



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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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.

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.

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>.

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;
- 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.

³ Procedural Manual of the Codex Alimentarius Commission (Definitions)

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

The Committee **is invited to consider for endorsement** the food additive provisions (see Annex 1) forwarded by:

- (a) The 32nd Session of the Codex Committee on Fish and Fishery Products (CCFFP);
- *Standard for Fish Sauce* (Codex STAN 302-2011)
 - Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (at Step 8 of the Procedure)
- (b) The 26th Session of the Codex Committee on Processed Fruits and Vegetables (CCPFV);
- Proposed draft Codex Standard for Table Olives (revision of Codex STAN 66-1981) (at Step 5/8)
 - *Standard for Certain Canned Citrus Fruits* (Codex STAN 254-2003)
 - *Standard for Preserved Tomatoes* (Codex STAN 13-1981)
 - *Standard for Processed Tomato Concentrates* (Codex STAN 57-1981)
- (c) The 18th Session of the FAO/WHO Coordinating Committee for Asia (CCASIA).
- Proposed Draft Regional Standard For Tempe (at Step 5/8)
 - *Regional Standard for Chili Sauce* (Codex STAN 306R-2011)
 - *Regional Standard for Fermented Soybean Paste* (Codex STAN 298R-2009)

Annex 1**CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS (CCFFP)****STANDARD FOR FISH SAUCE (CODEX STAN 302-2011)¹**

The Committee agreed to set a ML of 200mg/kg (as tartrates) for the provision of tartrates in the *Standard for Fish Sauce* as recommended by the CCFA.

DRAFT STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH²

(At Step 8 of the Procedure)

4. FOOD ADDITIVES**4.1 Smoked Fish**

<u>Acidity Regulators</u>				
These acidity regulators are in use and identified as technologically justified for pH control for the products complying with this Standard (e.g. to retard the growth of microorganisms that are acid-sensitive)				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
260	Acetic acid, glacial	GMP	Group ADI 'not limited' for acetic acid and its potassium and sodium salts (17 th JECFA, 1973, maintained at 49 th JECFA, 1997)	GSFA Table 3
330	Citric acid	GMP	Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts (17 th JECFA, 1973)	GSFA Table 3
325	Sodium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
334	Tartaric acid, L[+]	200 mg/kg	ADI of 0-30 mg/kg bw (17 th JECFA, 1973 and reconfirmed at 21 st JECFA, 1977)	Currently there are no provision for tartaric acid, L(+) in food category 09.2.5 of the GSFA Table 1/2. GSFA lists "tartrates" (INS 334, 335(i)(ii), 336(i)(ii), 337).
270	Lactic acid, L-, D-, DL-	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
326	Potassium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
327	Calcium lactate	GMP	ADI 'not limited' (17 th JECFA, 1973)	GSFA Table 3

¹ REP13/FFP, para. 13

² REP13/FFP, para. 40 and Appendix III

Antioxidants				
These antioxidants are in use and identified as technologically justified to retard lipid oxidation for the products complying with this Standard (e.g., high fat content fish).				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
301	Sodium ascorbate	GMP	Group ADI 'not specified' for ascorbic acid and its Ca, K and Na salts (25 th JECFA, 1981)	GSFA Table 3
316	Sodium erythorbate	GMP	ADI 'not specified' (37 th JECFA, 1990)	GSFA Table 3
325	Sodium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
Colours				
These colours are in use and identified as technologically justified to provide the desirable colour when the smoking process does not impart sufficient colour.				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
129	Allura Red AC	300 mg/kg	ADI of 0-7 mg/kg bw (25 th JECFA, 1981)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 300 mg/kg (note 22 "for use in smoked fish only").
160b(i)	Annato extracts, bixin-based	10 mg/kg, as bixin	ADI for bixin of 0–12 mg/kg bw and a group ADI for norbixin and its disodium and dipotassium salts of 0-0.6 mg/kg bw expressed as norbixin (67 th JECFA, 2006)	Currently there are no provision for annatto extracts, bixin-based in food category 09.2.5 of the GSFA Table 1/2.
110	Sunset yellow FCF	100 mg/kg	ADI of 0-4 mg/kg bw (74 th JECFA, 2011)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 100 mg/kg (note 22 "for use in smoked fish only").
102	Tartrazine	100 mg/kg	ADI of 0-7.5 mg/kg (8 th JECFA, 1964)	Currently there are no provision for tartrazine in food category 09.2.5 of the GSFA Table 1/2.
Packaging Gas				
These packaging gases are in use and identified as technologically justified in order to slow down oxidation and growth of aerobic microorganisms.				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
290	Carbon dioxide	GMP	ADI 'not specified' (29 th JECFA, 1985)	GSFA Table 3
941	Nitrogen	GMP	ADI "No ADI necessary" (24 th JECFA, 1980)	GSFA Table 3

Preservatives (for reduced oxygen packaged products only)				
These preservatives are in use and identified as technologically justified in order to prevent growth of <i>Listeria monocytogenes</i> .				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
200-203	Sorbates	2000 mg/kg as sorbic acid	Group ADI 0-25 mg/kg bw for sorbic acid and its Ca, K, & Na salts (17 th JECFA, 1973)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 1,000 mg/kg (note 42, "as sorbic acid").
210-213	Benzoates	200 mg/kg as benzoic acid	Group ADI of 0-5 mg/kg bw for benzoic acid and its salts (27 th JECFA, 1983 and maintained at the 46 th JECFA, 1996)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 200 mg/kg (notes 13 "as benzoic acid" and 21 "as anhydrous calcium disodium ethilendiaminetetraacetate").

4.2 Smoke-Flavoured Fish

Acidity Regulators				
These acidity regulators are in use and identified as technologically justified for pH control for the products complying with this Standard (e.g. to retard the growth of microorganisms that are acid-sensitive)				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
260	Acetic acid, glacial	GMP	Group ADI 'not limited' for acetic acid and its potassium and sodium salts (17 th JECFA, 1973, maintained at 49 th JECFA, 1997)	GSFA Table 3
330	Citric acid	GMP	Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts (17 th JECFA, 1973)	GSFA Table 3
325	Sodium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
334	Tartaric acid, L[+]	200 mg/kg	ADI of 0-30 mg/kg bw (17 th JECFA, 1973 and reconfirmed at 21 st JECFA, 1977)	Currently there are no provision for tartaric acid, L(+) in food category 09.2.5 of the GSFA Table 1/2. GSFA lists "tartrates" (INS 334, 335(i)(ii), 336(i)(ii), 337).
270	Lactic acid, L-, D-, DL-	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
326	Potassium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
327	Calcium lactate	GMP	ADI 'not limited' (17 th JECFA, 1973)	GSFA Table 3

Antioxidants				
These antioxidants are in use and identified as technologically justified to retard lipid oxidation for the products complying with this Standard (e.g., high fat content fish).				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
301	Sodium ascorbate	GMP	Group ADI 'not specified' for ascorbic acid and its Ca, K and Na salts (25 th JECFA, 1981)	GSFA Table 3
316	Sodium erythorbate	GMP	ADI 'not specified' (37 th JECFA, 1990)	GSFA Table 3
325	Sodium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
Carrier				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
1400	Dextrins, roasted starch	GMP ³	ADI "not specified" was established at the 26 th JECFA (1982) for all modified starches except for acetylated oxidized starch for which an ADI "not specified" was established at the 57 th JECFA (2001)	GSFA Table 3
Colours				
These colours are in use and identified as technologically justified to provide the desirable colour when the smoking process does not impart sufficient colour.				
129	Allura Red AC	300 mg/kg	ADI of 0-7 mg/kg bw (25 th JECFA, 1981)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 300 mg/kg (note 22 "for use in smoked fish only").
160b(i)	Annatto extracts, bixin-based	10 mg/kg, as bixin	ADI for bixin of 0–12 mg/kg bw and a group ADI for norbixin and its disodium and dipotassium salts of 0-0.6 mg/kg bw expressed as norbixin (67 th JECFA, 2006)	Currently there are no provision for annatto extracts, bixin-based in food category 09.2.5 of the GSFA Table 1/2.
110	Sunset yellow FCF	100 mg/kg	ADI of 0-4 mg/kg bw (74 th JECFA, 2011).	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 100 mg/kg (note 22 "for use in smoked fish only").
102	Tartrazine	100 mg/kg	ADI of 0-7.5 mg/kg (8 th JECFA, 1964)	Currently there are no provision for tartrazine in food category 09.2.5 of the GSFA Table 1/2.

³ Carry over from flavouring

Emulsifiers				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
433	Polyoxyethylene (20) sorbitan monooleate	1000 mg/kg ³	ADI of 0-25 mg/kg bw (17 th JECFA, 1973)	Currently there are no provision for Polyoxyethylene (20) sorbitan monooleate in food category 09.2.5 of the GSFA Table 1/2. GSFA lists "polysorbates" (INS 432-436).
Packaging Gas				
These packaging gases are in use and identified as technologically justified in order to slow down oxidation and growth of aerobic microorganisms.				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
290	Carbon dioxide	GMP	ADI 'not specified' (29 th JECFA, 1985)	GSFA Table 3
941	Nitrogen	GMP	ADI "No ADI necessary" (24 th JECFA, 1980)	GSFA Table 3
Preservatives (for reduced oxygen packaged products only)				
These preservatives are in use and identified as technologically justified in order to prevent growth of <i>Listeria monocytogenes</i> .				
INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
200-203	Sorbates	2000 mg/kg as sorbic acid	Group ADI 0-25 mg/kg bw for sorbic acid and its Ca, K, & Na salts (17 th JECFA, 1973)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 1,000 mg/kg (note 42, "as sorbic acid").
210-213	Benzoates	200 mg/kg as benzoic acid	Group ADI of 0-5 mg/kg bw for benzoic acid and its salts (27 th JECFA, 1983 and maintained at the 46 th JECFA, 1996)	GSFA Table 1/2 provision in food category 09.2.5 "Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms" is 200 mg/kg (notes 13 "as benzoic acid" and 21 "as anhydrous calcium disodium ethilendiaminetetraacetate").

4.3 Smoke-Dried Fish

No additives are permitted in smoke-dried fish.

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)**PROPOSED DRAFT CODEX STANDARD FOR TABLE OLIVES⁴
(Revision of CODEX STAN 66-1981)****(At Step 5/8)****4. FOOD ADDITIVES**

Acidity regulators, antioxidants, colour retention agents⁵, firming agents, flavour enhancers, preservatives, and thickeners⁶ used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CODEX STAN 192-1995) in food category 04.2.2.3 (Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce) or listed in Table 3 of the *General Standard for Food Additives* are acceptable for use in foods conforming to this Standard.

**STANDARD FOR CERTAIN CANNED CITRUS FRUITS⁷
(CODEX STAN 254-2003)**

The provisions for food additives in Section 4 should be replaced by the provisions indicated below. The technological justification in support of this proposal is given in the Annex to this Appendix:

4 FOOD ADDITIVES

Acidity regulators and firming agents used in accordance with Tables 1 and 2 of the *General Standard of Food Additives* (CODEX STAN 192-1995) in food category 04.1.2.4 (Canned or bottled (pasteurized) fruit) or listed in Table 3 of the *General Standard for Food Additives* are acceptable for use in foods conforming to this Standard.

**STANDARD FOR PRESERVED TOMATOES⁸
(CODEX STAN 13-1981)**

The provisions for food additives in Section 4 should be replaced by the provisions indicated below. The technological justification in support of this proposal is given in the Annex to this Appendix:

4 FOOD ADDITIVES

4.1 ACIDITY REGULATORS				
INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Notes
300	Ascorbic acid, L-	GMP	Group ADI 'not specified' for ascorbic acid and its Ca, K and Na salts (25 th JECFA, 1981)	GSFA Table 3
330	Citric acid	GMP	Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and	GSFA Table 3

⁴ REP13/PFV para. 38 and Appendix II

⁵ Table olives darkened with oxidation.

⁶ Table olives with stuffing.

⁷ REP13/PFV para. 124 and Appendix VI

⁸ REP13/PFV paras 112-113 and 123 and Appendix VI

4.1 ACIDITY REGULATORS				
INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Notes
			ammonium salts (17 th JECFA, 1973)	
331(i)	Sodium dihydrogen citrate	GMP	Group ADI 'not limited' for citric acid and its calcium, potassium, sodium and ammonium salts (23 rd JECFA, 1979)	GSFA Table 3
331(iii)	Trisodium citrate	GMP	ADI not limited' (17 th JECFA, 1973)	GSFA Table 3
332(i)	Potassium dihydrogen citrate	GMP	Group ADI 'not limited' for citric acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
332(ii)	Tripotassium citrate	GMP	ADI not limited' (17 th JECFA, 1973)	GSFA Table 3
333(iii)	Tricalcium citrate	GMP	ADI 'not limited' (17 th JECFA, 1973)	GSFA Table 3
380	Triammonium citrate	GMP	Group ADI 'not limited' for citric acid and its calcium, potassium, sodium and ammonium salts (23 rd JECFA, 1979)	GSFA Table 3
507	Hydrochloric acid	GMP	ADI not limited' (9 th JECFA, 1965)	GSFA Table 3
514(i)	Sodium sulfate	GMP	ADI "not specified" (57 th JECFA, 2001)	GSFA Table 3
515(i)	Potassium sulfate	GMP	ADI 'not specified' (29 th JECFA, 1985)	GSFA Table 3
575	Glucono delta-lactone	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3
577	Potassium gluconate	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3
578	Calcium gluconate	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3
580	Magnesium gluconate	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3
.2 FIRING AGENTS				
Firming agents listed in Table 3 of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1995) for food category 04.2.2.4 (Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds) are acceptable for use in foods conforming to this Standard.				

STANDARD FOR PROCESSED TOMATO CONCENTRATES⁹
(CODEX STAN 57-1981)

The provisions for food additives in Section 4 should be replaced by the provisions indicated below. The technological justification in support of this proposal is given in the Annex to this Appendix:

4 FOOD ADDITIVES

4.1 ACIDITY REGULATORS				
INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Notes
300	Ascorbic acid, L-	GMP	Group ADI 'not specified' for ascorbic acid and its Ca, K and Na salts (25 th JECFA, 1981)	GSFA Table 3
330	Citric acid	GMP	Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts (17 th JECFA, 1973)	GSFA Table 3
331(i)	Sodium dihydrogen citrate	GMP	Group ADI 'not limited' for citric acid and its calcium, potassium, sodium and ammonium salts (23 rd JECFA, 1979)	GSFA Table 3
331(iii)	Trisodium citrate	GMP	ADI not limited' (17 th JECFA, 1973)	GSFA Table 3
332(i)	Potassium dihydrogen citrate	GMP	Group ADI 'not limited' for citric acid and its salts (23 rd JECFA, 1979)	GSFA Table 3
332(ii)	Tripotassium citrate	GMP	ADI not limited' (17 th JECFA, 1973)	GSFA Table 3
333(iii)	Tricalcium citrate	GMP	ADI not limited' (17 th JECFA, 1973)	GSFA Table 3
380	Triammonium citrate	GMP	Group ADI 'not limited' for citric acid and its calcium, potassium, sodium and ammonium salts (23 rd JECFA, 1979)	GSFA Table 3
507	Hydrochloric acid	GMP	ADI not limited' (9 th JECFA, 1965)	GSFA Table 3
514(i)	Sodium sulfate	GMP	ADI "not specified" (57 th JECFA, 2001)	GSFA Table 3
515(i)	Potassium sulfate	GMP	ADI 'not specified' (29 th JECFA, 1985)	GSFA Table 3
575	Glucono delta-lactone	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3
577	Potassium gluconate	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3

⁹ REP13/PFV paras 114 and 123 and Appendix VI

4.1 ACIDITY REGULATORS				
INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Notes
578	Calcium gluconate	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3
580	Magnesium gluconate	GMP	Group ADI "not specified" for glucono-delta-lactone and gluconates, excluding ferrous gluconate (51 st JECFA, 1998)	GSFA Table 3

ANNEX

TECHNOLOGICAL JUSTIFICATION FOR THE AMENDMENTS PROPOSED TO SECTION 4 – FOOD ADDITIVES IN CANNED CITRUS FRUITS, PRESERVED TOMATOES AND PROCESSED TOMATO CONCENTRATES

For consideration by the 45th Session of the Committee on Food Additives

STANDARD FOR CERTAIN CANNED CITRUS FRUITS

(CODEX STAN 254-2003)

The products covered by the Standard are included under food category 04.1.2.4 (Canned or bottled (pasteurized) fruit) of the GSFA. This food category is not listed in the Annex to Table 3 of the GSFA. As such, additives listed in Table 3 of the GSFA can be used in foods included in this food category in accordance with GMP, so that specific provisions for their use are not listed in food category 04.1.2.4 in Tables 1 and 2 of the GSFA.

Based on the current food additive provisions in the Standard, the Electronic Working Group on Food Additives of the Committee on Processed Fruits and Vegetables (CPFV/EWG-FA) concluded that use of food additives with functional classes of acidity regulators and firming agents are technologically justified.

Acidity regulators

There are no adopted provisions for acidity regulators in food category 04.1.2.4 of the GSFA. However, due to the hierarchy of the food category system, carnauba wax (INS 903), which is listed in food category 04.1.2, is allowed for use in foods included in food category 04.1.2.4 as an acidity regulator. In addition, the following draft provisions for acidity regulators are currently in the Step process for listing in food category 04.1.2.4:

Food Cat.	INS	GSFA Mainterm	ML	Notes	Step
04.1.2	903	Carnauba wax	400 mg/kg		Adopted 2004
04.1.2.4	262(ii)	Sodium diacetate	GMP		Step 7
04.1.2.4	334; 335(i),(ii); 336(i),(ii); 337	Tartrates	1300 mg/kg	45	Step 7

Table 3 of the GSFA lists the following acidity regulators:

INS	Additive Name	INS	Additive Name
170(i)	Calcium carbonate	365	Sodium fumarates
260	Acetic acid, glacial	380	Triammonium citrate
261	Potassium acetates	500(i)	Sodium carbonate
262(i)	Sodium acetate	500(ii)	Sodium hydrogen carbonate
263	Calcium acetate	500(iii)	Sodium sesquicarbonate
264	Ammonium acetate	501(i)	Potassium carbonate
270	Lactic acid, L-, D- and DL-	501(ii)	Potassium hydrogen carbonate
296	Malic acid, DL-	503(i)	Ammonium carbonate
297	Fumaric acid	503(ii)	Ammonium hydrogen carbonate
300	Ascorbic acid, L-	504(i)	Magnesium carbonate
325	Sodium lactate	504(ii)	Magnesium hydroxide carbonate
326	Potassium lactate	507	Hydrochloric acid
327	Calcium lactate	514(i)	Sodium sulfate
328	Ammonium lactate	514(ii)	Sodium hydrogen sulfate
329	Magnesium lactate, DL-	515(i)	Potassium sulfate
330	Citric acid	515(ii)	Potassium hydrogen sulfate (Step 3)
331(i)	Sodium dihydrogen citrate	524	Sodium hydroxide
331(iii)	Trisodium citrate	525	Potassium hydroxide
332(i)	Potassium dihydrogen citrate	526	Calcium hydroxide
332(ii)	Tripotassium citrate	527	Ammonium hydroxide
333(iii)	Tricalcium citrate	528	Magnesium hydroxide
350(i)	Sodium hydrogen DL-malate	529	Calcium oxide
350(ii)	Sodium DL-malate	575	Glucono delta-lactone
351(i)	Potassium hydrogen malate	577	Potassium gluconate
351(ii)	Potassium malate	578	Calcium gluconate
352(ii)	Calcium malate, DL-	580	Magnesium gluconate

Based on the current food additive provisions in the Standard, the CCPFV/EWG-FA concluded that all acidity regulators listed in Table 3 are needed for use in mandarin oranges, sweet orange varieties, and pummelos; and that citric acid is needed for use in grapefruit. The CCPFV/EWG-FA could not identify a justification for excluding acidity regulator listed in food category 04.1.2.4 or its parent categories, or in Table 3 of the GSFA for use in certain canned citrus fruits. However, the CPFV/EWG-FA could not identify a technological need for phosphates, sodium diacetate and tartrates. The CCPFV/EWG-FA also could not identify the technological need for other acidity regulators not listed in food category 04.1.2.4 or its parent food categories, or in Table 3 of the GSFA for use in certain canned citrus fruits.

Firming agents

There are no adopted provisions for any firming agents in food category 04.1.2.4. Phosphates were revoked in 2012 for use as a firming agent in food category 04.1.2.4.

Table 3 of the GSFA lists are the following firming agents:

INS	Additive Name	INS	Additive Name
333(iii)	Tricalcium citrate	516	Calcium sulfate
424	Curdlan	518	Magnesium sulfate
466	Sodium carboxymethyl cellulose (Cellulose gum)	526	Calcium hydroxide
509	Calcium chloride	578	Calcium gluconate
511	Magnesium chloride	580	Magnesium gluconate

Based on the current food additive provisions in the Standard, there is a technological need for calcium lactate and calcium chloride as firming agents in certain canned citrus fruits. The CCPFV/EWG-FA recommends that CCPFV requests CCFA to consider classifying calcium lactate as a firming agent in Table 3 of the GSFA. The CCPFV/EWG-FA could not identify a justification for excluding any firming agents listed in food category 04.1.2.4 or in Table 3 of the GSFA for use in certain canned citrus fruits. The CPFV/EWG-FA could not identify a technological need for other firming agents not listed in food category 04.1.2.4 or in Table 3 of the GSFA for use in certain canned citrus fruits.

STANDARD FOR PRESERVED TOMATOES**(CODEX STAN 13-1981)**

Preserved tomatoes are included under food category 04.2.2.4 (Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds) of the GSFA. This food category is not listed in the Annex to Table 3 of the GSFA. As such, additives listed in Table 3 of the GSFA can be used in foods included in this food category in accordance with GMP, so that specific provisions for their use are not listed in food category 04.2.2.4 in Tables 1 and 2 of the GSFA.

Based on the current food additive provisions in the Standard, the CPFV/EWG-FA concluded that use of food additives with functional classes of acidity regulators and firming agents are technologically justified.

Acidity regulators

Phosphates are the only adopted acidity regulators listed in food category 04.2.2.4 of the GSFA. However, there are several provisions in the Step process:

INS	GSFA Mainterm	ML	Notes	Step
338; 339(i)-(iii); 340(i)-(iii); 341(i)-(iii); 342(i),(ii); 343(i)-(iii); 450(i)-(iii),(v)-(vii); 451(i),(ii); 452(i)-(v); 542	Phosphates	2200 mg/kg	33	Adopted 2012
262(ii)	Sodium diacetate	GMP		Step 7
334; 335(i),(ii); 336(i),(ii); 337	Tartrates	10000 mg/kg	45	Step 7

According to the industry (WTPC)¹⁰, the use of the above food additives is not technologically justified in preserved tomatoes because:

- Phosphates are not used by tomato processors.
- Acetates, including sodium diacetate, should not be allowed as acidity regulators because they are metabolites that can occur naturally following raw material spoilage. Allowing these as additives would de-facto open a legal way of masking the use of partially altered tomatoes.
- Tartrates could cause major damages to pasteurization equipment used to treat the covering juice.

Therefore, the CPFV/EWG-FA could not identify a technological need for the above food additives.

Table 3 of the GSFA lists the following acidity regulators:

INS	Additive Name	INS	Additive Name
170(i)	Calcium carbonate	365	Sodium fumarates
260	Acetic acid, glacial	380	Triammonium citrate
261	Potassium acetates	500(i)	Sodium carbonate
262(i)	Sodium acetate	500(ii)	Sodium hydrogen carbonate
263	Calcium acetate	500(iii)	Sodium sesquicarbonate
264	Ammonium acetate	501(i)	Potassium carbonate
270	Lactic acid, L-, D- and DL-	501(ii)	Potassium hydrogen carbonate
296	Malic acid, DL-	503(i)	Ammonium carbonate
297	Fumaric acid	503(ii)	Ammonium hydrogen carbonate
300	Ascorbic acid, L-	504(i)	Magnesium carbonate
325	Sodium lactate	504(ii)	Magnesium hydroxide carbonate
326	Potassium lactate	507	Hydrochloric acid
327	Calcium lactate	514(i)	Sodium sulfate
328	Ammonium lactate	514(ii)	Sodium hydrogen sulfate
329	Magnesium lactate, DL-	515(i)	Potassium sulfate
330	Citric acid	515(ii)	Potassium hydrogen sulfate (Step 3)
331(i)	Sodium dihydrogen citrate	524	Sodium hydroxide
331(iii)	Trisodium citrate	525	Potassium hydroxide
332(i)	Potassium dihydrogen citrate	526	Calcium hydroxide
332(ii)	Tripotassium citrate	527	Ammonium hydroxide
333(iii)	Tricalcium citrate	528	Magnesium hydroxide
350(i)	Sodium hydrogen DL-malate	529	Calcium oxide
350(ii)	Sodium DL-malate	575	Glucono delta-lactone
351(i)	Potassium hydrogen malate	577	Potassium gluconate
351(ii)	Potassium malate	578	Calcium gluconate

¹⁰ The World Processing Tomato Council (WPTC) represents more than 95% of the worldwide production of preserved tomatoes.

INS	Additive Name	INS	Additive Name
352(ii)	Calcium malate, DL-	580	Magnesium gluconate

Based on the current food additive provisions in the Standard, the CPFV/EWG-FA concluded that citric acid, sodium dihydrogen citrate, trisodium citrate, potassium dihydrogen citrate, tripotassium citrate, calcium citrates, and glucono delta-lactone are needed as acidity regulators in preserved tomatoes.

According to the industry (WPTC), the following acidity regulators are not used in preserved tomatoes. WPTC also provided the following justification for excluding them:

- Acetic acid (260) should not be allowed as an acidity regulator because in its dissociated anionic form it is equivalent to dissociated anionic form of acetates, the presence of which could be used to mask spoilage.
- **Lactates** and **acetates** (INS 261, 262(i), 263, 264, 270, 325, 326, 327, 328, 329) should not be allowed as acidity regulators because they are metabolites that can occur naturally following raw material spoilage. Allowing these as additives would *de facto* open a legal way of masking the use of partially altered tomatoes.
- **Malates** and **fumarates** (INS 296, 297, 350(i), 350(ii), 351(i), 351(ii), 352(ii), 365) should be excluded for the same reason as for lactates and acetates, although these compounds are less frequent spoilage metabolites.
- **Hydroxydes** (INS 524, 525, 526, 527, 528) and **calcium oxide** (INS 529) are acidity regulators which are used to raise pH and thus have no technological justification for use in tomato products where acidity regulators are used to reduce the pH in order to guarantee microbiological stability.
- **Carbonates** (INS 170(i), 500(i), 500(ii), 500(iii), 501(i), 501(ii), 503(i), 503(ii), 504(i), 504(ii)) is that they can produce foam, but more importantly they can release gasses in the finished products that lead to a loss of vacuum (vacuum is, for the consumer, a sign of a metal can with no microbial spoilage or corrosion).

Industry also stated that hydrochloric acid (INS 507) and sulfates (INS 514(i), 514(ii), 515(i), 515(ii)) and glucono-delta-lactone (INS 575) and gluconates (INS 577, 578, 580) are not traditionally used as acidity regulators, but did not provide a justification for excluding their use in preserved tomatoes. The CPFV/EWG-FA also could not identify a technological for other acidity regulators that are not listed in food category 04.2.2.4 or in Table 3 of the GSFA for use in preserved tomatoes.

Thus, the following remaining acidity regulators are acceptable for use in preserved tomatoes:

INS	Additive Name
300	Ascorbic acid, L-
330	Citric acid
331(i)	Sodium dihydrogen citrate
331(iii)	Trisodium citrate
332(i)	Potassium dihydrogen citrate
332(ii)	Tripotassium citrate
333(iii)	Tricalcium citrate
380	Triammonium citrate
507	Hydrochloric acid
514(i)	Sodium sulphate
515(i)	Potassium sulphate
575	Glucono delta-lactone
577	Potassium gluconate
578	Calcium gluconate
580	Magnesium gluconate

Firming agents

Phosphates have been adopted for use as firming agents in food category 04.2.2.4:

INS	GSFA Mainterm	ML	Notes	Step
338; 339(i)-(iii); 340(i)-(iii); 341(i)-(iii); 342(i),(ii); 343(i)-(iii); 450(i)-(iii),(v)-(vii); 451(i),(ii); 452(i)-(v); 542	Phosphates	200 mg/kg	33	Adopted 2012

According to the industry (WPTC), phosphates are not used by tomato processors. Therefore, the CPFV/EWG-FA could not identify a technological need for phosphates as firming agents.

Table 3 of the GSFA lists the following firming agents:

INS	Additive Name	INS	Additive Name
333(iii)	Tricalcium citrate	516	Calcium sulfate
424	Curdlan	518	Magnesium sulfate
466	Sodium carboxymethyl cellulose (Cellulose gum)	526	Calcium hydroxide
509	Calcium chloride	578	Calcium gluconate
511	Magnesium chloride	580	Magnesium gluconate

Based on the current food additive provisions in the Standard (CODEX STAN 13-1981), the CPFV/EWG-FA concluded that calcium lactate, calcium citrates and calcium chlorides are needed as firming agents in preserved tomatoes. The CPFV/EWG-FA could not identify a justification for excluding any firming agents found in Table 3 of the GSFA for preserved tomatoes. However, the industry (WPTC) indicated that curdlan, sodium carboxymethyl cellulose, magnesium chloride, magnesium sulfite and magnesium gluconate are not widely used by industry in preserved tomatoes. The CPFV/EWG-FA could not identify a technological need in preserved tomatoes for other firming agents not listed in food category 04.2.2.4.or Table 3 of the GSFA.

STANDARD FOR PROCESSED TOMATO CONCENTRATES
(CODEX STAN 57-1981)

The products covered by the Standard are included under the following food categories in the GSFA:

- Canned tomato paste - 04.2.2.4 (Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds).
- Tomato puree - 04.2.2.5 (Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)).
- Tomato paste - 04.2.2.6 (Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5)).

These food categories are not listed in the Annex to Table 3 of the GSFA. As such, additives listed in Table 3 of the GSFA can be used in foods included in these food categories in accordance with GMP, so that specific provisions for their use are not listed in these food categories in Tables 1 and 2 of the GSFA.

Based on the current food additive provisions in the Standard, the CPFV/EWG-FA concluded that the use of food additives with the functional class acidity regulators is technologically justified.

Based on the current food additive provisions in the Standard and information provided by the industry (WTPC), and referring to the evaluation presented in Annex 4 concerning preserved tomatoes, no justification was provided for excluding the following acidity regulators listed in Table 3:

INS	Additive Name
300	Ascorbic acid, L-
330	Citric acid
331(i)	Sodium dihydrogen citrate
331(iii)	Trisodium citrate
332(i)	Potassium dihydrogen citrate
332(ii)	Tripotassium citrate
333(iii)	Tricalcium citrate
380	Triammonium citrate
507	Hydrochloric acid
514(i)	Sodium sulphate
515(i)	Potassium sulphate
575	Glucono delta-lactone
577	Potassium gluconate
578	Calcium gluconate
580	Magnesium gluconate

FAO/WHO COORDINATING COMMITTEE FOR ASIA (CCASIA)**PROPOSED DRAFT REGIONAL STANDARD FOR TEMPE¹¹****(at Step 5/8)****4. FOOD ADDITIVES**

4.1 None permitted.

4.2 Processing aids

Processing aids can be used in these products to control acidity during soaking the beans.

REGIONAL STANDARD FOR CHILI SAUCE^{12 13}**(CODEX STAN 306R-2011)**

With regard to the two food additives that were not endorsed, the Coordinating Committee agreed to recommend the maximum level (ML) for curcumin at 1000 mg/kg; and agreed not to include paprika oleoresin in the food additive list, noting that paprika oleoresin had been evaluated by JECFA as a spice and that spices were listed in Section 3.1.2 other permitted ingredients.

The Coordinating Committee also agreed to replace:

- Tartaric acid (INS 334) with Tartrates (INS 334 L(+)-tartaric acid; INS 335(i) monosodium tartrate; INS 335(ii) sodium L(+)-tartrate; INS 336(i) monopotassium tartrate; INS 336(ii) dipotassium tartrate; INS 337 potassium sodium L(+)-tartrate), ML 5000 mg/kg (as tartaric acid).
- Methyl parahydroxybenzoates (INS 214) with Parahydroxybenzoates (INS 214 ethyl para-hydroxybenzoates; INS 218 methyl para-hydroxybenzoates), ML 1000 mg/kg.
- Sodium saccharin (INS 954(iv)) with Saccharins (INS 952(i) saccharin; INS 952(ii) calcium saccharin; INS 952(iii) potassium saccharin; INS 952(iv) sodium saccharin), ML 150 mg/kg.

The Coordinating Committee did not agree to replace sodium polyphosphate (INS 452(i)) with Phosphates as the standard allowed the use of other acidity regulators in Table 3 of the *General Standard for Food Additives* (GSFA) (CODEX STAN 192-1995).

REGIONAL STANDARD FOR FERMENTED SOYBEAN PASTE^{12 14}**(CODEX STAN 298R-2009)**

The Coordinating Committee agreed to replace monopotassium tartrate (336(i)) with Tartrates (INS 334 L(+)-tartaric acid; INS 335(i) monosodium tartrate; INS 335(ii) sodium L(+)-tartrate; INS 336(i) monopotassium tartrate; INS 336(ii) dipotassium tartrate; INS 337 potassium sodium L(+)-tartrate), with the ML of 1000 mg/kg (as tartaric acid).

¹¹ REP13/ASIA paras 117 and appendix II

¹² REP13/ASIA paras 18-20

¹³ In response to the request of the 43rd CCFA (REP12/FA paras 37-38)

¹⁴ REP13/ASIA para. 19