

codex alimentarius commission E



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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Agenda Item 4

CX/FA 09/41/4

January 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-first Session

Shanghai, China, 16-20 March 2009

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

BACKGROUND

1. In accordance with the section concerning Relations between Commodity Committees and General Committees of the Codex Alimentarius Commission Procedural Manual, “*All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the Committee on Food Additives, preferably before the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.*”.

2. The following food additive and processing aids provisions of Codex standards have been submitted for endorsement since the 39th Session of the Codex Committee on Food Additives and are listed by:

- (i) Technological function, INS number and food additive name;
- (ii) Proposed level;
- (iii) ADI (mg additive/kg body weight per day); and
- (iv) Notes.

3. The following abbreviations have been used in the preparation of this paper:

INS International Numbering System for food additives. The INS has been prepared by the Codex Committee on Food Additives for the purpose of providing an agreed international numerical system for identifying food additives in ingredient lists as an alternative to the declaration of the specific name¹.

ADI Acceptable Daily Intake. An estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg)². The ADI is listed in units of mg per kg of body weight.

¹ Class Names and the International Numbering System for Food Additives (CAC/GL 36-2001).

² JECFA Glossary of Terms: <http://www.who.int/ipcs/food/jecfa/en/index.html>.

ADI “Not Specified”. A term applicable to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of JECFA, represent a hazard to health. For that reason, and for reasons stated in individual evaluations, the establishment of an acceptable daily intake expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of good manufacturing practice, i.e., it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance².

ADI “Not Limited”. A term no longer used by JECFA that has the same meaning as ADI "not specified"².

Temporary ADI. Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA. The temporary ADI is listed in units of mg per kg of body weight².

Conditional ADI. A term no longer used by JECFA to signify a range above the "unconditional ADI" which may signify an acceptable intake when special problems, different patterns of dietary intake, and special groups of the population that may require consideration are taken into account².

No ADI allocated. There are various reasons for not allocating an ADI, ranging from a lack of information to data on adverse effects that call for advice that a food additive or veterinary drug should not be used at all. The report should be consulted to learn the reasons that an ADI was not allocated².

Acceptable².

Flavouring agents: Used to describe flavouring agents that are of no safety concern at current levels of intake and subsequent reports of meetings on food additives). If an ADI has been allocated to the agent, it is maintained unless otherwise indicated.

Enzyme preparations: Used to describe enzymes that are obtained from edible tissues of animals or plants commonly used as foods or are derived from microorganisms that are traditionally accepted as constituents of foods or are normally used in the preparation of foods. Such enzyme preparations are considered to be acceptable provided that satisfactory chemical and microbiological specifications can be established.

Food additives: Used on some occasions when present uses are not of toxicological concern or when intake is self-limiting for technological or organoleptic reasons.

Acceptable Level of Treatment. ADIs are expressed in terms of mg per kg of body weight per day. In certain cases, however, food additives are more appropriately limited by their levels of treatment. This situation occurs most frequently with flour treatment agents. It should be noted that the acceptable level of treatment is expressed as mg/kg of the commodity. This should not be confused with an ADI².

Good Manufacturing Practice (GMP) in the Use of Food Additives³ means that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;

³ Procedural Manual of the Codex Alimentarius Commission (Definitions)

- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

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

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)

The 24th Session of the CCPFV referred to the CCFA for endorsement the sections on food additives of the Draft Standards for Jams, Jellies and Marmalades and Certain Canned Vegetables. *See* ALINORM 09/32/27, paras 87-95 and Appendices II, III and V.

The Committee also agreed to request the Committee on Food Additives to associate new functional classes with the food additives below in the *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1986), as follows:

- ascorbic acid (INS 300): preservative (proposed for Jams, Jellies and Marmalades) and acidity regulator (for Certain Canned Vegetables);
- mono- and diglycerides (INS 471): antifoaming agent (proposed for Jams, Jellies and Marmalades).

DRAFT STANDARD FOR JAMS, JELLIES AND MARMALADES`

(at Step 8 of the Procedure)

4. FOOD ADDITIVES

Only those food additive classes listed below are technologically justified and may be used in products covered by this Standard. Within each additive class only those food additives listed below, or referred to, may be used and only for the functions, and within limits, specified.

4.1 Acidity regulators, antifoaming agents, firming agents, preservatives and thickeners used in accordance with Table 3 of the *Codex General Standard for Food Additives* (CODEX STAN 192-1995) are acceptable for use in foods conforming to this Standard.

4.2 ACIDITY REGULATORS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
334; 335(i), (ii); 336(i), (ii); 337	Tartrates	3,000 mg/kg	0-30	

4.3 ANTIFOAMING AGENTS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
900a	Polydimethylsiloxane	10 mg/kg	0-0-8 (temporary)	

4.4 Colours

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
100(i)	Curcumin	500 mg/kg	0-3	
101(i), (ii)	Riboflavins	200 mg/kg	0-0.5	
104	Quinoline Yellow	100 mg/kg	0-10	
110	Sunset Yellow FCF	300 mg/kg	0-2.5	
120	Carmines	200 mg/kg	0-5	
124	Ponceau 4R (Cochineal Red A)	100 mg/kg	0-4	
129	Allura Red	100 mg/kg	0-7	
133	Brilliant Blue FCF	100 mg/kg	0-12.5	
140	Chlorophylls	GMP	Not limited	
141(i), (ii)	Chlorophylls and Chlorophyllins, Copper Complexes	200 mg/kg	0-15	
143	Fast Green FCF	400 mg/kg	0-25	
150a	Caramel I-Plain	GMP	Not specified	
150b	Caramel II Caustic Sulfite Process	80,000 mg/kg	0-160	
150c	Caramel III – Ammonia Process	80,000 mg/kg	0-200 (0-150 on solid basis)	

150d	Caramel IV – Sulfite Ammonia Process	1,500 mg/kg	0-200 (0-150 on solid basis)	
160a(i), a(iii), e, f	Carotenoids	500 mg/kg	0-5	
160a(ii)	Carotenes, Beta- (Vegetable)	1,000 mg/kg	Acceptable	
160d(i), 160d(iii)	Lycopenes	100 mg/kg	0-0.5	
161b(i)	Lutein from <i>Tagetes erecta</i>	100 mg/kg	0-2	
162	Beet Red	GMP	Not specified	
163(ii)	Grape Skin Extract		0-2.5	
172(i)-(iii)	Iron Oxides	200 mg/kg	0-0.5	

4.5 Preservatives

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
200-203	Sorbates	1,000 mg/kg	0-25	
210-213	Benzoates	1,000 mg/kg	0-5	
220-225, 227, 228, 539	Sulfites	50 mg/kg as residual SO ₂ in the end product, except when made with sulfited fruit when a maximum level of 100 mg/kg is permitted in the end product.	0-0.7 (as SO ₂)	

4.6 FLAVOURINGS

The following flavourings are acceptable for use in foods conforming to this Standard when used in accordance with good manufacturing practices: natural flavouring substances that are extracted from the named fruits in the respective product; natural mint flavour; natural cinnamon flavour; vanillin, vanilla or vanilla extracts.

DRAFT STANDARD FOR CERTAIN CANNED VEGETABLES (general provisions)

General Provisions

(at Step 8 of the Procedure)

4. FOOD ADDITIVES

Only those food additive classes listed below and in the corresponding Annexes are technologically justified and may be used in products covered by this Standard. Within each additive class only those food additives listed below and in the corresponding Annexes, or referred to, may be used and only for the functions, and within limits, specified.

4.1 Acidity regulators, colours, colour retention agents and calcium salts of firming agents used in accordance with Table 3 of the Codex General Standard for Food Additives (CODEX STAN 192-1995) are acceptable for use in foods conforming to this standard.

4.2 COLOURS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
102	Tartrazine	100 mg/kg	0-7.5	
133	Brilliant Blue FCF	20 mg/kg	0-12.5	
143	Fast Green FCF	200 mg/kg	0-25	
150(c)	Caramel III-Ammonia Process	GMP	0-200 (0-150 on solid basis)	
150(d)	Caramel IV- Sulfite Ammonia Process		0-200 (0-150 on solid basis)	

4.3 COLOUR RETENTION AGENTS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
385, 386	Ethylene Diamine Tetra Acetates	365 mg/kg	0-2.5	
512	Stannous Chloride	25 mg/kg calculated as tin. Should not be added to foods in uncoated tin cans.	14 (PTWI, as tin)	

Proposed Draft Annex on Sweet Corn (at Step 5/8 of the Procedure)

4 FOOD ADDITIVES

4.1 THICKENERS (for creamed corn only)

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
1400	Dextrins, roasted starch	GMP	Not specified	
1401	Acid-treated starch			
1402	Alkaline-treated starch			
1403	Bleached starch			
1404	Oxidized starch			
1405	Starches, enzyme treated			
1410	Monostarch phosphate			
1412	Distarch phosphate			
1413	Phosphated distarch			
1414	Acetylated distarch phosphate			
1420	Starch acetate			
1422	Acetylated distarch adipate			
1440	Hydroxypropyl starch			
1442	Hydroxypropyl distarch phosphate			
1450	Starch sodium octenyl			
1451	Acetylated oxidized starch			

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

The 30th Session of the CCNFSDU referred a level of 10 mg/kg of gum arabic (gum acacia) to the CCFA for endorsement as a coating agent for inclusion in Section D: Advisory List of Food Additives for Special Nutrient Forms in the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Use by Infants and Young Children* (CAC/GL 10-1979) (ALINORM 09/32/26, paras 55-62 and Appendix III).

**DRAFT ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL
DIETARY USE BY INFANTS AND YOUNG CHILDREN**

(at Step 8 of the Procedure)

SECTION D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

	INS No.	Name of the Food Additive	Maximum Level in Ready-to-use Food for infants and young children (mg/kg)	ADI (mg/kg bw)	Endorsement Status
(a)	414	Gum arabic (gum acacia)	10	Not specified	

FAO/WHO COORDINATING COMMITTEE ASIA (CCASIA)

The 16th Session of the CCASIA referred to the CCFA for endorsement the sections on food additives of the Draft Regional Standards for Gochujang and Proposed Draft Regional Standards for Fermented Soybean Paste and Edible Sago Flour. *See* ALINORM 09/32/15, paras 31, 51 and 76 and Appendices II, IV and V.

With regard to the clarifications requested by the CCFA on certain food additives for gochujang, the Coordinating Committee noted that sodium sorbate (INS 201) was not listed with the other sorbates because it was not easy to be dissolved in liquid and that there was no information on the use of this additive in the product. It was agreed that sodium polyphosphate (INS 452i) and potassium polyphosphate (INS 452ii) should be listed as acidity regulators with one single maximum use level for phosphates.

With regard to the food additive provisions for edible sago flour, the Coordinating Committee noted that the descriptor of Food Category 06.2.1 “Flours” of the GSFA only included flours produced from the milling of grain, cereals and tubers (e.g. cassava) and that, therefore, the use in this section of a general reference to the provisions of Tables 1 and 2 of the GSFA might not be appropriate. In view of this, the Committee agreed: to add in the section the food additive listing corresponding to food additives listed in the GSFA for Food Category 6.2.1; and to request CCFA to clarify whether Food Category 06.2.1 was intended to include products like sago flour. It was understood that in case of a positive reply from the CCFA, the listing of food additives would be replaced by the general reference to the provision of Tables 1 and 2 of the GSFA.

DRAFT REGIONAL STANDARD FOR GOCHUJANG

(at Step 8 of the Procedure)

4. FOOD ADDITIVES

The food additives listed below can be used within the scope of a permitted amount.

4.1 PRESERVATIVES

INS No	Name of Food Additives	Maximum level	ADI (mg/kg bw)	Endorsement Status
200	Sorbic acid	1000 mg/kg as sorbic acid, singly or in combination	0-25	Endorsed by 39 th CCFA
202	Potassium sorbate			
203	Calcium sorbate			

4.2 FLAVOUR ENHANCERS

INS No	Name of Food Additives	Maximum level	ADI (mg/kg bw)	Endorsement Status
621	Monosodium L-glutamate	limited by GMP	Not specified	Endorsed by 39 th CCFA
508	Potassium chloride	limited by GMP	Not limited	Endorsed by 39 th CCFA

4.3 ANTIOXIDANT

INS No	Name of Food Additives	Maximum level	ADI (mg/kg bw)	Endorsement Status
325	Sodium lactate	limited by GMP	Not limited	Endorsed by 39 th CCFA

4.4 ACIDITY REGULATOR

INS No	Name of Food Additives	Maximum level	ADI (mg/kg bw)	Endorsement Status
296	Malic acid (DL-)	limited by GMP	Not specified	Endorsed by 39 th CCFA
339(i)	Monosodium orthophosphate	5000 mg/kg as phosphorus, singly or in combination	70 (MTDI, as phosphorus)	Endorsed by 39 th CCFA
339(ii)	Disodium orthophosphate			
340(i)	Monopotassium orthophosphate			
340(ii)	Dipotassium orthophosphate			
452(i)	Sodium polyphosphates			
452(ii)	Potassium polyphosphates			

4.5 STABILIZER

INS No	Name of Food Additives	Maximum level	ADI (mg/kg bw)	Endorsement Status
412	Guar gum	limited by GMP	Not specified	Endorsed by 39 th CCFA
414	Gum arabic (acacia gum)	limited by GMP	Not specified	Endorsed by 39 th CCFA
415	Xanthan gum	limited by GMP	Not specified	Endorsed by 39 th CCFA

PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED SOYBEAN PASTE

(at Step 5/8 of the Procedure)

4. FOOD ADDITIVES

Acidity regulators, antioxidants, colours, flavours enhancers, preservatives, stabilizers and sweeteners listed in Table 3 of the *Codex General Standard for Food Additives* (CODEX STAN 192-1995) are acceptable for use in food conforming to this standard.

4.1 ACIDITY REGULATORS

INS No.	Name of Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
336(i)	Monopotassium tartrate	Limited by GMP	0-30	

4.2 ANTIOXIDANTS

INS No.	Name of Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
539	Sodium thiosulphate	30 mg/kg as sulphur dioxide	0-0.7 (as SO ₂)	

4.3 COLOURS

INS No.	Name of Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
101(i)	Riboflavin, synthetic	10 mg/kg	0-0.5	

4.4 PRESERVATIVES

INS No.	Name of Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
200	Sorbic acid	1000 mg/kg as sorbic acid, singly or in combination	0-25	
202	Potassium sorbate			
203	Calcium sorbate			
210	Benzoic acid	1000 mg/kg as benzoic acid, singly or in combination	0-5	
211	Sodium benzoate			
212	Potassium benzoate			

4.5 SWEETENERS

INS No.	Name of Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
950	Acesulfame potassium	350 mg/kg	0-15	
954	Sodium saccharin	200 mg/kg	0-5	

4.6 PROCESSING AIDS

INS No.	Name of Processing Aid	Endorsement Status
1101(i)	Protease	
	Hemicellulase	
1104	Lipase	
472c	Citric and fatty acid esters of glycerol	
270	Lactic acid	
452(i)	Sodium polyphosphates, glassy	
452(ii)	Potassium polyphosphates	

PROPOSED DRAFT REGIONAL STANDARD FOR EDIBLE SAGO FLOUR

(at Step 5 of the Procedure)

4. FOOD ADDITIVES

Flour treatment agents used in accordance with Tables 1 and 2 of the Codex *General Standard for Food Additives* (CODEX STAN 192-1995) in food category 06.2.1 “flours” are acceptable for use in foods conforming to this standard.

or

4.1 FLOUR TREATMENT AGENTS

INS	Name of Additive	Maximum Level	ADI (mg/kg bw)/Acceptable level of treatment	Endorsement Status
220	Sulfur dioxide	200 mg/kg as residual SO ₂	0-0.7 (as SO ₂)	
221	Sodium sulfite			
222	Sodium hydrogen sulfite			
223	Sodium metabisulfite			
224	Potassium metabisulfite			
225	Potassium sulfite			
227	Calcium hydrogen sulfite			
228	Potassium bisulfite			
539	Sodium thiosulfate			
925	Chlorine			2 500 mg/kg (treatment level)
926	Chlorine dioxide	2 500 mg/kg (treatment level)	Acceptable level of treatment: 0-30 mg/kg flour / 30-75 mg/kg flour for special purposes	
927a	Azodicarbonamide	45 mg/kg	0-45 mg/kg (acceptable level of treatment)	
928	Benzoyl peroxide	75 mg/kg	Acceptable level of treatment: 0-40 mg/kg flour /40-75 mg/kg flour for special purposes <i>Note:</i> residue in food is benzoate (Group ADI of 0-5mg/kg bw for benzoic acid and its calcium, potassium and sodium salts, benzyl acetate, benzyl alcohol, benzyl aldehyde and benzyl benzoate)	
1100	<i>alpha</i> -Amylase from <i>Aspegillus orizae</i> var.	GMP	Acceptable	
1101(i)	Protease	GMP	Acceptable	