codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/FA 07/39/5**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Thirty-ninth Session

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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...(and) will require to be endorsed by the Codex Committee on Food Additives*".

2. In consideration of the above and other provisions of the Codex Alimentarius Commission Procedural Manual, the attached food additive and processing aids provisions are being submitted to the Codex Committee on Food Additives 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 38th 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 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 name[1].

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].

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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.ilsi.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 imbalance[2].

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 weight[2].

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 account[2].

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 allocated[2].

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 ADI[2].

(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].

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3 See also Codex Alimentarius Commission Procedural Manual, 15th Edition, page 95.

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

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

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (At Step 8 of the Procedure)

The 28th Session of the CCNFSDU referred the Section on Food Additives of the *Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* to the CCFA for endorsement (ALINORM 07/30/26, Appendix II). The relevant discussion of the Committee (ALINORM 07/30/26, paras 56-68 and 83-85) is reproduced in Annex 1.

4. FOOD ADDITIVES

Only the food additives listed in this Section or in the Codex Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995).

The following food additives are acceptable for use in the preparation of infant formula, as described in Section 2.1 of this Standard (in 100 ml of product, ready for consumption prepared following manufacturer's instructions, unless otherwise indicated):

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	ADI (mg/kg bw)	Endorsement Status	Technological Justification
4.1 Thickeners						
4.1.1	412	Guar gum	0.1 g in liquid formulas containing hydrolysed protein	NS		Retains homogeneity
4.1.2	410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula	NS		Retains homogeneity
4.1.3	1412	Distarch phosphate	0.5 g singly or in combination in soy-based infant formula only 2.5 g singly or in combination in hydrolyzed protein- and/or amino acid based infant formula	NS		Retains homogeneity
4.1.4	1414	Acetylated distarch phosphate				Retains homogeneity
4.1.5	1413	Phosphated distarch phosphate				Retains homogeneity

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	ADI (mg/kg bw)	Endorsement Status	Technological Justification
4.1.6	1440	Hydroxypropyl starch	only			Retains homogeneity
4.1.7	407	Carrageenan[21)]	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only	NS		Retains homogeneity
4.2 Emulsifiers						
4.2.1	322	Lecithins	0.5 g in all types of infant formula[22)]	NL		Retains homogeneity
4.2.2	471	Mono- and diglycerides	0.4 g in all types of infant formula[22)]	NL		Retains homogeneity
4.3 Acidity Regulators						
4.3.1	524	Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula	NL		pH adjustment
4.3.2	500ii	Sodium hydrogen carbonate		NL		pH adjustment
4.3.3	500i	Sodium carbonate		NL		pH adjustment
4.3.4	525	Potassium hydroxide		NL		pH adjustment
4.3.5	501ii	Potassium hydrogen carbonate		NL		pH adjustment
4.3.6	501i	Potassium carbonate		NL		pH adjustment
4.3.7	526	Calcium hydroxide		NL		pH adjustment
4.3.12	270	L(+) lactic acid	Limited by GMP in all types of infant formula	NL		pH adjustment
4.3.13	330	Citric acid	Limited by GMP in all types of infant formula	NL		pH adjustment
	331	Sodium citrate	Limited by GMP in all types of infant formula			pH adjustment
	332	Potassium citrate	Limited by GMP in all types of infant formula			pH adjustment
4.4 Antioxidants						
4.4.2	307b	Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination	0.15-2		Protects from oxidation
4.4.3	304i	L-Ascorbyl palmitate	1 mg in all types of infant formula singly or in combination	0-1.25		Protects from oxidation
4.9 Packing Gases						
4.9.1	290	Carbon dioxide	GMP	NS		Used to pack under inert atmosphere
4.9.2	941	Nitrogen		No ADI necessary		Protect nutrient quality and guarantee product shelf life

[21)] Evaluation by JECFA is pending. National authorities may restrict its use until JECFA evaluation has been completed.
[22)] If more than one of the substances INS 322, 471 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances

ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (At Step 5 of the Procedure)

The 28th Session of the CCNFFSDU referred the Section D "Advisory List of Food Additives for Special Nutrient Forms" of the *Proposed Draft Revised Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* to the CCFA for endorsement (ALINORM 07/30/26, Appendix V). The relevant discussion of the Committee (ALINORM 06/29/26, paras 126-129) is reproduced in Annex 1.

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers:

	INS no.	**Additive/ Carrier**	**Maximum Level in Ready-to-use Food [mg/kg]**	**ADI (mg/kg bw)**	**Endorsement Status**
(a)	414	Gum arabic (gum acacia)	[10] or [100]	NS	
(b)	551	Silicon dioxide	10	NS	
(c)	421	Mannitol (B_{12} dry rubbing 0,1%)	10	NS	
(d)	1450	Starch sodium octenyl succinate	100	NS	
(e)	301	Sodium L-ascorbate (in coating of nutrient preparations containing PUFAs)	75	NS	

FAO/WHO COORDINATING COMMITTEE FOR ASIA (CCASIA)

PROPOSED DRAFT STANDARD FOR GOCHUJANG (At Step 5 of the Procedure)

The 15th Session of the CCASIA referred the Section on Food Additives of the *Proposed Draft Standard for Gochujang* to the CCFA for endorsement (ALINORM 07/30/15, Appendix II).

4. FOOD ADDITIVES

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

INS No.	Name of Food additives	Maximum Level	ADI (mg/kg bw)	Endorsement Status
4.1	**Preservatives**			
200	Sorbic acid	1.0 g/kg of sorbic acid, single or combination	0-25	
202	Potassium sorbate			
203	Calcium sorbate			
4.2	**Texturizers**			
452(i)	Sodium Polyphosphate	Limited by GMP	70 (MTDI, as phosphorus)	
452(ii)	Potassium Polyphosphate	Limited by GMP		
4.3	**Flavour Enhancing Agents**			
621	MSG (Monosodium L-glutamate)	Limited by GMP	NS	
508	Potassium chloride	Limited by GMP	NL	
4.4	**Antioxidant**			
325	Sodium lactate	Limited by GMP	NL	
4.5	**Acidity regulator**			
296	Malic acid (D-, L-)	Limited by GMP	NS	
339i	Monosodium orthophosphate	5000 mg/kg singly or in combination as phosphorus	70 (MTDI, as phosphorus)	
339ii	Disodium orthophosphate			
340i	Monopotassium orthophosphate			
340ii	Dipotassium orthophosphate			
4.6	**Stabilizer**			
412	Guar gum	Limited by GMP	NS	
414	Gum arabic (acacia gum)	Limited by GMP	NS	
415	Xanthan gum	Limited by GMP	NS	

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)

The 23rd Session of the CCPFV referred the Sections on Food Additives of the *Draft Standard for Pickled Fruits and Vegetables, Draft Standard for Processed Tomato Concentrates, Draft Standard for Preserved Tomatoes* and *Draft Standard for Certain Canned Citrus Fruits* to the CCFA for endorsement (ALINORM 07/30/27, Appendices II, III, IV and V).

DRAFT STANDARD FOR PICKLED FRUITS AND VEGETABLES
(At Step 8 of the Procedure)

4 FOOD ADDITIVES

4.1 ACIDITY REGULATORS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
260	Acetic Acid	GMP	NL	
262(i)	Sodium Acetate			
270	Lactic Acid		NL	
296	Malic Acid		NS	
330	Citric Acid		NL	

4.2 ANTIFOAMING AGENTS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
900(a)	Polydimethylsiloxane	10 mg/kg	0-1.5	

4.3 ANTIOXIDANTS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
300	Ascorbic Acid	GMP	NS	

4.4 COLOURS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
101(i), (ii)	Riboflavins	500 mg/kg	0-0.5	
140	Chlorophylls	GMP	NL	
141(i), (ii)	Chlorophyll, Copper Complexes	100 mg/kg	0-15	
150(d)	Caramel Colour, Class IV	500 mg/kg	0-200	
160(ai), (aii), (e), (f)	Carotenoids	500 mg/kg	0-5	
162	Beet Red	GMP	NS	
163(ii)	Grape Skin Extract	500 mg/kg	0-2.5	

4.5 FIRMING AGENTS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
327	Calcium Lactate	GMP	NL	
509	Calcium Chloride		NL	

4.6 FLAVOUR ENHANCERS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
621	Monosodium L-Glutamate	GMP	NS	

4.7 **PRESERVATIVES**

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
200-203	Sorbates	1000 mg/kg as sorbic acid	0-25	
210-213	Benzoates	1000 mg/kg as benzoic acid	0-5	
220-225, 227, 228, 539	Sulphites	100 mg/kg	0-0.7 as SO_2	

4.8 SEQUESTRANTS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
385, 386	EDTAs	250 mg/kg	0-2.5	
451(i)	Sodium Tripolyphosphate	2200 mg/kg as phosphorus	70 (MTDI, as phosphorus)	
452(i)	Sodium metaphosphate			

4.9 SWEETENERS

3	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
950	Acesulfame Potassium	200 mg/kg	0-15	
951	Aspartame	200 mg/kg	0-40	
954	Saccharin	160 mg/kg	0-5	
955	Sucralose	150 mg/kg	0-15	

DRAFT STANDARD FOR PROCESSED TOMATO CONCENTRATES
(At Step 8 of the Procedure)

4 **FOOD ADDITIVES**

4.1 ACIDITY REGULATORS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
330	Citric Acid	GMP	NL	
331(i)	Sodium dihydrogen citrate			
331(iii)	Trisodium citrate			
332(i)	Potassium dihydrogen citrate			
332(iii)	Tripotassium citrate			
333	Calcium citrates			

DRAFT STANDARD FOR PRESERVED TOMATOES
(At Step 8 of the Procedure)

4 FOOD ADDITIVES

4.1 ACIDITY REGULATORS

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
330	Citric Acid	GMP	NL	
331(i)	Sodium Dihydrogen Citrate			
331(iii)	Trisodium Citrate			
332(i)	Potassium dihydrogen Citrate			
332(ii)	Tripotassium Citrate			
333	Calcium Citrates			
575	Glucono delta-Lactone		NS	

4.2 **FIRMING AGENTS**

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
327	Calcium Lactate	GMP	NL	
333	Calcium Citrates		NL	
509	Calcium Chloride		NL	

DRAFT STANDARD FOR CERTAIN CANNED CITRUS FRUITS
(At Step 8 of the Procedure)

4 FOOD ADDITIVES

4.1 ACIDITY REGULATORS

All Acidity Regulators in Table 3 and in Food Category 04.1.2.4 of the Codex General Standard for Food Additives (CODEX STAN 192-1995).

For Mandarin Oranges, Sweet Orange varieties and Pummelos at the maximum levels established by the GSFA.

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
330	Citric Acid	GMP (Grapefruit)	NL	

4.2 **FIRMING AGENTS – For all citrus fruits covered by the Standard**

INS No.	Name of the Food Additive	Maximum Level	ADI (mg/kg bw)	Endorsement Status
509	Calcium Chloride	GMP	NL	
327	Calcium Lactate		NL	

CODEX COMMITTEE ON FATS AND OILS (CCFO)

DRAFT STANDARD FOR FAT SPREAD AND BLENDED SPREAD (At Step 8 of the Procedure)

The 20th Session of the CCFO referred the Section on Food Additives of the Draft Standard for Fat Spread and Blended Spread to the CCFA for endorsement (ALINORM 07/30/17, Appendix II). The relevant discussion of the Committee (ALINORM 07/30/17, paras 126-129) is reproduced in Annex 1.

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 the limits, specified.

Additive Functional Classes

a. Acidity regulators,
b. Antifoaming agents,
c. Antioxidants,
d. Colours,
e. Emulsifiers,
f. Flavour enhancers,
g. Packing gases,
h. Preservatives,
i. Stabilizers, and
j. Thickeners.

Acidity regulators, antifoaming agents, antioxidants, colours, emulsifiers, flavour enhancers, packing gases, preservatives, stabilizers and thickeners used in accordance with Table 3 of the Codex General Standard for Food Additives are acceptable for use in foods conforming to this Standard.

4.1 Flavours

Natural flavouring substances and artificial flavouring substances.

4.2 Acidity Regulators

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
262(ii)	Sodium Diacetate	1,000 mg/kg	0-15	
334; 335(i), 335(ii); 336(i), 336(ii); 337	Tartrates	100 mg/kg (as tartaric acid)	0-30	
338; 339(i), 339(ii), 339(iii); 340(i), 340(ii), 340 (iii); 341(i), 341(ii), 341(iii); 342(i), 342(ii); 343(i), 343(ii), 343(iii); 450(i), 450(ii), 450(iii), 450(v), 450(vi); 450(vii), 451(i), 451(ii); 452(i), 452(ii), 452(iii), 452(iv), 452(v); 542	Phosphates	1,000 mg/kg (as Phosphorus)	70 (MTDI, as phosphorus)	

4.3 Antifoaming Agents

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
900a	Polydimethylsiloxane	10 mg/kg (frying purposes, only)	0-1.5	

4.4 Antioxidants

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
304, 305	Ascorbyl Esters	500 mg/kg (as ascorbyl stearate)	0-1.25	
320	Butylated Hydroxyanisole	200 mg/kg (fat or oil basis) singly or in combination.	0-0.5	
321	Butylated Hydroxytoluene		0-0.3	
310	Propyl Gallate		0-1.4	

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
319	Tertiary-Butylhydroquinone		0-0.7	
388, 389	Thiodipropionates	200 mg/kg (as thiodipropionic acid)	0-3	
306, 307	Tocopherols	500 mg/kg	0.15-2	
385, 386	EDTAs	100 mg/kg (as anhydrous calcium disodium EDTA)	0-2.5	
384	Isopropyl Citrates	100 mg/kg	0-14	

4.5 Colours

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
120	Carmines	500 mg/kg	0-5	
160b	Annatto Extracts	[100 mg/kg]	0-12 (for bixin) / 0-0.6 (for norbixin and its salts)	
150b	Caramel Colour Class II	500 mg/kg	0-160	
150c	Caramel Colour Class III	500 mg/kg	0-200 (0-150 on solids basis)	
150d	Caramel Colour Class IV	500 mg/kg	0-200 (0-150 on solids basis)	
160a(ii)	Carotenes, Vegetable (Natural carotenes)	1000 mg/kg	AC	
100(i)	Curcumin	10 mg/kg	0-3	
160a(i)	Beta-carotene (synthetic)	35 mg/kg singly or in combination	0-0.5	
160e	Beta-Apo-8'-Carotenal			
160f	Beta-Apo-8'-Carotenoic Acid, methyl or ethyl ester			
101(i), 101(ii)	Riboflavins	300 mg/kg	0-0.5	

4.6 Emulsifiers

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
472e	Diacetyltartaric and Fatty Acid Esters of Glycerol	10,000 mg/kg	0-50	
475	Polyglycerol Esters of Fatty Acids	5,000 mg/kg	0-25	
476	Polyglycerol Esters of Interesterified Ricinoleic Acid	4,000 mg/kg	0-7.5	
432, 433, 434, 435, 436	Polysorbates	10,000 mg/kg (singly or in combination)	0-25	
477	Propylene Glycol Esters of Fatty Acids	20,000 mg/kg	0-25	
491, 492, 493, 494, 495	Sorbitan Esters of Fatty Acids	10,000 mg/kg (singly or in combination)	0-25	
481(i), 482(i)	Stearoyl-2-Lactylates	10,000 mg/kg (singly or in combination)	0-20	
484	Stearyl Citrate	100 mg/kg (fat or oil basis)	0-50	
474	Sucroglycerides	10,000 mg/kg	0-30	
473	Sucrose Esters of Fatty Acids	10,000 mg/kg	0-30	

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
479	Thermally oxidized soya bean oil interacted with mono and diglycerides of fatty acids	5,000 mg/kg (in fat emulsions for frying or baking purpose, only).	0-30	

4.7 Preservatives

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
210, 211, 212, 213	Benzoates	1,000 mg/kg (singly or in combination (as benzoic acid))	0-5	
200, 201, 202, 203	Sorbates	2,000 mg/kg (singly or in combination (as sorbic acid))	0-25	
If used in combination, the combined use shall not exceed 2000 mg/kg of which the benzoic acid portion shall not exceed 1000 mg/kg.				

4.8 Stabilizers and Thickeners

INS No.	Additive	Maximum Use Level	ADI (mg/kg bw)	Endorsement Status
405	Propylene Glycol Alginate	3,000 mg/kg	0-70	

FAO/WHO COORDINATING COMMITTEE FOR THE NEAR EAST REGION (CCNEA)

The Fourth Session of the CCNEA referred the Sections on Food Additives of the *Draft Regional Standard for Humus with Tehena* and *Draft Regional Standard for Canned Foul Medames* to the CCFA for endorsement (ALINORM 07/30/40, Appendices II and III).

DRAFT REGIONAL STANDARD FOR CANNED HUMUS WITH TEHENA
(At Step 8 of the Procedure)

4. FOOD ADDITIVES

Only those food additives listed below may be used and only within the limits specified.

4.1 ACIDIFYING AGENT

INS No.	Food Additive	Maximum Level	**ADI (mg/kg bw)**	**Endorsement Status**
330	Citric acid	Maximum acidity 1% expressed as citric acid	NL	

4.2 ANTICLOTTING AGENT

INS No	Food Additive	Maximum Level	**ADI (mg/kg bw)**	**Endorsement Status**
500i	Sodium carbonate	GMP	NL	

4.3 STABILIZER

INS No	Food Additive	Maximum Level	**ADI (mg/kg bw)**	**Endorsement Status**
501i	Potassium carbonate	GMP	NL	

DRAFT REGIONAL STANDARD FOR CANNED FOUL MEDAMES
(At Step 8 of the Procedure)

4. FOOD ADDITIVES

Only those food additives listed below may be used and only within the limits specified.

4.1 ACIDITY REGULATOR

INS NO	**FOOD ADDITIVE**	**MAXIMUM LEVEL**	**ADI (mg/kg bw)**	**Endorsement Status**
330	Citric acid	Maximum acidity 1% expressed as citric acid	NL	

4.2 ANTIOXIDANT, PRESERVATIVE

INS NO	**FOOD ADDITIVE**	**MAXIMUM LEVEL**	**ADI (mg/kg bw)**	**Endorsement Status**
385, 386	EDTAs[1]	365 mg/kg	0-2.5	

[1] As anhydrous calcium disodium EDTA.

Annex 1

REPORT OF THE 28TH SESSION OF CCNFSDU (EXCERPT)

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION A DRAFT REVISED STANDARD FOR INFANT FORMULA (Agenda Item 4a) (ALINORM 07/30/26, paras 56-68)

Section 4. Food Additives (Section A: Draft Revised Standard for Infant Formula)

56. The Delegation of Switzerland presented the report of the electronic working group that had worked between the sessions in order to redraft the Section on additives at the request of the last session of the Committee and pointed out that the approaches to the use of additives in infant formula varied widely between delegations.

General considerations

57. The Delegation of Switzerland, while presenting the report of the working group, recalled the background of consideration by JECFA of additives for use in infant foods, as follows. The Committee noted that the *Principles for the Safety Assessment of Food Additives and Contaminants* (WHO EHC 70, 1987) confirmed the principles that had been developed by the FAO/WHO Meeting on Additives in Baby Foods (1971), establishing a distinction between baby foods suitable for infants up to 12 weeks and older infants, due to physiological reasons, and concluded that "it is prudent that foods intended for infants under 12 weeks should contain no additives at all". However the *Principles* recognized "that in practice there may be certain exceptions on technological grounds", which were further specified. It was also noted that some additives had been evaluated by JECFA specifically for use in infant foods (for infants below 12 weeks) while others had been evaluated for the general population but not for this group of population.

58. The Committee noted that the basis of the advice provided by JECFA on additives in foods for young infants had been established in 1971 and agreed that further advice on the inclusion of additives in infant formula was necessary. The Committee agreed to ask the CCFA to put forward the following question to JECFA: to what extent an ADI established by JECFA, whether numerical or not specified, applied to young infants below 12 weeks; what scientific principles should apply to the evaluation of additives intended for this group of population; and whether the establishment of an ADI in itself was sufficient or whether other issues had to be addressed.

59. The Committee discussed whether the establishment of specific principles for use of additives in infant formula should be developed, as proposed by some delegations, and agreed that it would be preferable to defer consideration of this matter pending advice from JECFA.

60. Some delegations recalled that the revised Standard for Processed Cereal Based Foods for Infants and Young Children referred to the carry over of additives, and proposed to include a similar wording in the standard. The Chair recalled that the products were not the same and that carry over of additives was not allowed in the current Standard for Infant Formula. After some discussion, the Committee agreed to insert the text used for cereal based foods as an introduction to the list of additives and to ask the advice of the CCFA on the applicability of the language for carry over to infant formula.

Additives for inclusion in the Draft Standard

61. In view of the above considerations, the Committee considered the options put forward by the working group on how to proceed with the current section on additives:

1) Proceed with all food additives already listed in the current standard; defer discussion of other additives after JECFA has provided its opinion

2) Proceed with non controversial additives cleared by JECFA specifically for infants

3) Defer consideration of Section 4 until JECFA has provided its opinion

62. The EC explained that in their view the use of food additives in foods intended for infants and young children should be limited to those where there is a clear technological need and where that function can not be fulfilled by an additive on the list and expressed preference for option 2.

63. The Committee agreed to proceed with the first option and to establish a working group chaired by Switzerland during the session to identify the additives that could be included in the current Draft Standard and those that would require further consideration. The Committee considered three lists of additives that were proposed by the working group: Table 1: additives that are considered suitable for use in infant formula and formula for special medical purposes (FSMP) intended for infants use (sections A and B); Table 2 including additives for which suitability for use in sections A and B should be determined; and Table 3 including additives intended only for FSMP (section B).

64. As regards Table 1, the Delegation of the United States expressed the view that the list of additives in the current standard should be retained in view of their long history of use, with the understanding that it could be amended when new scientific advice became available.

65. The Delegation of the EC proposed to delete carrageenan from the current list in view of its adverse effects to health of young infants, until the JECFA reevaluation scheduled for 2007 became available. After some discussion, the Committee agreed to insert a footnote to the effect that national authorities may restrict the use of carrageenan until the evaluation by JECFA had been completed.

66. The Committee agreed that Table 1 would include all those additives and levels of use that were considered suitable for in infant formula and formula for special medical purposes and would be forwarded to the CCFA for endorsement and to the Commission as section 4 of the Draft Standard.

67. The Committee agreed to forward the additives in Table 2 to the CCFA for advice on their suitability in the products covered by sections A and B and evaluation by JECFA if required, in the light of the advice that would be provided on the general questions mentioned above. The Committee agreed to forward the additives in Table 3 to CCFA for advice on their suitability in the products covered by section B and evaluation by JECFA if required. Tables 2 and 3 are presented in Appendix III.

68. The Committee expressed its appreciation to the Delegation of Switzerland and to the working group for their comprehensive work in order to facilitate the update of the additives section.

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AT STEP 7 (Agenda Item 4 b) (ALINORM 07/30/26, paras 83-85)

Section 4. Food Additives (Section B: Formulas for Special Medical Purposes Intended for Infants)

83. The Observer from ISDI informed the Committee that more additives had been used in the products covered by this section as compared to infant formula for technological reasons due to their composition.

84. The Committee discussed whether to continue work on additional list of additives at this stage or after final adoption of the Draft Standard and concluded that it would not continue work on additives at this stage.

85. The Committee noted that additional additives may be needed for Formula for Special Medical Purposes, therefore inserted a sentence to clarify that such uses may be determined by national authorities.

PROPOSED DRAFT REVISION OF THE ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR THE USE BY INFANTS AND YOUNG CHILDREN AT STEP 4 (Agenda Item 6) (ALINORM 07/30/26, paras 126-129)

Section D Advisory List of Food Additives for Special Nutrient Forms

126.The Committee clarified the title of Section D to refer to “nutrient” compounds rather than to “vitamin”.

127.The Committee agreed to clarify uses of nutrients and food additives in introductory paragraph of Section D, and that the additives in the list may be used as nutrient carriers as proposed by the Delegation of the European Community.

128.It was proposed to increase the level of uses for Gum Arabic (gum acacia) from 10 mg/kg to 100 mg/kg due to technological reasons and reflect the level in the current standard. However, no agreement was reached on this proposal, therefore the Committee decided to put both figures in square brackets.

129.The Committee agreed to send the Section D for endorsement to CCFA as these additives were in addition to those allowed in the respective standards.

Annex 2

REPORT OF THE 20TH SESSION OF CCFO (EXCERPT)

DRAFT STANDARD FOR FAT SPREADS AND BLENDED FAT SPREADS (Agenda Item 3)
(ALINORM 07/30/17, paras 32-57)

32) The Committee recalled that its last session had finalised the provisions in the Draft Standard, with the exception of the section on additives, returned to Step 6 for redrafting by an electronic working group coordinated by the United States. The redrafted section was circulated for comments in CL 2006/39-FO.

33) The Committee considered the report of the working group held during the session and chaired by Dr Dennis Keefe (United States), with Ms Kathy Twardek (Canada) as Rapporteur. The working group had considered the Recommendations 1 to 4 of the Circular Letter and updated these recommendations in the light of the comments received. The Committee discussed the proposals put forward in CRD 14, as follows.

Flavours (Recommendation 1)

34) The Committee agreed that the section on additives would allow "Natural flavouring substances and artificial flavouring substances" under "Flavours", which was consistent with the provisions included in other Codex standards.

Functional Classes (Recommendation 2)

35) The Committee agreed that the functional classes mentioned in Recommendation 2 were technologically justified and inserted an introductory paragraph clarifying how the classes should be used in the standard.

36) The reference to "antioxidant synergists" was deleted as this is a sub-class of the antioxidants.

37) The Committee agreed to request the Committee on Food Additives to clarify whether packing gases should be considered a food additive functional class.

Maximum Use Levels (Recommendation 3)

38) The Committee amended the introductory paragraph in order to clarify the conditions of use of the additives within the functional classes.

Antioxidants

39) The Delegation of the European Community expressed the view that synthetic antioxidants (BHA, BHT, TBHQ and propyl gallate) were not needed in products within the scope of this standard, as such products are generally refrigerated, which allows a suitable shelf life. However, the EC recognized that in other parts of the world such products are not refrigerated and therefore in the context of the development of an international standard these additives could be included.

40) As regards tocopherols (INS 306 and 307), the Committee agreed to request the CCFA to clarify the appropriate INS numbers corresponding to the tocopherols that have been assigned an ADI by JECFA.

Colours

41) As regards annatto extracts, the Delegation of the United States informed the Committee that the 67th JECFA Session had reevaluated annatto extracts and established one ADI for bixin and a group ADI for norbixin and its sodium and potassium salts, and specifications for all extracts which are covered by the established ADIs, and tentative specifications for oil processed bixin. The reevaluation would be considered by the CCFA and it was expected that the levels of use and INS numbers would be reconsidered.

42) The Committee agreed to request the Committee on Food Additives to clarify the safe acceptable maximum use level based on recent advice from JECFA on the specifications of identity and purity and ADIs for annatto extracts. The level of 100 mg/kg was placed in square brackets pending advice from the CCFA.

43) The Committee recalled that it was its responsibility to propose levels of use on the basis of technological justification, and had an extensive discussion on the levels of use for annatto extracts and other colours. It was also recalled that technological justification should be provided in accordance with Section 3.2 of the Preamble of the General Standard for Food Additives.

44) The Delegation of the European Community expressed the view that the level of 100 for annatto extracts in fat spreads was too high and not technologically justified and that there was no technological need for Caramel Class II, III and IV. Other delegations indicated that they commonly used these colours at the levels proposed in some types of fat spreads, especially in flavoured products.

45) The Committee considered a proposal to establish two levels of use for certain colours according to the type of fat spread: a lower level for margarine and similar fat spreads, and a higher level for "flavoured" fat spreads, e.g. products with flavours such as fruit or chocolate. Some delegations supported this proposal as it would cover all possible cases but found it difficult to define precisely the type of spreads that would be covered. The Delegation of Japan objected to the establishment of two levels as it considered that there was clear technological justification for the level proposed, even for margarine type products, and that the definition of additional types of fat spreads might affect the other sections in the standard, which had been already finalised.

46) The Delegation of the United States pointed out that all additives should be used in accordance with the principle of good manufacturing practice (GMP), as described in section 3.3 of the GSFA, and even when a numerical level existed, they were used only in the amount necessary for technological purposes. The Delegation also indicated that a single level of use would be less trade restrictive.

47) After some further discussion, the Delegation of the European Community indicated that it had considered the comments of other delegations and recognised that the standard covers other products than margarine and minarine, for which it did not consider that caramel colours or high levels of annatto were needed. However the Delegation noted that other delegations had described certain specific products, especially flavoured fat spreads, in which these colours were needed, and in the interest of progressing this important standard, the EC could agree to the use of these colours, taking into account that the CCFA was requested to consider safe appropriate levels for annatto extracts.

48) The Delegation of Costa Rica, referring to its written comments, proposed to include Chlorophyll copper complexes (INS 141). As no specific level was indicated in the comments, the Delegation clarified that the level of use should be 1000 mg/kg. However, the Committee could not support this proposal as several delegations pointed out that there was no sufficient technological justification. It was also noted that additives with a numerical ADI should have numerical levels of use, unless clear justification was provided for use at a GMP level.

Emulsifiers

49) The Delegation of the European Community indicated that, although several limitations in the conditions for use were proposed in their written comments, most of these limitations could be removed. The Committee therefore agreed that only Thermally oxidised soya bean oil interacted with mono and diglycerides of fatty acids (INS 479) would be limited to fat emulsions for frying and baking purposes.

Other additives

50) The Committee agreed that all the other additives proposed by the working group in CRD 14 should be included in the standard.

Use of Additives in Table 3 of the GSFA (Recommendation 4)

51) Several delegations supported the proposal to insert a reference allowing all additives in Table 3 of the GSFA within the functional classes mentioned under Recommendation 1. As a consequential amendment, food category 02.2.1.2 Margarine would be proposed for deletion from the Annex to Table 3 excluding certain food categories from the application of GMP level for additives with ADI "not specified".

52) The Delegation of the European Community, while supporting the use of the additives in Table 3, expressed the view that all additives should be listed in the standard and considered by the Committee. If they were included only by reference to Table 3, changes to Table 3 might be made in the framework of the development of the GSFA without seeking the advice from the Committee as to technological justification.

53) The Delegation of the United States, supported by other delegations and the Observer from IFMA, expressed the view that there was no need to review in detail the additives allowed at GMP as there was no safety concern and their use was clearly limited by the technological function performed for a particular food. The Delegation also pointed out that the Commission had agreed that the GSFA should be the single reference point for food additives and that all additives in individual standards were subject to endorsement and incorporation into the GSFA.

54) The Secretariat recalled that the last session of the Commission had made some recommendations in order to clarify the review and amendment of food additives provisions in the GSFA and individual standards, and noted that the adoption of the food additive provisions applicable to margarine in the GSFA had been deferred by the Commission pending finalisation of the Draft Standard for Fat Spreads and Blended Spreads.

55) After some discussion, the Delegation of the European Community maintained its position that the Committee should be involved in considering the technological need for individual food additives in products within the scope of this standard. However, it noted that CCFA should always inform other committees when developments in the GSFA may impact on products within the remit of other committees. The Delegation therefore agreed to a reference to Table 3 of the GSFA. However, it stressed the importance for the CCFO to monitor developments in the CCFA and the GSFA and make appropriate comments or proposals when necessary.

56) The Committee agreed to insert a reference to Table 3 of the GSFA within the functional classes allowed in the standard, and to recommend that CCFA delete food category 02.2.1.2 Margarine from the Annex to Table 3. The Committee agreed to forward the additives section to the CCFA for endorsement.

57) The Committee expressed its thanks to Dr Keefe and to the working group for their excellent work between the sessions and at the current session, which had allowed the Committee to address complex issues in a constructive manner and to finalise the additives section.