01.0), liquid egg products (10.2.1) and meat and meat products (08.0). Furthermore, the use in liquid egg products should be proposed by providing a numerical limit.

NITRITES (INS 249)

The European Community questions the need for nitrites in cooked fish and fish products (09.2.4.1) and does not consequently support this entry.

RIBOFLAVINES (INS 101i, 101ii)

The technical need for using colour in foodstuffs like fats and oils essentially free from water (02.1), surface-treated fresh fruit (04.1.1.2), surface-treated fresh vegetable (04.2.1.2), bread and ordinary bakery wares (07.1), other sugars (11.2), vegetable nectar (14.1.3.2, 14.1.3.4) and composite foods (16.0) could deceive the consumer and seems unjustified. These entries cannot therefore be supported.

SILICON DIOXIDE (INS 551)

The proposal to use silicon dioxide in white sugar, dextrose anhydrous etc (11.1.1) is in contradiction with the Codex Standard for Sugars. Therefore, the European Community does not support this entry. Furthermore, the EC would like to question the need of silicon dioxide in flours and starches (06.2) and in processed fish and fish products (09.2) and consequently does not support these entries.

SODIUM ALUMINIUM PHOSPHATES (INS 541i, 541ii)

The European Community questions the technological necessity of this aluminium containing additive in unripened cheese (01.6.1) and confectionery (05.2).

SORBITAN ESTERS OF FATTY ACIDS

Sorbitan Monostearate (INS 491), Sorbitan Tristearate (INS 492), Sorbitan Monolaurate (INS 493), Sorbitan Monooleate (INS 494), Sorbitan Monopalmitate (INS 495)

In a number of the suggested applications the additive seems to be technically irrelevant. Examples are: surface-treated fresh fruit (04.1.1.2), dried pastas and noodles and like products (06.4.2), pre-cooked pastas and noodles and like products (06.4.3) and grapes wines (14.2.3). Therefore, the EC cannot support these proposals.

SUCRALOSE (INS 955)

There is no technical need to use sucralose in frozen and dried fruit (04.1.2.1 and 04.1.2.2), therefore this proposal cannot be supported. In EC legislation intense sweeteners are only permitted in energy-reduced or no added sugar varieties for the majority of foodstuffs.

TARTRAZINE (INS 102)

The use of tartrazine in lard, tallow, fish oil and other animal fats (02.1.3), margarine and similar products (02.2.1.2) and beer and malt beverages (14.2.1) should be technologically justified and at the same time it should be demonstrated that the consumer is not misled.

Consequently the EC does not support these proposals.

INDONESIA:

Indonesia supports the following food additives:

- Annatto extract
- BHA
- Gallate, propyl
- Phosphate
- Propylene glycol
- Tocopherols

- TBHQ

for use in Food Category Number 06.4.3, to advance to step 5 of the procedure.

Indonesia considers those food additives are technology justified for that food category.

UNITED STATES OF AMERICA:

This responds to CL 2004/44-FAC (September 2004) which requests comments on: (i) proposed draft food additive provisions at Step 3 in the Codex General Standard for Food Additives (GSFA); and (ii) new proposals for the use of Neotame (INS 961) and Polyvinyl Alcohol (INS 1203) for inclusion in the Codex GSFA at Step 3. The United States of America appreciates the opportunity to provide the following comments for consideration at the forthcoming 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC).

1. Proposed draft food additive provisions at Step 3 in the GSFA (CL 2004/44-FAC, Appendix I)

The United States proposes that all of the proposed draft food additive provisions at Step 3 in Tables 1, 2, and 3 of the GSFA be advanced for adoption at Step 5. The United States believes this would be advantageous because the GSFA would be simplified and condensed, while not compromising the Committee's ability to fully discuss each of the draft provisions in the Standard.

Currently, the GSFA contains provisions for the use of an additive in a given food category at different use levels and at multiple steps. The United States recalls that, in part, this situation is a result of information provided at the request of the Committee to, in principle, assign numeric maximum levels for additives with numerical acceptable daily intakes (ADIs). Multiple provisions for the same additive in the same food category creates confusion in interpreting the information in the GSFA, and is inconsistent with the Codex Step process. Advancing the draft provisions at Step 3 for adoption at Step 5 would allow for the combination of multiple draft provisions for a given food category. For example, acesulfame potassium currently has provisions for use in beverage whiteners (01.3.2) at 2000 mg/kg (Step 3) and at GMP (Step 6). Advancing the provision for use at 2000 mg/kg to Step 5 would result in a consequential revision that would discontinue the Committee's work on the provision for use at GMP at Step 6.

In advancing the proposed draft food additive provisions and subsequent simplification of the GSFA, information in the GSFA will not be lost. The primary information on the use

of food additives provided by Member States and Non-Governmental Organizations is retained in the Source Worksheets that are the basis for the GSFA.

The United States believes that advancing all of the proposed draft food additive provisions at Step 3 for adoption at Step 5 will enable CCFAC to move forward with the elaboration of the GSFA in a more efficient, transparent, and clear manner.

2. New food additive provisions for inclusion in the GSFA at Step 3

The United States proposes that the following new food additive provisions be included in Tables 1 and 2 of the GSFA at Step 3. Based on information available to the United States, the following maximum levels are safe and adequate to achieve their intended technical effects.

Neotame (INS 961; Sweetener, Flavor Enhancer)

Food Category No.	Food	Use Level (mg/kg)
01.7	Yogurt	15
05.3	Chewing gum	250
07.2.1	Cakes	35
11.6	Tabletop sweetener	12
14.1.4.1	Carbonated beverages	17
14.1.4.3	Powdered lemonade	16

14.1.5	Pasteurized tea	8
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Polyvinyl Alcohol (INS 1203; Coating, Surface Finishing Agent)

Food Category No.	Food	Use Level (mg/kg)
13.6	Dietary supplements	18,000 ⁴

3. Other Comments

D-Tagatose (INS 963) was assigned a full ADI of Not Specified by the 63rd JECFA (2004). Therefore, the United States proposes that 37th CCFAC include D-tagatose in Table 3 of the GSFA at Step 3 and request information on its use in food categories listed in the Annex to Table 3 for inclusion in Tables 1 and 2 of the GSFA.

VENEZUELA:

PROPOSED DRAFT PROVISIONS ON FOOD ADDITIVES.

ADDITIVE	COMMENTS:
Cyclamate	The permitted maximum level should be 1600 mg/kg.
Allura Red AC	In Venezuela the use of this colour in fresh eggs, margarine and cheese analogues is not permitted.
Amaranth	This additive is forbidden.
Aspartame	It is necessary to take into account the latest studies indicating that this additive accumulates in the human body.
Bett Red	Is not used in foods.
Brilliant Blue FCF	In Venezuela not permitted in margarine, chocolate and derivatives.
Diacetiltartaric and Fatty Acid Esters of Glycerol	The use in fresh meat and vegetable juices is not permitted.
Fast Green FCF	The use in fresh meat is not permitted.
Grape Skin Extract	The use of this additive is not permitted.
Indigotine	Is not used in margarine.
Nisin	Is only permitted in cheese.
Ponceau 4R	Is not permitted in fresh eggs, cheese analogues and vegetable juices.
Tartrazine	Is not permitted in fresh eggs and vegetable juices. In foods where its use is permitted, its presence must be stated on the labelling.

Note: Calcium Ribonucleotides, Curdlan, Disodium Ribonucleotides 5', Guaiac Resin, Iron Oxides, Isomalt, Konjac Fluor, polydimethylsiloxane, Processed Eucheum Sea Weed and Saccharin have not been used in this country.

⁴Note: For use in aqueous film coating formulations applied to dietary supplement tablets or capsules

AAC:

The AAC (European cereal starch industry) would like to make the following comments regarding the above-mentioned document:

TABLE 1

- For convenience and clarity purpose, **we would suggest to create a general class “modified starches” that would regroup all the 15 modified starches listed in Table 1** (INS 1422, 1414, 1401, 1402, 1403, 1400, 1412, 1405, 1442, 1440, 1410, 1404, 1413, 1420, 1450) instead of having them split in the alphabetical order list. Also, we would prefer the same function descriptors applying to all modified starches.
- Due to the fact that modified starches have similar generic functions, we do not see any reason for discrepancies in the proposed conditions of use: **we would therefore recommend that the conditions of uses for all the modified starches be identical.**
- **The food category 06.2.2 “starches” is listed for phosphate with a maximum level of 6200 mg/kg. In our understanding, this inclusion results from a confusion based on a misinterpretation of information related to purity criteria of modified starches as regards the maximum limit for phosphate (resulting from the use of phosphate as reagent).** The AAC would therefore be in favour of the deletion of category 06.2.2. for phosphate.

We would be grateful if you could take these comments into consideration before advancing these food additives provisions to step 5 of the procedure.

TABLE 3

The AAC supports that the provision related to acetylated oxidised starch INS 1451 included in table 3 of the GSFA at Step 3 is advanced at step 5 of the procedure.

AMFEP:

In the GSFA, Table One - *Additives Permitted for Use Under Specified Conditions in Certain Food Categories or Individual Food Items – Provisions at Step Three* - the following enzymes are included:

- I. INS 1100: Alpha-Amylase (Bacillus subtilis)
 Function: Enzyme, flour treatment agent
 Food Cat. No.: 06.2.2
 Food Category: Starches
- II. INS 1100: Alpha-Amylase (Carbohydrase) (Bacillus licheniformis)
 Function: Enzyme, Flour Treatment Agent
 Food Cat. No.: 06.2.2
 Food Category: Starches
- III. INS 1103: Invertase (Saccharomyces cerevisiae)
 Function: Stabiliser, Thickener
 Food Cat. No.: 11.3
 Food Category: Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3
 Food Cat. No.: 11.4
 Food Category: Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)

Regarding I and II, the application of Alpha-Amylases in Starches should not be considered as an additive application but as a processing aid application. Amfep proposes to delete the Food Category Starches for this specific enzyme.

Regarding III, Amfep proposes to delete the function thickener as invertase does the reverse: liquefying sugar.

CEFS:

CEFS (Comité Européen des Fabricants de Sucre), on behalf of all sugar manufacturers in the EU and Switzerland, would like to present comments on the proposed draft food additive provisions of the General Standard for Food Additives.

At its 33rd Session, CCFAC adopted new subcategories for category 11.0 ("Sweeteners, including honey") of the Food Category System.

The new subcategories allow to separate sugars defined in the Codex Standard for Sugars (standardised sugars) and non standardised sugars. Standardised sugars are included in subcategory 11.1 and are classified according to their need in additives (owing to the maximum levels permitted in the Standard for Sugars).

The other new subcategories (11.2-11.6) comprising all other products originally present in the old category 11.0, are also listed owing to their need in additives.

CEFS is concerned to reach a consistency between the Codex Standard for Sugars (CXSN 212-2001 rev 1) and the GSFA. A lack of correspondence between both standards could lead to abuse and unfair trade practices. It is the reason why CEFS insists on the following principles :

- 1) For **standardised sugars** (subcategory 11.1) : only the additives allowed in the Codex Standard for Sugars (CXSN 212-2001-rev 1) should be permitted in the GSFA. The Committee on Sugars includes experts that are able to justify the necessity or the non-necessity of the use of additives on a technological basis. According to the expertise of the vertical Committee on Sugars, there is no technological justification for more or other additives. There is a world wide consensus with respect to this, since the Codex Standard for Sugars has recently been revised (endorsement at the 24th Meeting of the Commission of the Codex Alimentarius in Geneva, July 2001)
- 2) For **non-standardised sugars** (subcategories 11.2-11.4) : CEFS is open to the addition of other additives if there is a technological justification and need, and in amounts which do not present a hazard for health. Moreover, the labelling should mention the presence of the additives. Additives added to products of the category 11.0 which are intended to be used exclusively in the preparation of a food that is in conformity with the additive provisions of the GSFA do not have to be included in category 11.0 according to the carry-over principle (preamble of the GSFA, paragraph 4.2).

According to these principles, CEFS propose the following modifications to the proposed draft food additive provisions at step 3 of the General Standard for Food Additives:

- ❖ **The suppression of proposed additive provisions for the whole category 11.1 (products defined in the Codex Standard for Sugars)**

Since category 11.1 is subdivided into 5 subcategories for which the Codex Standard already defines additive provisions for Sugars, there is no need to determine additive provisions for the whole category 11.1. Moreover, except for sulphites, there is no technological justification for the addition of additive provisions to any subcategory within category 11.1.

Consequently, we should propose to remove from the proposed draft food additive provisions at step 3 of the GSFA the following proposed additive provision for the entire category 11.1. :

Microcrystalline Cellulose (INS 460i)

- ❖ **The adjustment of proposed additive provisions of subcategories 11.1.1, 11.1.2, 11.1.3 and 11.1.5 with provisions of the Codex Standard for Sugars**

The Codex Standard for Sugars lays down maximum levels for sulphites in all the sugars that it defines (except lactose) and seven anticaking agents in powdered sugar and powdered dextrose (subcategory 11.1.2.). This means that the sugar Commodity Committee only recognised technological needs for sulphites in sugars and anticaking agents in powdered sugars.

To reach consistency, the following proposed additive provisions should be suppressed:

Subcategory	Additives	Justification
11.1.1. White sugar, dextrose anhydrous, dextrose monohydrate, fructose	Silicon dioxide (INS 551)	Anti-caking agents are only necessary and laid down for powdered sugars (11.1.2) in the Codex Standard for Sugars
11.1.2. Powdered sugar, powdered dextrose	Caramel colour III (INS 150c) Caramel colour IV (INS 150d)	These additives are not laid down in the Codex Standard for Sugars
11.1.3. Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar	Acetic Acid, Glacial (INS:260)	This additive is not laid down in the Codex Standard for Sugars.

ELC

TABLE 1

ELC would like to make a general comment on certain proposals at step 3 in Table 1 of the GSFA, which aim to replace GMP with numerical maximum limits.

ELC understands that Table 1 specifies, for each food additive or food additive group with a numerical ADI the food or food categories in which the additive is recognised for use, the maximum use levels for each food or food category and its technological function. Table 1 also includes the uses of those additives with non-numerical ADIs for which a maximum use is specified.

ELC insists that numerical ADIs should not necessarily mean numerical limitation of use: possibility of use according to GMP should be maintained for specific categories of products and for additives with high numerical ADIs, which are unlikely to be exceeded. In this respect, particular attention should be given to caramel colours Class III and IV, for which significant moves for certain food or food categories from GMP at step 6 to numerical maximum limits at step 3 are observed.

Additional specific comments to Table 1

Due to the fact that polyols (erythritol, lactitol, maltitol, mannitol, sorbitol, xylitol) have similar generic functions, ELC does not see any reason for discrepancies in the proposed conditions of use: we would therefore recommend that the conditions of uses for all the polyols be identical. The same applies to intense sweeteners for which the basic case of need is the same for all substances listed in the draft GSFA.

TABLE 3

ELC supports that the three additives included in Table 3 at step 3 are advanced at step 5.

IFAC:

Sucralose (INS 955) is included in Table One, Appendix I, CL 2004/44-FAC, for a number of uses but not for Food Category 12.3, Vinegars. Sucralose was reviewed by JECFA at its 37th session in 1990 and allocated a permanent ADI of 0-15 mg/kg bw. The then existing tentative specifications were revised and the “tentative” classification deleted.

The International Food Additives Council, the NGO representing producers of high quality articles used as food additives, requests that Food Category 12.3, Vinegars, be added at Step 3 to the list of food categories in which Sucralose (INS 955) is permitted. The stability of sucralose allows it to function well as a sweetener in such products.

Further to December 15, 2004 comments requesting that Food Category 12.3, Vinegars, be added to the list of food categories in which Sucralose (INS 955) is permitted, the International Food Additives Council asks that sucralose be allowed at a maximum use level in accordance with Good Manufacturing Practices (GMP).

ISA:

I. Table-top sweeteners (food category 11.6)

a) Regulate the use of all sweeteners in table-top products (category 11.6) according to GMP

As per the Draft Food Category System of the Codex General Standard for Food Additives (ALINORM 04/27/12, Appendix V, part 1), tabletop sweeteners (Category 11.6) “include products that are preparations of high-intensity sweeteners and/or of polyols which may contain other additives and/or nutritive ingredients, such as carbohydrates. These products, which are sold to the final consumer, may be in powder, solid (e.g. tablets or cubes), or liquid form”.

While recognising the new principle in the GSFA that all additives assigned a numerical ADI should be assigned maximum use levels, we also note that CCFAC, in the report of its 35th session (ALINORM 03/12A, April 2003, article 44), acknowledges that **exceptions can be made** from this principle. The ISA believes strongly that table-top sweeteners present a specific category of products (11.6) where such exceptions should be permitted and we would like to request that the use of all sweeteners in table-top products should be regulated according to GMP.

Reasons for the ISA request that all sweeteners used in table-top products should be regulated according to GMP:

- 1) Sweeteners are particularly **self-limiting** in this application (per dose unit (e.g. 1 tablet, 1 sachet), a tabletop sweetener would not contain more sweetener than necessary to achieve the sweetening intensity equivalent to a dose unit of approximately 4 g of sucrose (1 teaspoonful or 1 cube);
- 2) as table-top sweeteners are being **sold to the ultimate consumer**, it is the latter that determines the amount consumed (consumers would sweeten according to taste, but not oversweeten);
- 3) additionally, **“use levels” refer to the food as consumed** and tabletop sweeteners are only consumed in conjunction with other foods (coffee, etc);
- 4) real intake data show **no evidence of exceeding the ADI**.

With the proposed maximum use levels for the given sweeteners in food category 11.6 it would be impossible for manufacturers of table-top sweeteners to continue making the table-top products they make today despite the fact that these products are safe and intake studies show that consumers do not exceed the ADI. If there is no safety issue we find it unjustified that maximum use levels have been proposed that make it impossible to continue producing existing products. Table-top sweeteners have very specific characteristics. Due to the high intensity of sweetness, they are formulated to be used in very small weight quantities (e.g. small tablets for use in coffee) by the consumer. A portion of table-top sweeteners (tablet, powder or liquid) is defined by its sugar equivalence, i.e. per dose unit equivalent to 4 g of sugar.

We hope the below examples help show that the proposed maximum use levels in food category 11.6 as per the CCFAC draft proposal (CL 2004/44-FAC- App.1) and the draft GSFA (35th CCFAC) are impractical and would make it impossible to formulate tabletops in the future:

Example I: Saccharin (INS 954)

- Sweetness intensity: 300 - 500 times sweeter than sugar.
- Typical quantity per dose unit for a sweetness equivalent to 4 g of sugar is 10 to 12,5 mg.

- Saccharin, as sodium saccharin, may be compressed in pure form to small tablets: in this case, 1 tablet, containing 10 to 12,5 mg of saccharin, without any carriers or other functional additives, would be made up of 100 % pure sodium saccharin, or 1,000.000 mg per kg of this preparation.
- Given another formulation of tablets, with some carriers, amounting to a total weight of, say, 50 mg per tablet, the same content of 12,5 mg of saccharin would present 25 % of the formulation, or 250.000 mg per kg.
- Presented in form of powder, diluted with some nutritive carrier to typically 1 g (typical presentation in sachets), this same content of 12,5 mg of saccharin would amount to 1,25 % or 12.500 mg per kg.
- The CCFAC draft proposal sets a proposed maximum use level of 4545 mg per kg. To achieve a content of 12,5 mg of saccharin per dose unit, this quantity would need to be diluted to a total mass of 2,75 g - in order to replace 4 g of sugar, making it virtually impossible to formulate into tablets and meaningless in any other presentation.

Example II: Aspartame (INS 951)

- Sweetness intensity: ca. 200 times sweeter than sugar.
- Typical quantity per dose unit for a sweetness equivalent to 4 g of sugar is 20 mg.
- Presented in form of tablets of, say, 50 mg, these 20 mg of aspartame would amount to 40 % or 400.000 mg per kg of this product.
- Packed in tablets of 100 mg, these 20 mg of aspartame would still amount to 20 % or 200.000 mg per kg.
- Presented in form of powder, in sachets of 1 g, these 20 mg would make up 2 % or 20.000 mg per kg.
- The draft GSFA proposes a maximum use level of 1000 mg per kg. Based on this maximum use level, the 20 mg of aspartame needed to replace the sweetness intensity of 4 g of sugar would have to be packed into 20 g of product - making it impossible and meaningless to formulate into tabletop sweeteners.

b) Extension of list of additives approved for use in category 11.6

As a general practice, Codex lists all additives approved for use in a given category of food. The ISA would like to extend the list of additives for food category 11.6. Annex II lists additives petitioned for use in tabletop sweeteners (Cat. 11.6) by ISA members, amended or other than listed in table 1 to CODEX draft GSFA, rev. 35th CCFAC, or in CL 2004/44-FAC.

II. Maximum use levels for Neotame (INS 961)

With regard to the proposed maximum use levels for Neotame (INS 961) the ISA supports the list in CL 2004/44-FAC with two exceptions: food category 05.2 (Confectionary including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4) and food category 05.3 (chewing gum). The ISA would like to request the maximum use level for these two categories to be increased from 330 mg/kg to 1000 mg/kg since products in these food categories are already on the market in several countries (e.g. the USA) with higher maximum use levels than 330 mg/kg.

III. Maximum use levels for other sweeteners

The ISA has carefully looked through the proposals in CL 2004/44-FAC for acesulfame-K (INS 950), aspartame (INS 951), cyclamate (INS 952), saccharin (INS 954) and sucralose (INS 955), and support all the maximum use levels that are proposed at step 3, except for the use levels proposed in food category 11.6 for acesulfame-K (INS 950), aspartame (INS 951), saccharin (INS 954) and sucralose (INS 955). In line with our above-mentioned argument we would like to propose that these sweeteners are regulated by GMP in this food category.

While agreeing with the proposed maximum levels, we would like to draw your attention to the fact that some submitted comments seem to address single sweeteners and comment on the case of need of these. The ISA wants to stress that the basic case of need for intense sweeteners is the same for all substances listed in

the Draft GSFA. The ISA therefore proposes that the listings for all intense sweeteners are discussed at the same time to avoid unjustified discrepancies in listings in the General Standard.

IV. Inclusion of the sweetener aspartame-acesulfame salt (INS 962) in table 1 of Codex

The ISA would like to request for the sweetener aspartame-acesulfame salt (INS 962) to be included in table 1 of the GSFA. The sweetener was approved by the Joint WHO/FAO Expert Committee on Food Additives (JECFA) in June 2000. JECFA concluded that the aspartame and acesulfame moieties in aspartame-acesulfame salt (INS 962) are covered by the acceptable daily intake (ADI) values previously established for aspartame (INS 951) and acesulfame-K (INS 950) separately (respectively 0-40 mg/kg bodyweight per day for aspartame and 0-15 mg/kg bodyweight per day for acesulfame-K). In our opinion aspartame-acesulfame salt (INS 962) could therefore be added to table 1 of the GSFA with the following entry:

“aspartame-acesulfame salt (INS 962) may be used in all categories where aspartame (INS 951) and acesulfame-K (INS 950) can be used. The maximum use levels for aspartame-acesulfame salt (INS 962), except for food category 11.6 in which we request that all sweeteners in use are regulated by GMP, are derived from the maximum use levels for its constituent parts, aspartame (INS 951) and acesulfame-K (INS 950). When using aspartame-acesulfame salt (INS 962), possibly in combination with the individual sweeteners (INS 950 or INS 951), the maximum use levels for aspartame (INS 951) and acesulfame-K (INS 950) should not be exceeded.”

List of additives petitioned for use in tabletop sweeteners (Cat. 11.6) by ISA members, amended or other than listed in table 1 to CODEX draft GSFA, rev. 35th CCFAC, or in CL 2004/44-FAC

INS N°	Name	Max. Level
950	Acesulfame-K	Extend to GMP
951	Aspartame	extend to GMP
962	Aspartame-acesulfame	GMP requested (ISA has proposed the inclusion of aspartame-acesulfame (962) in table 1 of GSFA)
578	Calcium Gluconate	GMP
327	Calcium Lactate	GMP
552	Calcium Silicate	GMP
150a	Caramel Colour, class 1	GMP
410	Carob Bean Gum	GMP
407	Carrageenan	GMP
330	Citric Acid	GMP
468	Crosscarmellose	GMP
968	Erythritol	GMP
637	Ethyl Maltol	GMP
418	Gellan Gum	GMP
575	Glucono Delta-Lactone	GMP
422	Glycerol	GMP
640	Glycine	GMP
412	Guar Gum	GMP
414	Gum Arabic	GMP
463	Hydroxypropyl Cellulose	GMP

464	Hydroxypropyl Methyl Cellulose	GMP
953	Isomalt	GMP
966	Lactitol	GMP
641	L-Leucine	GMP
296	Malic Acid	GMP
965	Maltitol + Maltitol Syrup	GMP
636	Maltol	GMP
421	Mannitol	GMP
461	Methyl Cellulose	GMP
465	Methyl Ethyl Cellulose	GMP
460i	Microcrystalline Cellulose	GMP
471	Mono- and Diglycerides	GMP
440	Pectins	GMP
	"Phosphates"	GMP
1200	Polydextrose	GMP
460iii	Powdered cellulose	GMP
954	Saccharin (and Na, K, Ca salts)	extend to GMP
470	Salts of Myristic, Palmitic and Stearic acids	extend to include Mg-salts of these acids
551	Silicon Dioxide	GMP
500i	Sodium Carbonate	GMP
466	Sodium Carboxymethyl Cellulose	GMP
331i	Sodium Dihydrogen Citrate	GMP
500ii	Sodium Hydrogen Carbonate	GMP
420	Sorbitol & Sorbitol Syrup	GMP
955	Sucralose	Extend to GMP
957	Thaumatococcus	GMP
413	Tragacanth Gum	GMP
331iii	Trisodium Citrate	GMP
415	Xanthan Gum	GMP
967	Xylitol	GMP

OIV:General comments

The OIV makes the following comments at the request of CL 2004/44-FAC on food additives provisions at step 3.

The OIV commented on some of these additives provisions previously at the request of CL 2003/34-FAC

The OIV seeks to better define the prescriptions and conditions of use of oenological practices uniquely necessary for the obtaining and conservation of grape wines (category 14.2.3) by limiting inputs which are not technologically justified.

In carefully examining the document CL 2004/44-FAC, the OIV proposes the withdrawal of certain additives, particularly colourings and sweeteners of the GSFA as not necessary to the development of healthy products in accordance with usual practice and which risk creating confusion in consumers.

Finally, the OIV recalls that “CCFAC noted concerns expressed by the OIV as to the excessive use of additives in the category 14.2.3 and decided to put them to the working group for consideration at the thirty-fifth session of CCFAC” (alinorm 03/12 § 63).

Specific comments

Acesulfam Potassium (Group VI)

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
ACESULFAME POTASSIUM	sweetener	950	14.2.3.	Grape Wines	500 mg/kg		3

No sweeteners should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified.

The OIV recommends this draft provision be deleted from category 14.2.3 of the GSFA

Annatto extracts

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
ANNATTO EXTRACTS	colour	160b	14.2.3.	Grape Wines	10 mg/kg		3
ANNATTO EXTRACTS	colour	160b	14.2.3.3	Fortified Grape Wines	15 mg/kg		3

No colours should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from category 14.2.3 and 14.2.3.3. of the GSFA

Ascorbic acid

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
ASCORBIC ACID	Antioxidant	300	14.2.3.	Grape Wines	250 mg/kg		3

Addition of ascorbic acid to wine to gain the protection of its antioxidising properties against the effects of oxygen in the air, which alters its colour and taste is an œnological practice approved by the OIV (Resolution oeno 12/2001). Isoascorbic acid or D-ascorbic acid or erythorbic acid have the same antioxidising power as ascorbic acid and may also be used in wine-making for this purpose. The dose used must not go above 250 mg/l.

The OIV supports the provision as to ascorbic acid, limited to 250 mg/kg, being endorsed in the GSFA for category 14.2.3.

Caramel Color Class II

Caramel Color Class III**Caramel Color Class IV**

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
CARAMEL COLOUR CLASS II	Colour	150b	14.2	Alcoholic beverages	50000 mg/kg		3
CARAMEL COLOUR CLASS III	Colour	150c	14.2	Alcoholic beverages	50000 mg/kg		3
CARAMEL COLOUR CLASS IV	Colour	150d	14.2	Alcoholic beverages	50000 mg/kg		3

No colours should be used for still grape wines category (14.2.3.1.) and sparkling grape wines (14.2.3.2.). Their use in these categories does not seem technologically justified and could mislead consumers.

However, the addition of caramel to colour certain liqueur wines (14.2.3.3) is a generally accepted practice.

Moreover, an ADI for Class I 'Not specified' was established at the 29th JECFA (1985), an ADI for Class II of 0-160 mg/kg bw was established at the 55th JECFA (2000), an ADI for Class III of 0-200 mg/kg bw (0-150 mg/kg bw on solids basis) was established at the 29th JECFA (1985) and an ADI for Class IV of 0-200 mg/kg bw (0-150 mg/kg bw on solids basis) was established at the 29th JECFA (1985).

The OIV recommends this draft provision be deleted from category 14.2. of the GSFA and strongly recommends precisising each sub-category in which these colours could be accepted.

Carotenes, Vegetable

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Carotenes, vegetable	Colour	160 aii	14.2.3.1	Still Grape Wines	600 mg/kg		3
Carotenes, vegetable	Colour	160 aii	14.2.3.2	Sparkling Grape Wines	1000 mg/kg		3
Carotenes, vegetable	Colour	160 aii	14.2.3.3	Fortified Grape Wines	600 mg/kg		3

No colours should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from categories 14.2.3.1, 14.2.3.2. and 14.2.3.3. of the GSFA

This provision could be maintained in categories 14.2.4. and 14.2.7

Carotenoids

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Carotenoids	Colour	160 ai 160 e	14.2.3.	Sparkling Grape	1000 mg/kg		3

		160 aii 160 f		Wines			
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No colours should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from category 14.2.3 of the GSFA

Citric acid

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Citric acid	Acidity regulator antioxidant, sequestrant	330	14.2.3.	Grape Wines	4000 mg/kg		3

Increasing titration or real acidity (decreasing the pH) through the addition of lactic acid, L(-) DL malic acid or citric acid to balance the taste of wines and further a favourable biological development and a good level of preservation is an œnological practice approved by the OIV (Resolutions oeno 4/1999 and oeno 14/2001).

The addition of acids to wine is permissible only insofar as the initial acidity is not raised by more than 54 meq/l (i.e. 4000 mg of tartaric acid per litre).

The OIV supports the provision as to citric acid, at the dose mentioned, being endorsed in the GSFA for category 14.2.3.

Curcumin

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Curcumin	Colour	100i	14.2.3.1	Still Grape Wines	200 mg/kg		3
Curcumin	Colour	100i	14.2.3.2	Sparkling Grape Wines	200 mg/kg		3

No colours should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from categories 14.2.3.1 and 14.2.3.2. and 14.2.3.3. of the GSFA

Erythorbic acid

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Erythorbic acid	Antioxidant	315	14.2.3.	Grape Wines	250 mg/kg		3

Addition of ascorbic acid to wine to gain the protection of its antioxidising properties against the effects of oxygen in the air, which alters its colour and taste is an œnological practice approved by the OIV (Resolution oeno 12/2001). Isoascorbic acid or D-ascorbic acid or erythorbic acid have the same antioxidising power as ascorbic acid and may also be used in wine-making for this purpose. The dose used must not go above 250 mg/l.

The OIV supports the provision as to Erythorbic acid, limited to 250 mg/kg, being endorsed in the GSFA for category 14.2.3.

Grape Skin Extract

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Grape skin extract	Colour	163ii	14.2.3.2	Sparkling Grape Wines	1500 mg/kg		3
Grape skin extract	Colour	163ii	14.2.3.3	Fortified Grape Wines	1500 mg/kg		3

No colours should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from categories 14.2.3.1, 14.2.3.2. and 14.2.3.3. of the GSFA

This provision could be maintained in categories 14.2.4. and 14.2.7

Lactic acid

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
LACTIC ACID (L-, D- & DL-)	Acidity regulator	270	14.2.3	Grape Wines	4000 mg/kg		3

Increasing titration or real acidity (decreasing the pH) through the addition of lactic acid, L(-) DL malic acid or citric acid to balance the taste of wines and further a favourable biological development and a good level of preservation is an œnological practice approved by the OIV (Resolutions oeno 4/1999 and oeno 14/2001).

The addition of acids to wine is permissible only insofar as the initial acidity is not raised by more than 54 meq/l (i.e. 4000 mg of tartaric acid per litre).

The OIV supports the provision as to lactic acid, at the dose mentioned, being endorsed in the GSFA for category 14.2.3.

Malic acid

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
MALIC ACID (DL-)	Acidity regulator	270	14.2.3	Grape Wines	4000 mg/kg		3

Increasing titration or real acidity (decreasing the pH) through the addition of lactic acid, L(-) DL malic acid or citric acid to balance the taste of wines and further a favourable biological development and a good level of preservation is an œnological practice approved by the OIV (Resolutions oeno 4/1999 and oeno 14/2001).

The addition of acids to wine is permissible only insofar as the initial acidity is not raised by more than 54 meq/l (i.e. 4000 mg of tartaric acid per litre).

The OIV supports the provision as to malic acid, at the dose mentioned, being endorsed in the GSFA for category 14.2.3.

Riboflavines

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
RIBOFLAVINES	Colour	101i	14.2.3.2	Sparkling	300 mg/kg		3

				Grape Wines			
RIBOFLAVINES	Colour	101i	14.2.3.3	Fortified Grape Wines	300 mg/kg		3

No colours should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from categories 14.2.3.1 and 14.2.3.2. and 14.2.3.3. of the GSFA

This provision could be maintained in categories 14.2.4. and 14.2.7

Sorbitan ester fatty acids

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Sorbitan esters of fatty acids	Emulsifier, stabilizer	491, 493, 495, 492, 494	14.2.3	Grape Wines	1000 mg/kg		3

The use of Sorbitan esters of fatty acids is questionable and does not seem technologically justified in the wine making process.

The OIV requests more information on the need for emulsifiers and stabilizers in category 14.2.3. grape wines

Tartrates

Name	Fonction	INS	Food N°	Category	Max level	Note	Step
Tartrates	Acidity regulator, stabilizer, thickener	334, 335i, 335ii, 336i, 336ii, 337	14.2.3.2	Sparkling Grape Wines	4000 mg/kg		3
Tartrates	Acidity regulator, stabilizer, thickener	334, 335i, 335ii, 336i, 336ii, 337	14.2.3.3	Fortified Grape Wines	4000 mg/kg		3

Increasing titration or real acidity (decreasing the pH) through the addition of lactic acid, L(-) DL malic acid or citric acid to balance the taste of wines and further a favourable biological development and a good level of preservation is an œnological practice approved by the OIV (Resolutions oeno 4/1999 and oeno 14/2001).

The addition of acids to wine is permissible only insofar as the initial acidity is not raised by more than 54 meq/l (i.e. 4000 mg of tartaric acid per litre).

However, in the wine making process, OIV only allows the use of Potassium salt of tartaric acid and does not accept the use of sodium salt.

In these conditions, the OIV supports the provision as to tartrates, at the dose mentioned, being endorsed in the GSFA for category 14.2.3.2 and 14.2.3.3 only for tartaric acid (INS 334), monopotassium tartrate (INS 336i) and dipotassium tartrate (INS 336ii)

In addition, the use of tartaric acid is very common in the wine making process and in particular for still grape wines. For this reason, the OIV proposes a new entry for tartrates in category 14.2.3.1 still grape wines at the dose of 4000 mg/kg for Tartaric acid (INS 334), monopotassium tartrate (INS 336i) and dipotassium tartrate (INS 336ii).