Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Eighty-sixth meeting
Geneva, 12–21 June 2018

SUMMARY AND CONCLUSIONS

Issued 3 July 2018

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Geneva, Switzerland, from 12 to 21 June 2018. The purpose of the meeting was to evaluate certain food additives (including flavouring agents).

Dr A. Mattia, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, served as Chairperson, and Dr. Richard Cantrill, Canada, served as Vice-Chairperson.

Dr M. Lipp, Office for Food Safety, Food and Agriculture Organization of the United Nations, and Dr A. Tritscher, Department of Food Safety and Zoonoses, World Health Organization, served as Joint Secretaries.

The present meeting was the eighty-sixth in a series of similar meetings. The tasks before the Committee were (a) to undertake safety evaluations of certain food additives (including flavouring agents); and (b) to review and prepare specifications for certain food additives (including flavouring agents).

The Committee evaluated the safety of eight food additives, revised the specifications for 19 other food additives (including 16 modified starches), evaluated 69 flavouring agents according to the revised Procedure for the Safety Evaluation of Flavouring Agents and revised the specifications for three flavouring agents.

The report of the meeting will be published in the WHO Technical Report Series. Its presentation will be similar to that of previous reports – namely, general considerations, comments on specific substances and recommendations for future work. An annex will include detailed tables (similar to the tables in this report) summarizing the main conclusions of the Committee in terms of acceptable daily intakes and other toxicological, dietary exposure and safety recommendations. Information on the specifications for the identity and purity of certain food additives (including flavouring agents) examined by the Committee will also be included.

The participants in the meeting are listed in Annex 1. Items of a general nature that the Committee would like to disseminate quickly are included in Annex 2. Future work and recommendations are listed in Annex 3.

Toxicological and dietary exposure monographs on most of the substances that were considered will be published in WHO Food Additives Series No. 77. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs 22.

More information on the work of JECFA is available at:

http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/

and

http://www.who.int/foodsafety/areas_work/chemical-risks/jecfa/en/

Toxicological information and information on specifications

Food additives evaluated toxicologically and assessed for dietary exposure

Food additive	Specifications	Acceptable daily intakes (ADIs) and other toxicological and dietary exposure conclusions
Anionic methacrylate copolymer (AMC)	N, T[a]	**The Committee was unable to complete the evaluation of AMC.** While the copolymer itself is not of health concern, genotoxicity concerns remains for the residual monomer methacrylic acid. The specifications were made tentative pending the completion of the safety evaluation of AMC.
Basic methacrylate copolymer (BMC)	N	**The Committee established an ADI "not specified" for basic methacrylate copolymer.** The Committee concluded that the use of BMC that complies with the specifications established at the current meeting is not of safety concern when the food additive is used as a coating or glazing agent for solid food supplements and for foods for special medical purposes and micronutrient encapsulation for food fortification. The NOAELs for BMC ranged from 750-2000 mg/kg bw per day which were the highest doses tested. The Committee evaluated exposure to BMC for the copolymer and its monomers (n-butyl methacrylate, 2-(dimethylamino)ethyl methacrylate and methyl methacrylate). Estimated exposures to BMC range from 3.0 to 135 mg/kg bw per day. The total monomeric content of BMC is less than 0.3%. The Committee concluded that the toxicological data on the residual monomers do not give rise to concerns when taking into account the low dietary exposures.
Erythrosine	R[b]	**The Committee concluded that the new data that have become available since the previous evaluation of erythrosine do not give reason to revise the ADI and confirmed the previous ADI of 0–0.1 mg/kg bw.** The Committee noted that the dietary exposure estimate for erythrosine of 0.09 mg/kg bw per day (95th percentile for children) was close to the upper bound of the ADI. Given that this estimate of exposure is for children and it is a high percentile for consumers only, such a level is unlikely to occur every day over a lifetime. Therefore, the Committee concluded that dietary exposures to erythrosine for all age groups do not present a health concern.

Food additive	Specifications	Acceptable daily intakes (ADIs) and other toxicological and dietary exposure conclusions
Indigotine	R[b]	The Committee considered the new data that had become available since the previous evaluation as well as previously evaluated studies and **concluded that there are no reasons to revise the ADI and confirmed the previous ADI of 0–5 mg/kg bw**. The Committee noted that the conservative dietary exposure estimate of 0.8 mg/kg bw per day (95th percentile for children and toddlers) is less than the upper bound of the ADI of 0–5 mg/kg bw. The Committee concluded that dietary exposure to indigotine for all age groups does not present a health concern.
Lutein	R[c,d]	Free lutein, lutein esters and free zeaxanthin including *meso*-zeaxanthin are biochemically and toxicologically equivalent. At the present meeting the Committee concluded that there were sufficient toxicological data to complete a safety assessment of lutein and lutein esters from *Tagetes erecta*, synthetic zeaxanthin and *meso*-zeaxanthin. Free lutein, lutein esters and free zeaxanthin and *meso*-zeaxanthin are substances of low toxicity for which no adverse effects have been observed in a broad range of toxicological studies in laboratory animals and clinical studies in humans. Based on the absence of toxicity in a wide range of studies, **the Committee established a group ADI "not specified" for lutein from *Tagetes* erecta, lutein esters from *Tagetes* erecta and zeaxanthin (synthetic).** M*eso*-zeaxanthin was not included in this group ADI, as specifications are not currently available. **The group ADI of 0-2 mg/kg bw for lutein from *Tagetes erecta* and zeaxanthin (synthetic) was withdrawn.**
Neutral methacrylate copolymer (NMC)	N, T	**The Committee established an ADI "not specified" for NMC. The ADI "not specified" was made temporary because the specifications are tentative**. The Committee concluded that the use of NMC that complies with the specifications established at the current meeting is not of safety concern when the food additive is used as a coating or glazing agent for solid food supplements and for foods for special medical purposes. The NOAELs for NMC ranged from 454–2000 mg/kg bw per day, and these were the highest doses tested. The Committee evaluated exposure to NMC for the copolymer and its monomers (methyl methacrylate and ethyl acrylate). Estimated exposures to NMC range from 5.8 to 86 mg/kg bw per day. The total monomeric content of NMC is less than 0.01%. Toxicological data on the residual monomers do not give rise to concerns when taking into account the low dietary exposures.
Sorbitol syrup	-	Sorbitol syrup (INS 420(ii)) is currently included in the Codex General Standard for Food Additives (GSFA) although it has not been assigned an ADI or determined, on the basis of other criteria, to be safe. The Committee was therefore requested to consider the previous evaluations of sorbitol, hydrogenated glucose syrups and other relevant substances, and advise on the need for a

Food additive	Specifications	Acceptable daily intakes (ADIs) and other toxicological and dietary exposure conclusions
		separate evaluation of sorbitol syrup or if the ADI "not specified" for sorbitol is also applicable for sorbitol syrup. Based on the similarity of the chemical constituents of sorbitol syrup to the previously evaluated sorbitol, maltitol syrup and polyglycitol syrup, **the Committee concluded that there is no need for a separate evaluation of sorbitol syrup and established an ADI "not specified" for sorbitol syrup.**
Spirulina extract	N, T	**The Committee established a temporary ADI "not specified" for spirulina extract.** The ADI was based on the absence of toxicity in repeated-dose animal studies with spirulina extract and dried spirulina. **The ADI "not specified" was made temporary due to the tentative nature of the specifications**. Expressed as phycocyanins, estimated dietary exposure from the use of spirulina extract as a food colour based on the Budget method and exposure to spirulina extract and dried spirulina from other dietary sources, including food ingredients, dietary supplements, and coatings of food supplements was 190 mg/kg bw for adults (60 kg/person) and 650 mg/kg bw for a child (15 kg/person). The Committee concluded that this dietary exposure does not present a health concern.

- : no specifications prepared; N: new specifications; R: existing specifications revised; T: tentative specifications

[a] The specifications were made tentative pending the completion of the safety evaluation of AMC.

[b] At the current meeting, high-performance liquid chromatographic (HPLC) methods were added for determining subsidiary colouring matters and organic compounds other than colouring matters. The method of assay was changed to visible spectrophotometry, and spectrophotometric data were provided for the colour dissolved in water.

[c] The specifications for lutein esters from *Tagetes erecta* and zeaxanthin (synthetic) were maintained.

[d] At the current meeting, the identity test for melting range was deleted, the identity tests for carotenoids and spectrophotometry were updated, the test for propylene glycol was incorporated verbatim and the previous reference removed, and the method of assay was updated.

Food additives considered for specifications only

Food additive	Specifications
Cassia gum	R[a]
Citric and fatty acid esters of glycerol	R, T[b]
Glycerol ester of wood rosin	R[c]
Modified starches	R[d], T

R: existing specifications revised; T: tentative specifications

[a] The Committee, at its current meeting, received analytical methods and included the most suitable validated method in the specifications monograph. However, this method uses chloroform for the extraction of anthraquinones. Extraction with n-hexane and diethyl ether resulted in poor recovery of anthraquinones. The Committee recommends that the JECFA Secretariat be notified if an alternative extraction solvent is identified. The specifications were revised and the tentative status was removed.

[b] 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.

[c] The Committee received information on the manufacture of GEWR from the rosin obtained from the stumps of two additional species namely *Pinus halepensis* and *Pinus brutia* as source materials. Recognizing the natural variability of the composition of wood rosin, the Committee removed the restriction to certain pine species within the specifications. Since the specifications monograph for GEWR does not contain an assay, the Committee

recommended that the JECFA Secretariat be notified upon the development and validation of an appropriate assay. The existing specifications were revised.

[d] The Committee reviewed data on the method of manufacture, identity, and purity of all 16 modified starches. Based on the information received, and available information the Committee noted that:

- All processes are performed under similar manufacturing conditions and result in minor chemical modifications. Given the chemical and physical similarities of modified starches, the Committee at previous meetings considered the application of a read-across approach to be appropriate for the toxicological evaluation of these substances.
- All 16 modified starches had been assigned an ADI of "not specified".
- All modified starches can be additionally bleached or fragmented; therefore revision in the specifications of bleached or fragmented starches would imply the revision of all 16 monographs;
- Microbiological specifications were not present in the existing specifications for all modified starches.
- Several specifications were common to all modified starches (such as for heavy metals impurities content and microbiological considerations). Revision of those common specifications would affect all 16 monographs;
- As a result of the wide range of products manufactured, the identification tests required to unambiguously chemically characterize each modified starch in individual specifications may be cumbersome, potentially unavailable, and unlikely to reflect market requirements.
- It may not be possible to publish identification tests based on market requirements without unduly revealing proprietary information.
- Based on the points noted above, individual specifications for several modified starches may remain tentative for an indefinite period or may need to be withdrawn.

The Committee therefore recommended that a new approach to the specifications monographs should be introduced 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).

The specification for lead included in the General specifications be decreased from 2 mg/kg to 0.2 mg/kg. The limit of lead for starch sodium octenylsuccinate for use in infant formula and formula for special medical purposes intended for infants was set to 0.1 mg/kg in the General specifications.

The methods for the determination of free adipic acid and adipate groups, residual vinyl acetate, free octenyl succinic acid and octenyl succinate esters were revised and a method for the determination of propylene chlorohydrins was added.

Flavouring agents evaluated by the revised Procedure for the Safety Evaluation of Flavouring Agents

A. Alicyclic primary alcohols, aldehydes, acids and related esters

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Mixture of 1-Vinyl-3-cyclohexenecarbaldehyde and 4-Vinyl-1-cyclohexenecarbaldehyde	2253	N	No safety concern
p-Mentha-1,8-dien-7-ol	974	N	No safety concern
p-Mentha-1,8-dien-7-yl acetate	975	N	No safety concern
Formyl-6,6-dimethylbicyclo[3.1.1]hept-2-ene	980	N	No safety concern
Myrtenol	981	N	No safety concern
Myrtenyl acetate	982	M	No safety concern

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class II			
(1-Methyl-2-(1,2,2-trimethylbicyclo[3.1.0]hex-3-ylmethyl)cyclopropyl)methanol	2254	N	No safety concern
Structural class III			
(±)-Bicyclo[2.2.1]hept-5-ene-2-carboxylic acid, ethyl ester	2255	N	No safety concern
Flavouring agent excluded at Step 1 of the Procedure			
p-Mentha-1,8-dien-7-al (Perillaldehyde)	973	M	Genotoxicity data for *p*-mentha-1,8-dien-7-al raise concerns for potential genotoxicity

N: new specifications

M: existing specifications maintained;

B. Carvone and structurally related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Pinocarvyl isobutyrate	2242	N	No safety concern
Carvyl palmitate	2243	N	No safety concern
Structural class III			
6-Hydroxycarvone	2244	N	No safety concern
Flavouring agents not evaluated according to the revised Procedure			
(+)-Carvone	380.1	M	The Committee did not re-evaluate (+)-carvone (No. 380.1) according to the revised Procedure given the lack of information on the oral exposure from all sources and the need to review the ADI. A review of the ADI is recommended based on the evaluation of all biochemical and toxicological data. Also, data are needed for an exposure assessment for oral exposure to (+)-carvone from all sources to complete the evaluation for (+)-carvone.
(-)-Carvone	380.2	M	The Committee did not re-evaluate (-)-carvone (No. 380.2) according to the revised Procedure given the lack of information on the oral exposure from all sources

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
			and the lack of toxicological data.

M: existing specifications maintained; N: new specifications

C. Furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class III			
2-Pentylfuran	1491	M[a]	No safety concern
2-Heptylfuran	1492	M[a]	No safety concern
2-Decylfuran	1493	M[a]	No safety concern
3-Methyl-2-(3-methylbut-2-enyl)-furan	1494	M[a]	No safety concern
2,3-Dimethylbenzofuran	1495	M[a]	No safety concern
2,4-Difurfurylfuran	1496	M[a]	No safety concern
3-(2-Furyl)acrolein	1497	M[a]	No safety concern
2-Methyl-3(2-furyl)acrolein	1498	M[a]	No safety concern
3-(5-Methyl-2-furyl)prop-2-enal	1499	M[a]	No safety concern
3-(5-Methyl-2-furyl)butanal	1500	M[a]	No safety concern
2-Furfurylidene-butyraldehyde	1501	M[a]	No safety concern
2-Phenyl-3-(2-furyl)prop-2-enal	1502	M[a]	No safety concern
2-Furyl methyl ketone	1503	M[a]	No safety concern
2-Acetyl-5-methylfuran	1504	M[a]	No safety concern
2-Acetyl-3,5-dimethylfuran	1505	M[a]	No safety concern
3-Acetyl-2,5-dimethylfuran	1506	M[a]	No safety concern
2-Butyrylfuran	1507	M[a]	No safety concern
(2-Furyl)-2-propanone	1508	M[a]	No safety concern
2-Pentanoylfuran	1509	M[a]	No safety concern
1-(2-Furyl)butan-3-one	1510	M[a]	No safety concern
4-(2-Furyl)-3-buten-2-one	1511	M[a]	No safety concern
Pentyl 2-furyl ketone	1512	M[a]	No safety concern
Ethyl 3-(2-furyl)propanoate	1513	M[a]	No safety concern
Isobutyl 3-(2-furan)propionate	1514	M[a]	No safety concern
Isoamyl 3-(2-furan)propionate	1515	M[a]	No safety concern
Isoamyl 3-(2-furan)butyrate	1516	M[a]	No safety concern
Phenethyl 2-furoate	1517	M[a]	No safety concern
Propyl 2-furanacrylate	1518	M[a]	No safety concern
2,5-Dimethyl-3-oxo-(2*H*)-fur-4-yl butyrate	1519	M[a]	No safety concern
Furfuryl methyl ether	1520	M[a]	No safety concern
Ethyl furfuryl ether	1521	M[a]	No safety concern

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Difurfuryl ether	1522	M[a]	No safety concern
2,5-Dimethyl-3-furanthiol acetate	1523	M[a]	No safety concern
Furfuryl 2-methyl-3-furyl disulfide	1524	M[a]	No safety concern
3-[(2-Methyl-3-furyl)thio]-2-butanone	1525	M[a]	No safety concern
O-Ethyl S-(2-furylmethyl)thiocarbonate	1526	M[a]	No safety concern
(E)-Ethyl 3-(2-furyl)acrylate	2103	M[a]	No safety concern
di-2-Furylmethane	2104	M[a]	No safety concern
2-Methylbenzofuran	2105	M[a]	No safety concern

M: existing specifications maintained

[a] The text indicating that the safety evaluation for these flavouring agents had not been completed was removed from the specifications and the specifications were maintained as full

D. Linear and branched-chain aliphatic, unsaturated, unconjugated alcohols, aldehydes, acids and related esters

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
trans-6-Octenal	2240	N	No safety concern
2,6-Dimethyl-5-heptenol	2241	N	No safety concern

N: new specifications

E. Maltol and related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class II			
Maltol	1480	M	No safety concern[a]
Structural class III			
Ethyl maltol isobutyrate	2252	N	No safety concern

M: existing specifications maintained

N: new specifications

[a] The previously established ADI for maltol was withdrawn by the Committee.

F. Menthol and structurally related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Menthyl formate	2246	N	No safety concern
Menthyl propionate	2247	N	No safety concern
l-Menthyl butyrate	2248	N	No safety concern
dl-Isomenthol	2249	N	No safety concern

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Dimenthyl glutarate	2250	N	No safety concern
Menthol	427	M	No safety concern[a]
Structural class III			
(±)-2-[(2-*p*-Menthoxy)ethoxy]ethanol	2251	N	No safety concern

M: existing specifications maintained

N: new specifications

[a] The ADI of menthol of 0–4 mg/kg bw established at the fifty-first meeting was maintained.

G. Miscellaneous nitrogen-containing substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class III			
2-(((3-(2,3-Dimethoxyphenyl)-1*H*-1,2,4-triazol-5-yl)thio)methyl)pyridine	2235	N	No safety concern
S)-1-(3-(((4-Amino-2,2-dioxido-1*H*-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbutan-1-one	2236	N	No safety concern
2-(4-Methylphenoxy)-*N*-(1*H*-pyrazol-3-yl)-*N*-(thiophen-2-ylmethyl)acetamide	2237	N	No safety concern

N: new specifications

H. Saturated aliphatic acyclic branched-chain primary alcohols, aldehydes, and acids

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
8-Methyldecanal	2238	N	No safety concern
8-Methylnonanal	2239	N	No safety concern

N: new specifications

Flavouring agents considered for specifications only

Flavouring agent	No.	Specifications	
L-menthyl lactate	433		R[a]
L-malic acid	619		R[b]
Glutamyl-valyl-glycine	2123		R[c]

[a] The CAS number was changed from 59259-38-0 to 61597-98-6 and the name to L-menthyl L-lactate.

[b] The specification for specific rotation were removed

[c] The melting point range was revised.

Annex 1

Eighty-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives

Geneva, 12–21 June 2018

Members

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Annex 2

General considerations

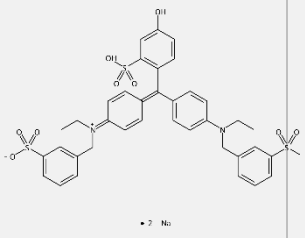
An edited version of this section will appear in the report of the eighty-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It is reproduced here so that the information can be disseminated quickly. This draft will be subject to editing.

Corrigenda for specifications monographs

The following requests for corrections in JECFA Food Additives Specifications Monographs were received by the JECFA Secretariat. The Committee at the current meeting evaluated the information provided and made the following corrections. These corrections will be published in the electronic versions and in the online database of JECFA Food Additives Specifications Monographs. The information is provided here to make interested parties aware of these changes.

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	Improves readability It was unclear whether the criterion "Not more than 50 mg/kg" extended to methanol, ethanol, isopropanol and ethyl acetate.

Food additive	Original text	New text	Additional information
		Ethyl acetate: Not more than 50 mg/kg	
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
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

Food additive	Original text	New text	Additional information
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

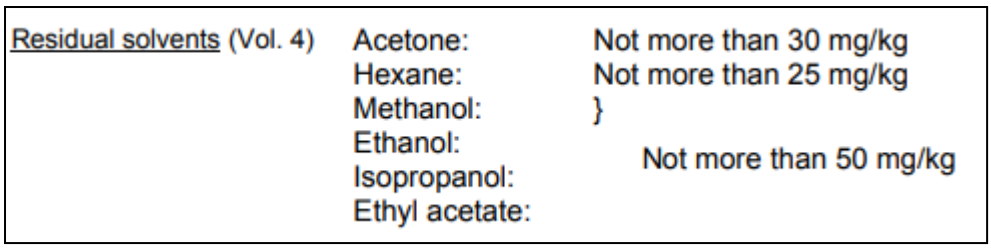
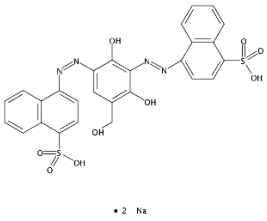
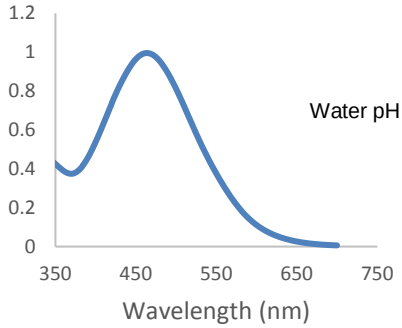
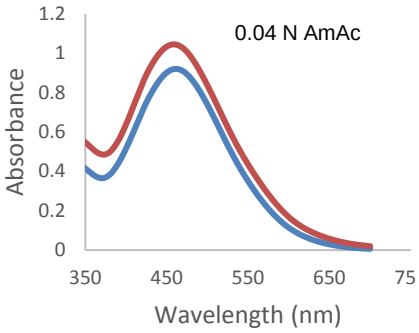


Table 1

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	

Annex 3

Future work and recommendations

Specific food additives (other than flavouring agents)

Anionic Methacrylate Copolymer
The Committee noted that there were insufficient data to reach a conclusion on the genotoxic potential of methacrylic acid. Further studies to clarify the in vivo carcinogenic potential are required.

Citric and fatty acid esters of glycerol
The specifications of CITREM were made tentative, requiring a suitable validated method for the determination of total citric acid content, along with performance characteristics of the method and data on the total citric acid content in at least five batches of products currently available in commerce, determined using that method.
The Committee noted 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. Specifications will be withdrawn if suitable information is not provided by **December 2019**.

Neutral Methacrylate Copolymer
The Committee noted that there was no data submitted for a suitable method of assay. Tentative specifications for NMC were prepared and made tentative requiring a suitable validated method of assay.

Spirulina extract
The Committee received limited analytical data on *spirulina* extract. In order to remove the tentative designation from the specifications, the following information on the products of commerce is requested by **December 2019**:

- Full compositional characterization of commercial products in both liquid and powder forms.
- Full compositional characterization of the aqueous extract before formulation/standardization.
- Validated analytical methods for identification of the substance with a suitable specificity (including validation data and representative batch data).
- Validated analytical methods for the determination of the purity of the substance with a suitable specificity (including validation data and representative batch data).

Modified starches

The Committee requested additional data and a suitable method for the determination of propylene chlorohydrins in Hydroxypropyl starch (INS 1440) and Hydroxypropyl distarch phosphate (INS 1442) in order to consider lowering this limit.

The Committee requests suitable microbiological acceptance criteria and supporting data for all modified starches.

Table 1. The annexes and the modified starches to which they apply along with required information:

ANNEX	Modification	Starches to which it applies	Information required
1	Minor fragmentation	INS 1400: Dextrin roasted starch; INS 1401: Acid treated starch; INS 1402: Alkaline treated starch; INS 1405: Enzyme-treated starch All modified starches that are additionally fragmented.	A suitable method for dispersion and a method for reducing sugars and data on at least 5 representative batches using the method(s) from each of the fragmentation processes.
2	Bleaching	INS 1403: Bleached starch All modified starches if additionally bleached.	Suitable method(s) for the determination of residual reagents and data on at least 5 representative batches using the method(s).
3	Esterification and/or crosslinking with phosphorus containing compounds	INS 1410: Monostarch phosphate; INS 1412: Distarch phosphate; INS 1413: Phosphated distarch phosphate; INS 1414: Acetylated distarch phosphate; INS 1442: Hydroxypropyl distarch phosphate	A suitable method for identification of crosslinking and data on at least 5 representative batches of crosslinked and non-crosslinked starches.
4	Acetylation	INS 1420: Starch acetate; INS 1414: Acetylated distarch phosphate; INS 1422: Acetylated distarch adipate; INS 1451: Acetylated oxidized starch	Currently no additional information required.
5	Oxidation	INS 1404: Oxidized starch; INS 1451: Acetylated oxidized starch	A suitable method for determination of residual hypochlorite and data on at least 5 representative batches using the method.
6	Esterification with octenyl succinic anhydride	INS 1450: Starch sodium octenyl succinate	Currently no additional information required.
7	Etherification with propylene epoxide	INS 1440: Hydroxypropyl starch; INS 1442: Hydroxypropyl distarch phosphate	A suitable method for the determination of propylene chlorohydrin with detection limit lower than 0.1 mg/kg and data on at least 5 representative batches of Hydroxypropyl starch using the method
8	Crosslinking with adipic anhydride	INS 1422: Acetylated distarch adipate	A suitable method for identification of crosslinking and data on at least 5 representative batches of crosslinked and non-crosslinked starches. Levels of free adipic acid in at least 5 representative batches

Flavouring agents

Carvone and structurally related substances

For (+)-carvone (No. 380.1), the Committee concluded that a review of the ADI is recommended based on the evaluation of all biochemical and toxicological data. Also, data are needed for an exposure assessment for the oral exposure to (+)-carvone from all sources.

The ADI for (+)-carvone is maintained pending review of the ADI at a future meeting. The Committee recommends that the re-evaluation is completed within three years.

For (-)-carvone (No. 380.2), the Committee concluded that toxicological data on (-)-carvone are necessary. Also, data are needed for an exposure assessment for the oral exposure to (-)-carvone from all sources

Maltol and related substances

The Committee could not verify the NOEL of 100 mg/kg bw in rats that was used to derive the ADI of 0–1 mg/kg bw for maltol (No. 1480) during its twenty-fifth meeting because of uncertainties in the administered dose levels and the effects observed in several studies described in the monograph of that meeting.

The Committee withdrew the ADI for maltol. The Committee concluded that access to either the original studies or submission of new data would be needed to reaffirm or amend the ADI.

The ADI for ethyl maltol was maintained.