CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 3(b) **CX/FA 19/51/4**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-first Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 86th JECFA MEETING

Codex members and Observers wishing to submit comments at Step 3 on the proposed draft Specifications for the Identity and Purity of Food Additives arising from the 86th JECFA Meeting (Annex 1) should do so as instructed in CL 2018/95-FA available on the Codex webpage/Circular Letters 2018: http://www.codexalimentarius.org/circular-letters/en/.

BACKGROUND

1. New specifications for food additives were prepared at the 86th JECFA meeting (Geneva, 12-21 June 2018).

2. Full specifications for 24 flavourings were developed, specifications for 3 flavourings were revised, and the specifications for 45 flavourings were maintained.

3. Full specifications for 6 additives were developed: basic methacrylate copolymer (BMC) (INS 1205), cassia gum (INS 427), erythrosine (INS 127), glycerol ester of wood rosin (INS 445(iii), indigotine (INS 132) and lutein from *Tagetes erecta* (INS 161b(i)).

4. Consequently, the tentative status of the specifications was removed for cassia gum.

5. Tentative specifications for 5 food additives were developed: anionic methacrylate copolymer (AMC) (INS 1207), citric and fatty acid esters of glycerol (INS 472c), modified starches, neutral methacrylate copolymer (NMC) (INS 1206), spirulina extract (INS 134).

6. The Committee further recommended a new approach to the specifications monographs for modified starches to account for the chemical similarity between all modified starches, their functional diversity, the variety of chemicals used in their manufacture, and the corresponding diversity of impurities. The Committee recommended that all modified starches be included in a modular monograph titled “Modified starches” that contains common requirements “General specifications for modified starches”] consisting of specifications that apply to all 16 modified starches (INS 1400, 1401, 1402, 1403, 1404, 1405, 1410, 1412, 1413, 1414, 1420, 1422, 1440, 1442, 1450, 1451), and annexes with specifications applicable to each individual modified starch based on the treatment(s) received. The Committee drafted a new modular specifications monograph titled “Modified starches” consisting of an explanatory introduction, “General specifications for modified starches,” and eight annexes. The new modular specifications monograph for modified starches is printed in FAO Monograph 22, and will replace the 16 existing individual specifications for modified starches (INS 1400, 1401, 1402, 1403, 1404, 1405, 1410, 1412, 1413, 1414, 1420, 1422, 1440, 1442, 1450, 1451).

7. The full specifications to be discussed and considered by the CCFA51 for adoption are listed in Annex 1, whereas other specifications for food additives which were designated as tentative or maintained by the 86th JECFA are listed in Annex 2. In addition, a list of errata is also reprinted in Annex 2 and presented for information to the committee.

8. The specification monographs is available (in English only) on the JECFA Online Edition of: "Combined Compendium of Food Additive Specifications” www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/ as FAO JECFA Monographs 22, FAO, Rome, 2018. The publication will be available to download as pdf-document at the FAO JECFA website at: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/

Recommendations

9. CCFA51 is being asked to review the specifications designated as “Full” for the food additives listed in Annex 1 with a view to recommending their adoption by CAC42 as Codex Specifications, taking into account comments received.

Annex 1

PROPOSED DRAFT SPECIFICATIONS RESULTING FROM THE 86TH JECFA MEETING

(at Step 3)

FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS *FULL* (FAO JECFA Monographs 22, Rome, 2018):[1]

Basic methacrylate copolymer (BMC) (INS 1205) (N)

Cassia Gum (INS 427) (R)

Erythrosine (INS 127) (R)

Glycerol ester of wood rosin (INS 445(iii) (R)

Indigotine (INS 132) (R)

Lutein from *Tagetes erecta* (INS 161b(i)) (R)[2]

NEW SPECIFICATIONS FOR FLAVOURING AGENTS (FAO JECFA Monographs 22, Rome, 2018)[1]

974 p-Mentha-1,8-dien-7-ol (N)

975 p-Mentha-1,8-dien-7-yl acetate (N)

980 Formyl-6,6-dimethylbicyclo[3.1.1]hept-2-ene (N)

981 Myrtenol (N)

2235 2-(((3-(2,3-Dimethoxyphenyl)-1H-1,2,4-triazol-5-yl)thio)methyl)pyridine (N)

2236 S)-1-(3-(((4-Amino-2,2-dioxido-1H-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbutan-1-one (N)

2237 2-(4-Methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide (N)

2238 8-Methyldecanal (N)

2239 8-Methylnonanal (N)

2240 trans-6-Octenal (N)

2241 2,6-Dimethyl-5-heptenol (N)

2242 Pinocarvyl isobutyrate (N)

2243 Carvyl palmitate (N)

2244 6-Hydroxycarvone (N)

2246 Menthyl formate (N)

2247 Menthyl propionate (N)

2248 l-Menthyl butyrate (N)

2249 dl-Isomenthol (N)

2250 Dimenthyl glutarate (N)

2251 (±)-2-[(2-p-Menthoxy)ethoxy]ethanol (N)

2252 Ethyl maltol isobutyrate (N)

2253 Mixture of 1-Vinyl-3-cyclohexenecarbaldehyde and 4-Vinyl-1-cyclohexenecarbaldehyde (N)

2254 (1-Methyl-2-(1,2,2-trimethylbicyclo[3.1.0]hex-3-ylmethyl)cyclopropyl)methanol (N)

2255 (±)-Bicyclo[2.2.1]hept-5-ene-2-carboxylic acid, ethyl ester (N)

[1] (M) existing specifications maintained; (N) new specifications; (R) revised specifications; (T) tentative specifications.
[2] The specifications for lutein esters from *Tagetes erecta* (INS 161b(iii)) and zeaxanthin (synthetic) (INS 161h(i)) were maintained.

Flavouring agents considered for revision of specifications only[1]

433 L-menthyl lactate (R)

619 L-malic acid (R)

2123 Glutamyl-valyl-glycine (R)

Annex 2

OTHER SPECIFICATIONS RESULTING FROM THE 86th JECFA MEETING

(for information only)

SPECIFICATIONS DESIGNATED AS *TENTATIVE* (FAO JECFA Monographs 22, Rome, 2018):[1]

Anionic methacrylate copolymer (AMC) (INS 1207) (N, T)

Citric and fatty acid esters of glycerol (INS 472c) (R, T)[3]

Modified Starches (INS 1400, 1401, 1402, 1403, 1404, 1405, 1410, 1412, 1413, 1414, 1420, 1422, 1440, 1442, 1450, 1451) (R, T)

Neutral methacrylate copolymer (NMC) (INS 1206) (N, T)

Spirulina Extract (INS 134) (N, T)

Specifications of flavouring agents maintained[1]

380.1 (+)-Carvone (M)

380.2 (-)-Carvone (M)

427 Menthol (M)

973 p-Mentha-1,8-dien-7-al (Perillaldehyde) (M)

982 Myrtenyl acetate (M)

1480 Maltol (M)

1491 2-Pentylfuran (M)[4]

1492 2-Heptylfuran (M)[4]

1493 2-Decylfuran (M)[4]

1494 3-Methyl-2-(3-methylbut-2-enyl)-furan (M)[4]

1495 2,3-Dimethylbenzofuran (M)[4]

1496 2,4-Difurfurylfuran (M)[4]

1497 3-(2-Furyl)acrolein (M)[4]

1498 2-Methyl-3(2-furyl)acrolein (M)[4]

1499 3-(5-Methyl-2-furyl)prop-2-enal (M)[4]

1500 3-(5-Methyl-2-furyl)butanal (M)[4]

1501 2-Furfurylidene-butyraldehyde (M)[4]

1502 2-Phenyl-3-(2-furyl)prop-2-enal (M)[4]

1503 2-Furyl methyl ketone (M)[4]

1504 2-Acetyl-5-methylfuran (M)[4]

1505 2-Acetyl-3,5-dimethylfuran (M)[4]

1506 3-Acetyl-2,5-dimethylfuran (M)[4]

1507 2-Butyrylfuran (M)[4]

1508 (2-Furyl)-2-propanone (M)[4]

1509 2-Pentanoylfuran (M)[4]

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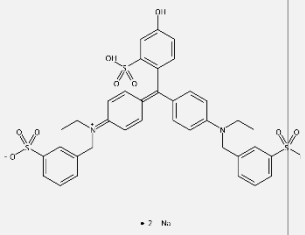
[3] The Committee did not receive a replacement method for the obsolete packed column gas chromatographic method for the determination of total citric acid, in its specifications monograph. The Committee noted further that the method for total glycerol still uses chloroform. The Committee encouraged the submission of a method for total glycerol that eliminates the use of chloroform. Specifications were revised and made tentative pending the availability of data. Specifications will be withdrawn if suitable information is not provided by December 2019.

[4] The text “The safety evaluation for these flavouring agents had not been completed” was removed from the specifications and the specifications were maintained as full.

1510 1-(2-Furyl)butan-3-one (M)[4]
1511 4-(2-Furyl)-3-buten-2-one (M)[4]
1512 Pentyl 2-furyl ketone (M)[4]
1513 Ethyl 3-(2-furyl)propanoate (M)[4]
1514 Isobutyl 3-(2-furan)propionate (M)[4]
1515 Isoamyl 3-(2-furan)propionate (M)[4]
1516 Isoamyl 3-(2-furan)butyrate (M)[4]
1517 Phenethyl 2-furoate (M)[4]
1518 Propyl 2-furanacrylate (M)[4]
1519 2,5-Dimethyl-3-oxo-(2H)-fur-4-yl butyrate (M)[4]
1520 Furfuryl methyl ether (M)[4]
1521 Ethyl furfuryl ether (M)[4]
1522 Difurfuryl ether (M)[4]
1523 2,5-Dimethyl-3-furanthiol acetate (M)[4]
1524 Furfuryl 2-methyl-3-furyl disulphide (M)[4]
1525 3-[(2-Methyl-3-furyl)thio]-2-butanone (M)[4]
1526 O-Ethyl S-(2-furylmethyl)thiocarbonate (M)[4]
2103 (E)-Ethyl 3-(2-furyl)acrylate (M)[4]
2104 di-2-Furylmethane (M)[4]
2105 2-Methylbenzofuran (M)[4]

THE PUBLICATION OF AN ERRATA TO EXISTNG SPECIFICATIONS:

Food additive	Original text	New text	Additional information
Calcium disodium ethylenediaminetetra acetate (INS 385) **Monograph 1 (2006)**	CAS No. 662-33-9	CAS No. 62-33-9	Transcription error
Chlorophyllins, copper complexes sodium and potassium salts (INS 141(ii)) **Monograph 5 (2008)** **Test for "Free ionisable copper"**	Accurately weigh about 1 g of the sample and dissolve in 20 ml of arachid oil….	Accurately weigh about 1 g of the sample and **mix** in 20 ml of arachid oil….	Correction
Curcumin (INS: 100(i)) **Monograph 1 (2006)**	The criteria for several residual solvents are listed under the heading "Residual solvents" (see Fig. 1).	Acetone: Not more than 30 mg/kg Hexane: Not more than 25 mg/kg Methanol: Not more than 50 mg/kg Ethanol: Not more than 50 mg/kg Isopropanol: Not more than 50 mg/kg Ethyl acetate: Not more than 50 mg/kg	Improves readability It was unclear whether the criterion "Not more than 50 mg/kg" extended to methanol, ethanol, isopropanol and ethyl acetate.
Ethyl acetoacetate ethyleneglycol ketal **JECFA No: 1969** **JECFA 73 (2010)**	CAS No. 1648615	CAS No. 6413-10-1	Transcription error
Ethyl 2-methyl pentanoate **JECFA No: 214** **JECFA 55 (2000)**	CAS No. 28959-02-6	CAS No. 39255-32-8	Wrong CAS number
***cis*-3-Hexen-1-ol** **JECFA No.: 315** **JECFA 51 (1998)**	98.0% (sum of (*Z*) and (*E*) isomers, =<92.0% (*Z*))	98.0% (sum of (*Z*) and (*E*) isomers, =>92.0% (*Z*))	Transcription error
Monosodium L-glutamate (INS: 621) **Monograph 1 (2006)**	CAS No. 142-47-2	CAS No. 6106-04-3	Wrong CAS number
Myrcene **JECFA No.: 1327** **JECFA 63 (2004)**	Specific gravity: 0.789–1.793	Specific gravity: 0.789–0.793	Transcription error

Food additive	Original text	New text	Additional information
Polyoxyethylene (20) sorbitan monostearat (Polysorbate 60) **(INS 435)** **Monograph 16 (2014)**	CAS No. 9005-07-6	CAS No. 9005-67-8	Wrong CAS number
Sodium aluminium silicate (INS 554) **Monograph 20 (2017)**	Within the assay, the limits for silicon dioxide, aluminium oxide and sodium oxide are expressed "on dried basis".	Within the assay, the limits for silicon dioxide, aluminium oxide and sodium oxide are expressed "on **ignited** basis".	Transcription error
Silicon dioxide, amorphous (INS 551) **Monograph 20 (2017)**	CAS No. 112696-00-8 (hydrated silica)	CAS No. 112926-00-8 (hydrated silica)	Transcription error
	Pyrogenic silica is produced in an essentially anhydrous state, whereas the wet process products are obtained as hydrates or contain surface absorbed water.	Pyrogenic silica is produced in an essentially anhydrous state, whereas the wet process products are obtained as hydrates or contain surface a**d**sorbed water.	Transcription error
Sodium thiosulfate (INS 539) **Monograph 1 (2006)**	CAS No. 7772-98-7	CAS No. 10102-17-7	CAS No. 7772-98-7 refers to the anhydrous form. The specifications in the monograph refer to the pentahydrate form.
Brown HT and its aluminium lake **(FAO JECFA Monographs 19, 82nd meeting, 2016)**	Text in the Table 1 "Values for synthetic colours for use in performing tests for colouring matters content by spectrophotometry"	See Table 1, below	
Fast Green FCF **(FAO JECFA Monographs 19, 82nd meeting, 2016)**	Chemical structure in Table 1 "Values for synthetic colours for use in performing tests for colouring matters content by spectrophotometry"		

CAS: Chemical Abstracts Service; INS: International Numbering System for Food Additives; No.: number

Bolding and underlining for clarity only. This formatting will not be shown in the online database.

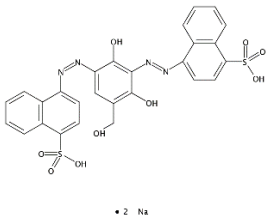
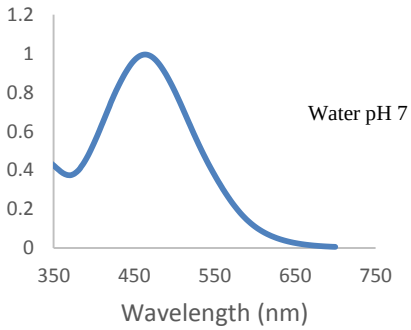
The criteria for several residual solvents are listed under the heading “Residual solvents” (see Fig. 1)

Figure1: Residual solvent criteria for curcumin as displayed in Monograph 1, 2006

Residual solvents (Vol. 4)	Acetone:	Not more than 30 mg/kg
	Hexane:	Not more than 25 mg/kg
	Methanol:	}
	Ethanol:	Not more than 50 mg/kg
	Isopropanol:	
	Ethyl acetate:	

Table 1

Replacement of the text for the spectrophotometric data for Brown HT and its aluminium lake originally published in “Table 1. Values for synthetic colours for use in performing tests for Colouring Matters Content by Spectrophotometry” (FAO JECFA Monographs 19, 82nd meeting, 2016)

JECFA name	Sample weight	Structure	Spectral data	Visible absorption spectrum
Brown HT	245.6 mg		Water, pH 7 λ_{max} = 464 A = 0.9957 Spec abs = 403 a = 40.3 Water λ_{max} = 464 A = 0.9804 Spec abs = 397 a = 39.7 0.04 N AmAc λ_{max} = 461 A = 0.9206 Spec abs = 373 a = 37.3	
Brown HT Aluminium Lake	53.3 mg		Straight colour (blue) 0.04 N AmAc λ_{max} = 461 A = 0.9206 Lake (red) 0.04 N AmAc λ_{max} = 458 A = 1.0451