

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 6

CX/FAC 99/5
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-first Session

The Hague, The Netherlands, 22-26 March 1999

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS

BACKGROUND

1. In accordance with the section concerning Relations between Commodity Committees and General Committees in the *Codex Alimentarius Commission Procedural Manual* (Tenth Edition, pages 76-78), "All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred and will require to be endorsed by the Codex Committee on Food Additives and Contaminants".
2. In consideration of the above and other provisions of the *Codex Alimentarius Commission Procedural Manual*, the attached food additive provisions are being submitted to the Codex Committee on Food Additives and Contaminants for endorsement. It is suggested that those food additives and corresponding use levels endorsed by the Committee be incorporated into the Codex General Standard for Food Additives.
3. The following food additive provisions of Codex standards are listed by (i) technological function, INS number and food additive name; (ii) proposed level; (iii) ADI (mg/kg body weight), and; (iv) notes.
4. **This document does not include previously endorsed food additives provisions at the same levels of use as specified in draft Codex standards recently considered by the Committee.**

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes	
CODEX COMMITTEE ON MILK AND MILK PRODUCTS, 3RD SESSION, MAY 1998 (ALINORM 99/11) ¹				
DRAFT REVISED STANDARD FOR BUTTER AT STEP 8 (Appendix IV) ²				
Colours				
160a(i)	β-Carotene (synthetic)	25 mg/kg	0-5	Temporarily endorsed (beta-carotene)
160a(ii)	Carotenenes (natural extracts)	600 mg/kg	Acceptable (provided the level of use does not exceed the level normally found in vegetables)	Temporarily endorsed (beta-carotene at 25 mg/kg)
160e	β-apo-Carotenal	35 mg/kg	0-5 (group ADI expressed as the sum of the carotenoids: β-carotene, β-apo-8'-carotenal and β-apo-8'-carotenoic acid, methyl and ethyl esters)	The CCMMP noted the technical need for colours in order to adjust seasonal variations in the natural colour and for the production of butter from sources other than cows' milk.
160f	β-apo-8'-Carotenoic acid, methyl or ethyl ester	35 mg/kg	0-5 (group ADI expressed as the sum of the carotenoids: β-carotene, β-apo-8'-carotenal and β-apo-8'-carotenoic acid, methyl and ethyl esters)	
Acidity Regulators				
339	Sodium phosphates	2 g/kg	MTDI 70 (as P from all sources)	Temporarily endorsed.
500(i)	Sodium carbonate)	Not limited) Maximum levels amended in accordance
500(ii)	Sodium hydrogen carbonate) Limited by GMP	Not specified) with the General Standard for Food
524	Sodium hydroxide)	Not limited) Additives.
526	Calcium hydroxide)	Not limited)

¹ The CCFAC at its 29th Session considered the food additives provisions of the revised standards for dairy products at Step 8 (then) and endorsed a majority of the provisions. The CCMMP at its 3rd Session in May 1998, agreed to add a number of food additives in the food additives provisions and to amend the maximum levels of certain food additives. They are being submitted to the CCFAC for endorsement.

² The 3rd Session of the CCMMP decided to add several colours and to amend the maximum levels for acidity regulators. These newly added colours and amended levels of acidity regulators are being submitted for endorsement.

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
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DRAFT REVISED STANDARD FOR EVAPORATED MILKS AT STEP 8 (Appendix VI)

Emulsifier

322	Lecithin	Limited by GMP	Not limited	new
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DRAFT REVISED STANDARD FOR SWEETENED CONDENSED MILKS AT STEP 8 (Appendix VII) ³

Emulsifier

322	Lecithin	Limited by GMP	Not limited	new
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DRAFT REVISED STANDARD FOR MILK POWDERS AND CREAM POWDERS AT STEP 8 (Appendix VIII)

Anticaking Agents

341(iii)	Tricalcium orthophosphate)	MTDI 70 (expressed as P from all sources)	
170(i)	Calcium carbonate)	Not specified	Endorsed except the use of potassium aluminium silicate and calcium aluminium silicate. These two substances were added by the 3rd Session of the CCMMP.
530	Magnesium oxide)	Not limited	
504(i)	Magnesium carbonate)	Not specified	
343	Trimagnesium phosphate)	MTDI 70	
559	Aluminium silicate)	Not specified	As no ADI has been allocated for potassium aluminium silicate, it is recommended to withdraw this substance.
552	Calcium silicate)	Not specified	
553	Magnesium silicates)	Not specified	
554	Sodium aluminosilicate)	Not specified	
551	Silicon dioxide, amorphous)	Not specified	
555	Potassium aluminium silicate)	No ADI allocated	
556	Calcium aluminium silicate)	Not specified	

Antifoaming Agent

900	Polydimethylsiloxane	Limited by GMP	0-1.5 (applies only to compounds with a relative molecular mass in the range of 200-300)	new
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³ In response to the question of the CCFAC on the inclusion of aspartame in sweetened condensed milks, the CCMMP at its 3rd Session decided to delete this substance from the food additive provision of the Draft Revised Standard for Sweetened Condensed Milks.

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes	
DRAFT REVISED STANDARD FOR CHEESE AT STEP 8 (Appendix IX) ⁴				
<i>Ripened cheeses, including mould ripened cheeses</i>				
Colours				
160a(i)	Carotenes(synthetic)	25mg/kg	0-5	
160e	β -apo-Carotenal	35 mg/kg	0-5 (group ADI expressed as the sum of the carotenoids: β -carotene, β -apo-8'-carotenal and β -apo-8'-carotenoic acid, methyl and ethyl esters)	
160f	β -apo-8'-Carotenoic acid, ethyl ester	35 mg/kg	0-5 (group ADI expressed as the sum of the carotenoids: β -carotene, β -apo-8'-carotenal and β -apo-8'-carotenoic acid, methyl and ethyl esters)	
171	Titanium dioxide	Limited by GMP	Not limited	
120	Carmines (for red marbled cheeses only)	Limited by GMP	0-5	
140	Chlorophylls (for green marbled cheeses only)	Limited by GMP	Not limited	
153	Vegetable carbon (For layered cheeses only)	Limited by GMP	No ADI allocated	Withdrawal recommended due to the lack of an ADI.
163	Anthocyanines (for red marbled cheeses only)	Limited by GMP	No ADI allocated	Withdrawal recommended due to the lack of an ADI.
162	Beet red	Limited by GMP	Not specified	
Bleaching Agents				
928	Benzoyl peroxide	1g/kg (used to bleach dairy ingredients on weight of bleached milk)	0-40	

⁴ The 3rd Session of the CCMMP decided to add a number of food additives in the Draft Revised Standard, including colours/bleaching agent and preservatives. These newly added food additives are now submitted for endorsement.

Food Additive		Maximum Level	ADI (mg/kg body weight)	Notes
Preservatives				
200	Sorbic acid)) 0-25 (As sum of sorbic acid and Ca, K	
201	Sodium sorbate) 3000 mg/kg, calculated as) and Na sorbates expressed as sorbic	
202	Potassium sorbate) sorbic acid) acid)	
203	Calcium sorbate))	
280	Propionic acid) 3000 mg/kg, calculated as	Not limited	
281	Sodium propionate) propionic acid	Not limited	
282	Calcium propionate)	Not limited	
Miscellaneous Additive				
508	Potassium chloride	Limited by GMP	Not specified	
<i>Sliced, cut, shredded or grated cheese</i>				
Preservatives				
200	Sorbic acid) 1 g/kg singly or in) 0-25 (As sum of sorbic acid and Ca, K	
202	Potassium sorbate) combination, calculated as) and Na sorbates expressed as sorbic	
203	Calcium sorbate) sorbic acid) acid)	
235	Pimaricin (natamycin)	10 mg/kg, for surface treatment, calculated on weight of cheese	0-0.3	At the 3rd Session of the CCMMP, a number of delegations opposed to the extension of the approval of pimaricin (natamycin)(INS 235) ¹ to Sliced, Cut, Shredded and Grated Cheese. Although the CCMMP felt that the substance should not be in the food as consumed, it referred the matter to the CCFAC and requested the Delegation of Canada to provide a written technical justification to the CCFAC.

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
CODEX COMMITTEE ON SUGARS (CL 1998/12-S)⁵			
REVISED DRAFT STANDARD FOR SUGARS ST STEP 6 (Appendix I)			
Antioxidant			
220 Sulphur dioxide	50 mg/kg for glucose syrup or dried glucose syrup used as a food ingredient 150 mg/kg for dried glucose used to manufacture sugar confectionery 400 mg/kg for glucose syrup used to manufacture sugar confectionery 70 mg/kg for plantation or mill white sugar 20 mg/kg for raw cane sugar	0-0.7 (for sulphur dioxide and sulphites)	Changed from 20 mg/kg which was endorsed by the 29th CCFAC. The maximum level of 70 mg/kg for plantation or mill white sugar was also recommended by the CCASIA at its 11th Session ⁶

⁵ The CCFAC at its 29th Session endorsed the food additives provision of the Draft Revised Standard for Sugars at its 29th Session as submitted. Since the 29th Session of the CCFAC, the United Kingdom Secretariat of the Codex Committee on Sugars has amended the maximum level of sulphur dioxide in plantation or mill white sugar; amended or included the maximum levels of sulphur dioxide in glucose syrup; and included the maximum level of sulphur dioxide in raw cane sugar. They are being submitted to the CCFAC for endorsement.

⁶ ALINORM 99/15, paras 76-78.

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
Anticaking Agents			
341(iii) Calcium phosphate, tribasic)	MTDI 70 (as P from all sources)	Proposed at 1.5% m/m for endorsement but the 29th CCFAC endorsed the provision at the maximum level of 1.5 mg/kg ⁷ . Magnesium silicate (no ADI allocated) has since been deleted.
504(i) Magnesium carbonate) 1.5% m/m singly or in	Not specified	
551 Silicon dioxide, amorphous) combination for powdered	Not specified	
552 Calcium silicate) sugar and powdered dextrose	Not specified	
553(ii) Magnesium trisilicate) (provided that starch is not	Not specified	
554 Sodium aluminosilicate) present)	Not specified	
556 Calcium aluminium silicate)	Not specified	

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES, 19TH SESSION, MARCH 1998 (ALINORM 99/27)⁸

DRAFT REVISED STANDARD FOR CANNED APPLESAUCE AT STEP 6 (Appendix II)

Acidifying Agents

296 Malic acid	Limited by GMP	Not specified	Endorsed for the existing standard
330 Citric acid	Limited by GMP	Not limited	Endorsed for the existing standard

Antioxidants

300 Ascorbic acid	150 mg/kg	Not specified	Endorsed for the existing standard. The CCPFV has not concluded the discussion on whether to allow the use of isoascorbic acid.
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Flavouring Agents

Natural and artificial flavours except those which reproduce the flavour of apple	Limited by GMP
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⁷ ALINORM 97/12A, page 55

⁸ The Codex Committee on Processed Fruits and Vegetables (CCPFV) at its 19th Session in March 1998 considered the Draft Revised Standards for Canned Applesauce and Canned Pears and decided to place a number of food additives and their maximum levels in square brackets pending information from Member countries. As no decision has been made on these provisions, they are not included in this paper. Once the CCPFV agrees on these provisions, they will be submitted to the CCFAC as necessary.

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes	
DRAFT REVISED STANDARD FOR CANNED PEARS AT STEP 6 (Appendix III)				
Acidifying Agents				
330	Citric Acid	Limited by GMP	Not limited	Endorsed for the existing standard
296	Malic Acid	Limited by GMP	Not specified	Endorsed for the existing standard
334	L-Tartaric Acid	Limited by GMP	0-30	Although endorsed previously for the existing standard, according to the current practice of the CCFAC, there is a need for a numerical maximum level.
270	Lactic Acid	Limited by GMP	Not limited	Endorsed for the existing standard

Flavouring Agents

Natural and Artificial Flavours, except those which reproduce the flavour of pears. Limited by GMP

The following Draft Standards were developed up to Step 5 by the Codex Coordinating Committee for Asia and therefore contained in ALINORM 99/15. They will be further elaborated by the Codex Committee on Processed Fruits and Vegetables.

DRAFT STANDARD FOR PICKLES AT STEP 6 (Appendix III)

Preservatives

220	Sulphur dioxide)	0-0.7 (for sulphur dioxide and sulphites)	
221	Sodium sulphite)	30 mg/kg (as sulphur dioxide)	
222	Sodium hydrogen sulphite)		
223	Sodium metabisulphite)		
224	Potassium metabisulphite)		
211	Sodium benzoate)	250 mg/kg as benzoic acid	0-5 (Group ADI for benzoic acid and its Ca, K and Na salts, benzoic acetate, alcohol and benzoate expressed as benzoic acid)
212	Potassium benzoate)		
200	Sorbic acid)	1000 mg/kg as sorbate	0-25 (As sum of sorbic acid and Ca, K and Na sorbates expressed as sorbic acid)
202	Potassium sorbate)		

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
Acidity Regulator			
260 Acetic acid (glacial)	Limited by GMP	Not limited	
Flavouring Agents			
Oleoresins	Limited by GMP		
DRAFT STANDARD FOR KIMCHI (Appendix IV)			
Flavouring Agents			
Natural flavours and nature-identical flavours, as defined in the <i>Codex Alimentarius</i> , Volume 1A)) Limited by GMP))		
Flavour Enhancers			
Disodium 5'-guanylate)	Not specified	
Disodium 5'-inosinate) Limited by GMP	Not specified	
Monosodium L-glutamate)	Not specified	
Acidity Regulators			
Lactic acid)	Not limited	
Citric acid) Limited by GMP	Not limited	
Acetic acid)	Not limited	
Thickening and Stabilizing Agents			
Carrageenan(including furcellaran))) 2 g/kg	Not specified (temporary)	“Limited by GMP” recommended
Xanthan gum)	Not specified	“Limited by GMP” recommended
Texturizer			
Sorbitol	Limited by GMP	Not specified	

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
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CODEX COMMITTEE ON COCOA PRODUCTS AND CHOCOLATE, 17TH SESSION, NOVEMBER 1998 (ALINORM 99/14)

PROPOSED DRAFT REVISED STANDARD FOR COCOA BUTTERS AT STEP 5 (Appendix II)

Processing Aid

Hexane (62°C - 82°C) 1 mg/kg (Use limited by GMP)

PROPOSED DRAFT REVISED STANDARD FOR COCOA (CACAO) MASS (COCOA/CHOCOLATE LIQUOR) AND COCOA CAKE, FOR USE IN THE MANUFACTURE OF COCOA AND CHOCOLATE PRODUCTS AT STEP 5 (Appendix III)

Acidity Regulators

503 (i)	Ammonium carbonate	Limited by GMP	Not specified
527	Ammonium hydroxide	Limited by GMP	Not limited
503 (ii)	Ammonium hydrogen carbonate	Limited by GMP	Not specified
170 (i)	Calcium carbonate	Limited by GMP	Not specified
526	Calcium hydroxide	Limited by GMP	Not limited
330	Citric acid	Limited by GMP	Not limited
504 (i)	Magnesium carbonate	Limited by GMP	Not specified
528	Magnesium hydroxide	Limited by GMP	Not limited
501 (i)	Potassium carbonate	Limited by GMP	Not specified
525	Potassium hydroxide	Limited by GMP	Not limited
501 (ii)	Potassium hydrogen carbonate	Limited by GMP	Not specified
500 (i)	Sodium carbonate	Limited by GMP	Not limited
524	Sodium hydroxide	Limited by GMP	Not limited
500 (ii)	Sodium hydrogen carbonate	Limited by GMP	Not specified
338	Orthophosphoric acid	2.5 g/kg expressed as P ₂ O ₅	MTDI 70 (as P from all sources)
334	Tartaric acid (L (+)-)	5 g/kg	0-30

Emulsifiers

471	Mono- and di-glycerides of fatty acids	Limited by GMP	Not specified
322	Lecithin	Limited by GMP	Not limited
442	Ammonium salts of phosphatidic acid	10 g/kg	0-30 (the phosphorus content is to be included in the ADI for phosphates)

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
Flavouring Agents			
Natural and artificial flavours, except those which reproduce the flavour of chocolate and milk	Limited by GMP		
Vanillin	Limited by GMP	0-10	
Ethyl vanillin	Limited by GMP	0-3	

PROPOSED DRAFT REVISED STANDARD FOR COCOA POWDERS (COCOAS) AT STEP 5 (Appendix IV)

Acidity Regulators

503(i)	Ammonium carbonate	Limited by GMP	Not specified
503(ii)	Ammonium hydrogen carbonate	Limited by GMP	Not specified
527	Ammonium hydroxide	Limited by GMP	Not limited
170(i)	Calcium carbonate	Limited by GMP	Not specified
330	Citric acid	Limited by GMP	Not limited
504(i)	Magnesium carbonate	Limited by GMP	Not specified
528	Magnesium hydroxide	Limited by GMP	Not limited
501(i)	Potassium carbonate	Limited by GMP	Not specified
501(ii)	Potassium hydrogen carbonate	Limited by GMP	Not specified
525	Potassium hydroxide	Limited by GMP	Not limited
500(i)	Sodium carbonate	Limited by GMP	Not limited
500(ii)	Sodium hydrogen carbonate	Limited by GMP	Not specified
524	Sodium hydroxide	Limited by GMP	Not limited
338	Orthophosphoric acid	2.5 g/kg, expressed as P ₂ O ₅ , on the cocoa fraction	MTDI 70 (expressed as P from all sources)
334	Tartaric acid (L (+)-)	5 g/kg on the cocoa fraction	0-30

Emulsifiers

471	Mono- and di-glycerides of fatty acids	Limited by GMP	Not specified
322	Lecithin	Limited by GMP	Not limited
442	Ammonium salts of phosphatidic acid	10 g/kg	0-30 (the phosphorus content is to be included in the ADI for phosphates)
473	Edible sucrose esters of fatty acids	10 g/kg	0-20

Temporarily endorsed

Food Additive	Maximum Level	ADI (mg/kg body weight)	Notes
Flavouring Agents			
Natural and artificial flavours, except those which reproduce the flavour of chocolate or milk	Limited by GMP		
Vanillin	Limited by GMP	0-10	
Ethyl vanillin	Limited by GMP	0-3	
Anti-caking Agents			
559 Aluminium silicate	10 g/kg in Cocoa sugar mixtures	Not specified	
552 Calcium silicate	10 g/kg in Cocoa sugar mixtures	Not specified	
553(i) Magnesium silicate	10 g/kg in Cocoa sugar mixtures	Not specified	
553(ii) Magnesium trisilicate	10 g/kg in Cocoa sugar mixtures	Not specified	
553(iii) Talc	10 g/kg in Cocoa sugar mixtures	Not specified	
555 Potassium aluminium silicate	10 g/kg in Cocoa sugar mixtures	No ADI allocated	Withdrawal recommended
554 Sodium aluminosilicate	10 g/kg in Cocoa sugar mixtures	Not specified (Group ADI for silicone dioxide and certain silicates)	
551 Silicone dioxide, amorphous	10 g/kg in Cocoa sugar mixtures	Not specified (Group ADI for silicone dioxide and certain silicates)	
341 (iii) Tricalcium phosphate	10 g/kg in Cocoa sugar mixtures	MTDI 70 (as P from all sources)	
Sweeteners			
953 Isomalt (Isomaltitol)	Limited by GMP	Not specified	
966 Lactitol	Limited by GMP	Not specified	
421 Mannitol	Limited by GMP	Not specified	
965 Maltitol and maltitol syrup	Limited by GMP	Not specified	
420 Sorbitol and sorbitol syrup	Limited by GMP	Not specified	
967 Xylitol	Limited by GMP	Not specified	