CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4a **CX/FA 12/44/5**

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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 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]. 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

[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.

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].

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

Temporary ADI. Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA. The temporary ADI is listed in units of mg per kg of body weight[2].

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 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].

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].

Good Manufacturing Practice (GMP) in the Use of Food Additives [3] 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 31st Session of the Codex Committee on Fish and Fishery Products (CCFFP);

(b) The 6th Session of the FAO/WHO Coordinating Committee for Near East (CCNEA); and

(c) The 33rd Session of the Codex Committee on Nutrition and Food for Special Dietary Purposes (CCNFSDU).

Annex 1

COMMITTEE ON FISH AND FISHERY PRODUCTS

Standard for Fish Sauce **(CODEX STAN 302-2011)**[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 limits, specified.

Functional Class	INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
Acidity regulators	334; 335(i), (ii); 336(i), (ii); 337	Tartrates	GMP	ADI of 0-30 mg/kg body weight (17th JECFA, 1973)	
	330, 331 (i), (iii) 332 (i), (ii)	Citrates	GMP	Group ADI 'not limited' for citric acid and its salts (23rd JECFA, 1979)	
	296, 350 (i), (ii) 351 (i), (ii) 352 (ii)	Malates	GMP	Group ADI 'not specified' for malic acid and its calcium, potassium and sodium salts (23rd JECFA, 1979)	
	300	Ascorbic acid	GMP	Group ADI 'not specified' for ascorbic acid and its calcium, potassium and sodium salts (25th JECFA, 1981)	***Consistency with CAC/GL 36-1989*** Name of INS 300 is "ascorbic acid, L-"
	325	Sodium lactate	GMP	ADI 'not limited' for lactic acid and its salts (23rd JECFA, 1979)	
	260	Acetic acid	GMP	Group ADI 'not limited' for acetic acid and its potassium and sodium salts (17th JECFA, 1973)	***Consistency with CAC/GL 36-1989*** Name of INS 260 is "acetic acid, glacial"

[1] REP11/FFP Appendix III; the *Standard for Fish Sauce* was adopted by the 34th CAC (REP11/CAC para. 39 and Appendix III)

Functional Class	INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
Flavour enhancers	621	Monosodium glutamate	GMP	Group ADI 'not specified' for glutamic acid and its ammonium, calcium, potassium, magnesium and sodium salts (31st JECFA, 1987)	***Consistency with CAC/GL 36-1989*** Name of INS 621 is "monosodium L-glutamate"
	630	Inosinic acid	GMP	Group ADI 'not specified' for inosinic acid and its calcium, potassium and sodium salts (29th JECFA, 1985)	***Consistency with CAC/GL 36-1989*** Name of INS 631 is "disodium 5'-inositate"
	631	Disodium Inosine 5'monophophate	GMP		
	627	Disodium 5' guanylate	GMP	Group ADI 'not specified' for 5'guanylic acid and its calcium and sodium salts (18th JECFA, 1974)	
Sweeteners	950	Acesulfame K	1,000 mg/kg	ADI of 0-15 mg/kg body weight (37th JECFA, 1990)	***Consistency with CAC/GL 36-1989*** Name of INS 950 is "acesulfame potassium"
	955	Sucralose	450 mg/kg	ADI of 0-15 mg/kg body weight (37th JECFA, 1990)	
	951	Aspartame	350 mg/kg	ADI of 0-40 mg/kg body weight (57th JECFA, 2001)	
Colours	150c	Caramel III-Ammonia caramel	50,000 mg/kg	ADI of 0-200 mg/kg body weight 0-150 mg/kg body weight on solid basis) (29th JECFA, 1985)	
Emulsifiers and Stabilizers	466, 468	Carboxymethyl cellulose and crosslinked carboxymethyl cellulose	GMP	ADI 'not specified' for modified celluloses (35th JECFA, 1989)	***Consistency with CAC/GL 36-1989*** Name of INS 466 is "Sodium carboxymethyl cellulose"

Functional Class	INS No.	Additive	Maximum level	ADI (mg/kg bw)	Note
Preservatives	210-213	Benzoates	1,000 mg/kg	Group ADI of 0-5 mg/kg body weight for benzoic acid and its salts (27th JECFA, 1983)	
	200-203	Sorbates	1,000 mg/kg	Group ADI of 0-25 mg/kg body weight for sorbic acid and its calcium, potassium and sodium salt, expressed as sorbic acid (27th JECFA, 1983)	

Related provisions in the GSFA: Corresponding food category of the GSFA for the *Standard for Fish Sauce* is food category 12.6.4 "Clear sauce, (e.g. fish sauce)". Provisions of Table 3 of the GSFA apply to this food category. Currently, Tables 1 and 2 of the GSFA include the following provisions for food category 12.6.4": ascorbyl esters (INS 304, 305) 350 mg/kg with Note 10[2]; neotame (INS 961) 12 mg/kg ; polysorbates (432-436) 5000 mg/kg; and steviol glycosides (INS 960) 350 mg/kg with Note 26[3]

[2] Note 10 "as ascorbyl stearate"
[3] Note 26 "as steviol equivalents"

FAO/WHO COORDINATING COMMITTEE FOR THE NEAR EAST

Regional Standard for Halwa Tehenia (Near East) **(CODEX STAN 309-2011)** [4]

4 FOOD ADDITIVES

4.1 Only acidity regulators and emulsifiers used in accordance with Table 3 of the *General Standard for Food Additives* (CODEX STAN 192-1995) are acceptable for use in foods conforming to this Standard.

4.2 Flavourings

Flavourings are acceptable for use in foods conforming to this Standard when used in accordance with good manufacturing practices and in compliance with the Codex *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).

Related provisions in the GSFA: Corresponding food category of the GSFA for the *Regional Standard for Halwa Tehenia* is food category 5.2.2 "Soft candy". Provisions of Table 3 of the GSFA apply to this food category. Currently, Tables 1 and 2 of the GSFA include the following provisions for food category 5.2.2 and parent category 5.2 "Confectionery including hard and soft candy, nougats, etc. other that food category 05, 05.3 and 05.4": propylene glycol esters of fatty acids (INS 477) 5000 mg/kg; riboflavins (INS 101(i), (ii)) 1000 mg/kg; saccharins (INS 954(i)-(iv)) 500 mg/kg with Notes 161[5] "and 163[6]; shellac, bleached (INS 904) at GMP with Note 3[7] ; sucralose (trichlorogalactosucrose) (INS 955) 1800 mg/kg with Notes 161[5] "and 164[8]; sucroglycerides (INS 474) 5000 mg/kg; sunset yellow FCF (INS 110) 300 mg/kg with Note 161[5]; tertiary buthylhydroquinone (INS 319) 200 mg/kg with Notes 15[9] and 130[10] "; acesulfame potassium (INS 950) 100 mg/kg with Notes 157[11] , 161[5] and 188[12] ; aspartame (INS 951) with Notes 161[5] and 148[13]; and chlorophylls and chlorophyllins, copper complex (INS 141(i-ii)) 100 mg/kg.

[4] REP11/NEA Appendix IV; the *Regional Standard for Halwa Tehenia (Near East)* was adopted by the 34th CAC (REP11/CAC para. 86 and Appendix III)
[5] Note 161 "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble"
[6] Note 163 "For use in microsweets and breath freshening mints at 3 000 mg/kg"
[7] Note 3 "Surface treatment"
[8] Note 164 "For use in microsweets and breath freshening mints at 30 000 mg/kg"
[9] Note 15 "Fat and oil basis
[10] Note 130 "Singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321), tertiary butylated hydroquinone (INS 319), and propyl gallate (INS 310)"
[11] Note 157 "For use in microsweets and breath freshening mints at 2 000 mg/kg"
[12] Note 188 "Not to exceed the maximum use level for acesulfame potassium (INS 950) singly or in combination with aspartame-acesulfame salt (INS 962)"
[13] Note 148 "For use in microsweets and breath freshening mints at 10 000 mg/kg"

COMMITTEE ON NUTRITION AND FOOD FOR SPECIAL DIETARY PURPOSES

***Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)[14]**

Additives considered as physiological body constituents				
	4.3 Acidity Regulators		**ADI (mg/kg bw)**	**Note**
339i, ii and iii	Sodium phosphates	0.1 g expressed as P_2O_5 singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) in all types of infant formula	A group MTDI of 70 mg/kg bw. As phosphorus from all food sources was established at the 26th JECFA (1982)	***Consistency with CAC/GL 36-1989*** Sodium dihydrogen phosphate - INS 339(i); disodium hydrogen phosphate - INS 339 (ii); trisodium phosphate – INS 339(iii)
340i, ii and iii	Potassium phosphates	0.1 g expressed as P_2O_5 singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) in all types of infant formula	A group MTDI of 70 mg/kg bw. As phosphorus from all food sources was established at the 26th JECFA (1982)	***Consistency with CAC/GL 36-1989*** Potassium dihydrogen phosphate - INS 340(i); dipotassium hydrogen phosphate - INS 340 (ii); tripotassium phosphate – INS 340(iii)

Related provisions in the GSFA: Corresponding food category of the GSFA for *the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* is food category 13.1.3 Formulae for special medical purposes intended for infants. Provisions of Table 3 of the GSFA do not apply to this food category. Currently, Tables 1 and 2 of the GSFA include only the following provision for food category 13.1.3: ascorbyl esters (INS 304, 305) 50 mg/kg with Notes 10[2], 15[9] and 72[15].

[14] REP12/NFSDU Appendix II and para. 6
[15] Note 72 "Ready-to-eat basis"