

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-sixth Session
Rotterdam, The Netherlands, 22 – 26 March 2003

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 (Thirteenth Edition, pages 95 - 96), “*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 (Part I) and processing aids (Part II) 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. It is also suggested that those processing aids and corresponding maximum levels endorsed by the Committee be incorporated into the Inventory of Processing Aids.

3. The following food additive and processing aids provisions of Codex standards have been submitted for endorsement since the 35th Session of the Codex Committee on Food Additives and Contaminants 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.

4. 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 and Contaminants 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.

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

² Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA 1956-2002), Section 5 - Explanation of Terms used in this Summary: <http://jecfa.ilsa.org/>.

- NS **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.
- NL **ADI “Not Limited”**. A term no longer used by JECFA that has the same meaning as ADI “not specified”².
- TE **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.
- CO **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 **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.
- AC **Acceptable**².
- 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.
- (L)GMP **(Limited by) Good Manufacturing Practice**. This statement refers to the limitation of a food additive in specified foods. It means that the additive in question is self-limiting in food for technological, organoleptic, or other reasons^{2,3}.

³ See also Codex Alimentarius Commission Procedural Manual, 13th Edition, page 96.

5. 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.
6. This document should be read in conjunction with the relevant sections of document CX/FAC 04/36/2-Part II – *Matters referred to the Committee by the Codex Alimentarius Commission and Other Codex Committees and Task Forces*.

PART I**ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES
IN CODEX COMMODITY STANDARDS****26TH SESSION OF THE
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS****DRAFT STANDARD FOR SALTED ATLANTIC HERRING
AND SALTED SPRAT¹****(At Step 8)**

INS No.	Food additive	Maximum level	ADI (mg/kg body weight)	Notes
Antioxidants				
310	Propyl gallate	100 mg/kg	0-1.4 mg/kg bw	<p>This additive was endorsed by the 35th Session of the Codex Committee on Food Additives and Contaminants (March 2003).</p> <p>The 26th Session of Codex Committee on Fish and Fishery Products (October 2003) agreed to delete this additive from the endorsed list of permitted additives as its use was not technologically justified in salted Atlantic herring and salted sprat.</p> <p>The Committee agreed to forward this amendment to the Codex Committee on Food Additives and Contaminants for endorsement (e.g. to delete this additive from the previous endorsed list of permitted additives for Atlantic herring and salted sprat).</p> <p>See CX/FAC 04/36/2-Part II paras. 75-76 for further details.</p>

¹ ALINORM 04/18, Appendix II.

**3RD SESSION OF THE
AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON
FRUIT AND VEGETABLE JUICES**

DRAFT CODEX GENERAL STANDARD FOR FRUIT JUICES AND NECTARS¹

(At Step 7)

INS No.	Food additive	Maximum level ²	ADI (mg/kg body weight)	Notes
Acidity Regulators				
330	Citric acid	3 g/l ³	NL	
330	Citric acid	5 g/l	NL	for fruit nectars
296	Malic acid	GMP	NS	only for pineapple juice and fruit nectars
334	Tartaric acid	4 g/l	0-30 mg/kg bw	only for grape juice and fruit nectars
Antioxidants				
300-303	Ascorbic acid and its salts	GMP	NS	
220-225, 227, 228, 539	Sulphites	50 mg/l ^{3,4}	0-0.7 mg/kg bw	as residual SO ₂
Carbonating Agents				
290	Carbon dioxide	GMP	NS	
Preservatives³				
210-213	Benzoic acid and its salts	1 g/l	0-5 mg/kg bw ⁵	single or in combination
200-203	Sorbic acid and its salts	1 g/l	0-25 mg/kg bw ⁶	single or in combination
Sequestrants³				
451(i)	Sodium tripolyphosphate	1 g/l	70 mg/kg bw ⁷	only to enhance the effectiveness of benzoates and sorbates
Stabilizers				
440	Pectins	GMP	NS	only for cloudy juices and fruit nectars

¹ ALINORM 03/39A, Appendix II.

² Calculated as served to the customer.

³ Subject to national legislation of the importing country.

⁴ Sulphites should be used where there is a technological necessity.

⁵ Expressed as benzoic acid equivalents.

⁶ Expressed as sorbic acid.

⁷ Maximum tolerable daily intake (MTDI) of 70 mg/kg bw for phosphorus from all sources, expressed as P.

INS No.	Food additive	Maximum level ²	ADI (mg/kg body weight)	Notes
Sweeteners				
950	Acesulfame potassium	350 mg/l	0-15 mg/kg bw	only for fruit nectars
951	Aspartame	600 mg/l	0-40 mg/kg bw	only for fruit nectars
952	Cyclamic acid and its salts	400 mg/l ³	0-11 mg/kg bw ⁸	only for fruit nectars
954	Saccharin and its salts	80 mg/l	0-5 mg/kg bw	only for fruit nectars
955	Sucralose	300 mg/l	0-15 mg/kg bw	only for fruit nectars

⁸ Cyclamates ADI expressed as cyclamic acid.

PART II**ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR PROCESSING AIDS
IN CODEX COMMODITY STANDARDS****3RD SESSION OF THE
AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON
FRUIT AND VEGETABLE JUICES****DRAFT CODEX GENERAL STANDARD FOR FRUIT JUICES AND NECTARS¹****(At Step 7)**

Function	Substance	Maximum level²	ADI (mg/kg body weight)	Notes
Antifoaming Agent	Polydimethylsiloxane	10 mg/l	0-1.5 mg/kg bw	<p>Polydimethylsiloxane is listed as an antifoaming agent at 10 mg/kg for fruit and vegetable juices in the General Standard for Food Additives and also as an antifoaming agent in the Inventory List for Processing Aids of the Codex Alimentarius.</p> <p>The 4th Session of the Ad Hoc Codex Intergovernmental Task Force on Fruit and Vegetable Juices (May 2003) agreed to request the Codex Committee on Food Additives and Contaminants to withdraw polydimethylsiloxane from the General Standard for Food Additives and to consider it as a processing aid for the products covered by the Standard for fruit juices and nectars.</p> <p>See CX/FAC 04/36/2-Part II paras. 77-78 for further details.</p>

¹ ALINORM 03/39A, Appendix II.

² Calculated as served to the customer.

Function	Substance	Maximum level ²	ADI (mg/kg body weight)	Notes
Clarifying Agents	Adsorbent clays		-	(bleaching, natural, or activated earths)
	Adsorbent resins		-	
Filtration Aids	Activated carbon		NL	only from plants
	Bentonite		NO	
Flocculating Agents	Calcium hydroxide	GMP	NL	only in grape juice
	Cellulose		-	
	Chitosan		-	
	Colloidal silica		NS	
	Diatomaceous earth		Decision postponed	
	Gelatin		NL	(from skin collagen)
	Ion exchange resins (cation and anion)		-	
	Isinglass		-	
	Kaolin		NS	
	Perlite		-	
	Polyvinylpolypyrrolidone		NS	
	Potassium tartrate	GMP	0-30 mg/kg bw	only in grape juice
	Precipitated calcium carbonate	GMP	NL	only in grape juice
	Rice hulls		-	
	Silicasol		-	
	Sulphur dioxide	10 mg/l	0-0.7 mg/kg bw	as residual SO ₂ ; only in grape juice
	Tannin		NS ³	

³ Gallotannins from certain natural sources.

Function	Substance	Maximum level ²	ADI (mg/kg body weight)	Notes
Enzyme Preparations	Pectinases (for breakdown of pectins)		NS ⁴ NO ⁵	Enzyme preparations may be used as processing aids provided these preparations do not result in a total liquefaction and do not substantially affect the cellulose content of the processed fruit.
	Proteinases (for breakdown of proteins)		-	
	Amylases (for breakdown of starch)		AC ⁶ NS ⁷	
	Cellulases (limited use to facilitate disruption of cell walls)		NO ⁸ NS ⁹	
Packing Gas ¹⁰	Nitrogen (INS 941)	GMP	No ADI necessary	
	Carbon dioxide	GMP	NS	

⁴ Pectinases from *Aspergillus niger*.

⁵ Pectinase from *Aspergillus alliaceus*.

⁶ alpha-Amylase from *Aspergillus oryzae*, var.

⁷ alpha-Amylase from *Bacillus megaterium* expressed in *Bacillus subtilis*; alpha-amylase from *Bacillus stearothermophilus*; alpha-amylase from *Bacillus stearothermophilus* expressed in *Bacillus subtilis*; alpha-amylase from *Bacillus subtilis*; carbohydrase (alpha-amylase) from *Bacillus licheniformis*; amyloglucosidase from *Aspergillus niger*, var.

⁸ Cellulase from *Penicillium funiculosum*.

⁹ Cellulase from *Trichoderma longibrachiatum*.

¹⁰ May also be used e.g., for preservation.