



Food and Agriculture Organization of the United Nations

World Health Organization

# JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES Sixty-first meeting (Food additives and contaminants)

Rome, 10-19 June 2003

# LIST OF SUBSTANCES SCHEDULED FOR EVALUATION AND REQUEST FOR DATA

Attached is the list of substances (Annex 1) scheduled for evaluation or re-evaluation at the sixty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This list has been prepared by the Joint FAO/WHO Secretariat of the Committee and is based on recommendations of the Codex Committee on Food Additives and Contaminants (CCFAC), previous Expert Committees, and direct requests from governments, other interested organizations, and producers of substances that have been evaluated previously.

#### Submission of data

Annex 1 lists the food additives and contaminants to be considered at the meeting. Governments, interested organizations, producers of these chemicals, and individuals are invited to submit data for the toxicological evaluations, for the preparation of specifications for the identity and purity and for estimating the intake of the food additives that are listed and toxicological, chemical, and intake data for the contaminants that are listed. The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. Summaries in the form of monographs are helpful, but they are not in themselves sufficient for evaluation.

Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA. Summaries of the studies will be published by FAO and WHO after the meetings in the form of specifications and toxicological monographs.

Neither FAO nor WHO have facilities for long-term storage. The submitted data will either be returned to the submitter at his expense or destroyed after the evaluations have been completed. It would be helpful if the preferred procedure for data disposal is indicated at the time of submission. If no reference is made to disposal, the data will be destroyed. For substances that are being re-evaluated, the FAO and WHO Secretariats of JECFA encourage the sponsor to contact them before submission of data to determine whether documents and data reviewed at previous meetings of the Committee should be resubmitted.

The secretariats of JECFA at FAO and WHO encourage electronic submissions. Such data should be presented preferably using standard word processing or document formats, and

should be submitted on disks or CD-ROMs. In particular, the Secretariat encourages the submission of food contaminant data according to the protocol provided by GEMS/Food.<sup>a</sup>

#### Date for submission

The submission of data on those compounds listed in Annex 1 is requested before 30 November 2002. This deadline applies to all data including those for specifications for food additives and flavouring agents.

### Toxicological data

Data relevant to the toxicological evaluations of the substances on the agenda including the results of studies:

- 1. metabolism and pharmacokinetic studies;
- 2. short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies;
- 3. epidemiological studies; and
- 4. special studies designed to investigate specific effects, such as the mechanism of toxicity, immune responses, or macromolecular binding

should be sent in duplicate (at least one in paper) to:

International Programme on Chemical Safety

Attention: Dr. J.L. Herrman World Health Organization

Avenue Appia 1211 Geneva 27 Switzerland

Facsimile: (+41 (0)22)791 4848 Telephone: (+41 (0)22)791 3569

E-mail: <a href="mailto:herrmanj@who.int">herrmanj@who.int</a>

If the data are voluminous, please contact Dr Herrman in advance of the submission of data to determine where the second copy should be sent.

### Technological data

Data relevant to the manufacturing, quality, use, occurrence, identification and quantification of the substances on the agenda including:

- specifications for the identity and purity of the listed food additives (specifications applied during development and toxicological studies; proposed specifications for commerce);
- 2. technological and nutritional considerations relating to the manufacture and use of the listed food additives;
- 3. levels of the listed food additives found in food or expected to be in food based on technological function and the range of foods in which they are used;
- 4. levels and patterns of contamination in food commodities of the listed contaminants;
- 5. analytical techniques for identifying and quantifying the listed substances;
- 6. sampling protocols for the listed contaminants;
- 7. effects of processing on levels of the listed contaminants in food as consumed, and

<sup>&</sup>lt;sup>a</sup> Instructions for the electronic submission of data on chemical contaminants in food. GEMS/Food Programme (WHO/SDE/PHE/FOS/00.2 - available at <a href="http://www.who.int/fsf/Chemicalcontaminants/index2.htm">http://www.who.int/fsf/Chemicalcontaminants/index2.htm</a>), WHO, Geneva, 2000.

8. methods available for the prevention and control of the listed contaminants should be sent in duplicate to:

Food and Nutrition Division Attention: Dr Manfred Luetzow

Food and Agriculture Organization of the United Nations

Via delle Terme di Caracalla

00100 Rome

Italy

Facsimile: (+39) 06 5705 4593 Telephone: (+39) 06 5705 5425 E-mail: manfred.luetzow@fao.org

The technological information for food additives is summarized by the Committee in technical data sheets. Guidelines for the preparation of data sheets are provided in Annex 2. Applicants are encouraged to consider those when preparing their submission.

#### Intake assessment data

All data relevant to:

- 1. food consumption;
- 2. levels and patterns of contamination in food commodities of the listed contaminants; and
- 3. effects of processing on levels of the listed contaminants in food as consumed should be sent in duplicate to the attention of Dr Luetzow at FAO and in duplicate to:

Food Safety Programme Attention: Dr G. Moy World Health Organization Avenue Appia 1211 Geneva 27

Switzerland Facsimile: (+41 (0)22)791 4807 Telephone: (+41 (0)22)791 3698

E-mail: moyg@who.int

#### Presentation of data

Please note that the above lists are not meant to be all-inclusive since it is recognized that other studies may, in some instances, assist in the evaluation.

Procedures for the evaluation of food additives and contaminants were published by WHO in 1987 (*Principles for the Safety Assessment of Food Additives and Contaminants in Food* – Environmental Health Criteria No. 70, available at <a href="http://www.who.int/pcs/jecfa/ehc70.html">http://www.who.int/pcs/jecfa/ehc70.html</a>). All relevant data, both positive and negative, should be submitted. Data should be presented, summarized and referenced in a clear and concise manner.

This call for data is available at both the FAO and WHO web sites:

http://www.fao.org/es/esn/jecfa/

http://www.who.int/pcs

# Annex 1 Joint FAO/WHO Expert Committee on Food Additives (JECFA) Sixty-first meeting, Rome, 10-19 June 2003

#### List of substances scheduled for evaluation or re-evaluation

General information: Links to available electronic versions of the reports published in the WHO Technical Report Series, monographs published in the WHO Food Additives Series, and specifications that are referenced below are available at <a href="http://www.who.int/pcs/jecfa/JECFA\_publications.htm">http://www.who.int/pcs/jecfa/JECFA\_publications.htm</a>. WHO procedural guidelines and guidelines for the preparation of toxicological working papers and guidelines for the preparation of working papers on contaminants, intake, and flavouring agents are available at <a href="http://www.who.int/pcs/jecfa/jecfa\_gls.htm">http://www.who.int/pcs/jecfa/jecfa\_gls.htm</a>. Appendix B of the guidelines for the preparation of working papers on the intake of food additives provides guidance to countries submitting their national assessments of intake.

Previous reports and monographs should be consulted to obtain background information on the previous evaluations. Detailed biographical references are available on page 13.

# 1. Food additives recommended for re-evaluation and/or review at previous meetings of the Joint FAO/WHO Expert Committee on Food Additives

### a. Toxicological and/or intake evaluation

Food additive	Reference	Information required
Annatto extracts	Twenty-sixth <sup>1</sup> and fifty- third <sup>2</sup> reports and FAS 17 <sup>3</sup>	All relevant information relating to toxicity, intake, and specifications
Curcumin	Forty-fourth <sup>4</sup> and fifty-first <sup>5</sup> reports, FAS 35 <sup>6</sup> , and FNP 52/6 <sup>7</sup>	The results of a reproductive toxicity study on a substance complying with the specifications for curcumin and information on intake
Diacetyltartaric and fatty acid esters of glycerol	Fifty-seventh report <sup>8</sup> , FAS 48 <sup>9</sup> , and FNP 52/9 <sup>10</sup>	<ul> <li>Information relevant to intake and information relating to the two-year toxicity study in rats:</li> <li>To assess whether some of the adverse effects that were observed were treatment-related, the groups treated with diacetyltartaric and fatty acid esters of glycerol should be compared with both untreated and monoglyceride-treated controls and the control groups should be compared with one another;</li> <li>Additional information on the incidence of mycocardial fibrosis and adrenal medullary hyperplasia in animals a the low and intermediate doses should be provided.</li> </ul>
Quillaia extracts	Fifty-seventh report <sup>8</sup> and FNP 52/9 <sup>10</sup>	Additional information on composition (minimum and maximum percentages of saponins in unpurified and semi-purified extracts)

### b. Specifications

Food additive	Reference	Information required	
β-Carotene from Blakeslea trispora	Fifty-seventh report <sup>8</sup> and FNP 52/9 <sup>10</sup>	Information on the method of analysis for residual solvents (ethyl acetate and isobutyl acetate)	
Monomagnesium phosphate, trisodium diphosphate	Fifty-seventh report <sup>8</sup> and FNP 52/9 <sup>10</sup>	Information on the loss on drying, loss on ignition test method for loss on ignition and assay method for the hydrates.	
Natamycin	Fifty-seventh report <sup>8</sup> and FNP 52/9 <sup>10</sup>	Information on the level and determination of water content, lead limit, specific rotation, assay value and method of assay for the commercial product; Comments on other aspects of the specifications are invited.	

# 2. Food additives for which requests have been received for re-evaluation by the Codex Committee on Food Additives and Contaminants (CCFAC) or sponsors

## a. Toxicological and intake evaluation

Food additive	Reference	Information required
D-Tagatose	Fifty-fifth <sup>11</sup> and fifty- seventh <sup>8</sup> reports, FAS 46 <sup>12</sup> and 48 <sup>9</sup> , FNP 52/8 <sup>13</sup>	All new relevant information relating to toxicity and intake (request of sponsor)

## b. Specifications

Food additive	Reference	Information required	
Magnesium silicate	Twenty-sixth report <sup>1</sup> , FAS	Information relevant to its use as a filtration aid	
	5 <sup>14</sup> , and FNP 52 <sup>15</sup>	(request of Thirty-fourth Session of CCFAC)	
Sucrose esters of	Forty-ninth report <sup>16</sup> and	Information relevant to specifications (request	
fatty acids	FNP 52/7	of Thirty-fourth Session of CCFAC)	
Talc	Fifty-fifth report <sup>11</sup> and FNP	nd FNP Information relevant to specifications (in par	
	52/8 <sup>13</sup>	cular regarding the analytical method for the	
		determination of the acid-soluble substances)	

# 3. Food additives not previously evaluated by JECFA that have been recommended for priority evaluation by CCFAC

Food additive	Information required
<ul> <li>Enzyme preparations:</li> <li>laccase enzyme preparation produced by a strain of Aspergillus oryzae containing the gene coding for laccase in Myceliophthora thermophila, inserted by recombinant DNA techniques</li> <li>an α-amylase enzyme preparation produced by a strain of Bacillus licheniformis containing a protein-engineered gene of Bacillus licheniformis coding for α-amylase, inserted by recombinant DNA techniques</li> <li>xylanase enzyme preparation produced by a strain of Fusarium venenatum containing the gene coding for xylanase from Thermomyces lanuginosus, inserted by recombinant DNA techniques</li> <li>mixed xylanase, β-glucanase enzyme preparations,</li> </ul>	All relevant information relating to toxicity, intake, and specifications
produced by a strain of Humicola insolens	
Ferrous bisglycinate, used as a nutritional source of iron	All relevant information relating to toxicity, intake from use as a nutritional source of iron, and specifications
Neotame	All relevant information relating to toxicity, intake, and specifications
Polyvinyl alcohol	All relevant information relating to toxicity, intake, and specifications

### 4. Request for evaluation from WHO

Substance	Reason for evaluation	Information required
Sodium	Proposed for use in purifying drinking-	All available relevant information
dichloroiso-	water; JECFA has been asked by the	relating to toxicity, intake, and
cyanurate	WHO Unit on Water, Sanitation and	specifications
(NaDCC)	Health to evaluate its safety	

### 5. Contaminants<sup>a</sup>

Contaminant	Reference	Information required
Cadmium	Fifty-fifth report <sup>11</sup> and FAS 46 <sup>12</sup>	Relevant information on toxicity as outlined in the report of the fifty-fifth meeting of JECFA
Methylmercury	Fifty-third report <sup>2</sup> and FAS 44 <sup>18</sup>	Results of the 96-month evaluation of the cohort of children in the Seychelles exposed pre- and post-natally to methylmercury in fish and other relevant toxicological, epidemiological, and intake data that have become available since the previous evaluation

# 6. Chemicals to be evaluated using the Procedure for the Safety Evaluation of Flavouring Agents

All available relevant information relating to toxicity, metabolism, intake, and specifications is required.

Group 1: Alicyclic, alicyclic-fused and aromatic-fused ring lactones

JECFA No.	NAME	CAS No.	FEMA No.
	All to A soft Letter with a Street to the second section		NO.
1157.	4-Hydroxy-4-methyl-5-hexenoic acid gamma lactone	1073-11-6	
1158.	(+/-) 3-Methyl-gamma-decalactone	67663-01-8	3999
1159.	4-Hydroxy-4-methyl-7-cis-decenoic acid gamma lactone	70851-61-5	3937
1160.	Tuberose lactone	153175-57-6	
1161.	Dihydromintlactone	92015-65-1	
1162.	Mintlactone	13341-72-5	3764
1163.	Dehydromenthofurolactone	75640-26-5	3755
1164.	(+/-)-(2,6,6-Trimethyl-2-hydroxycyclohexylidene)acetic acid gamma- lactone	15356-74-8	4020
1165.	Sclareolide	564-20-5	3794
1166.	Octahydrocoumarin	4430-31-3	3791
1167.	2-(4-Methyl-2-hydroxyphenyl)propionic acid-gamma-lactone	65817-24-5	3863
1168.	3-Propylidenephthalide	17369-59-4	2952
1169.	3-n-Butylphthalide	6066-49-5	3334
1170.	3-Butylidenephthalide	551-08-6	3333
1171.	Dihydrocoumarin	119-84-6	2381
1172.	6-Methylcoumarin	92-48-8	2699

Group 2: Aliphatic di- and trienals and related alcohols, acids, and esters

JECFA No.	NAME	CAS No.	FEMA No.
1173.	2,4-Pentadienal	764-40-9	3217
1174.	(E,E)-2,4-Hexadien-1-ol	111-28-4	3922
1175.	trans,trans-2,4-Hexadienal	142-83-6	3429
1176.	(E,E)-2,4-Hexadienoic acid	110-44-1	3921
1177.	Methyl sorbate	689-89-4	3714
1178.	Ethyl sorbate	2396-84-1	2459
1179.	2,4-Heptadienal	4313-03-5	3164

<sup>&</sup>lt;sup>a</sup> More substances require review than the JECFA Secretariat was able to include on the agenda of the sixty-first meeting. In order to accommodate the backlog, the Secretariat intends to evaluate certain contaminants at the sixty-second meeting of JECFA in February 2004. The contaminants tentatively scheduled for review are acrylamide, arsenic, ethyl carbamate, and polycyclic aromatic hydrocarbons.

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Group 2: Aliphatic di- and trienals and related alcohols, acids, and esters

JECFA	NAME	CAS	FEMA
No.		No.	No.
1180.	(E,E)-2,4-Octadien-1-ol	18409-20-6	3956
1181.	trans,trans-2,4-Octadienal	30361-28-5	3721
1182.	2-trans,6-trans-Octadienal	56767-18-1	3466
1183.	2,4-Nonadien-1-ol	62488-56-6	3951
1184.	2,6-Nonadien-1-ol	7786-44-9	2780
1185.	2,4-Nonadienal	6750-03-4	3212
1186.	Nona-2-trans-6-cis-dienal	557-48-2	3377
1187.	2-trans-6-trans-Nonadienal	17587-33-6	3766
1188.	(E,Z)-2,6-Nonadien-1-ol acetate	68555-65-7	3952
1189.	(E,E)-2,4-Decadien-1-ol	18409-21-7	3911
1190.	2-trans,4-trans-Decadienal	25152-84-5	3135
1191.	Methyl (E)-2-(Z)-4-decadienoate	4493-42-9	3859
1192.	Ethyl trans-2-cis-4-decadienoate	3025-30-7	3148
1193.	Ethyl 2,4,7-decatrienoate	78417-28-4	3832
1194.	Propyl 2,4-decadienoate	84788-08-9	3648
1195.	2,4-Undecadienal	13162-46-4	3422
1196.	trans,trans-2,4-Dodecadienal	21662-16-8	3670
1197.	2-trans-6-cis-Dodecadienal	21662-13-5	3637
1198.	2-trans-4-cis-7-cis-Tridecatrienal	13552-96-0	3638

Group 3: Aliphatic branched-chain unsaturated alcohols, aldehydes, acids, and related esters

JECFA	NAME	CAS	FEMA
No.		No.	No.
1199.	(+/-) 2-Methyl-1-butanol	137-32-6	3998
1200.	3-Methyl-2-buten-1-ol	556-82-1	3647
1201.	2-Methyl-2-butenal	1115-11-3	3407
1202.	3-Methyl-2-butenal	107-86-8	3646
1203.	Ammonium isovalerate	7563-33-9	2054
1204.	3-Methylcrotonic acid	541-47-9	3187
1205.	trans-2-Methyl-2-butenoic acid	80-59-1	3599
1206.	Isobutyl 2-butenoate	589-66-2	3432
1207.	2-Methylallyl butyrate	7149-29-3	2678
1208.	4-Methyl-2-pentenal	5362-56-1	3510
1209.	2-Methyl-2-pentenal	623-36-9	3194
1210.	2-Methyl-2-pentenoic acid	3142-72-1	3195
1211.	2,4-Dimethyl-2-pentenoic acid	66634-97-7	3143
1212.	2-Methylheptanoic acid	1188-02-9	2706
1213.	Isobutyl angelate	7779-81-9	2180
1214.	2-Butyl-2-butenal	25409-08-9	3392
1215.	2-Isopropyl-5-methyl-2-hexenal	35158-25-9	3406
1216.	2-Ethyl-2-heptenal	10031-88-6	2438
1217.	2-Methyl-2-octenal	73757-27-4	3711
1218.	4-Ethyloctanoic acid	16493-80-4	3800
1219.	dl-Citronellol	106-22-9	2309
1220.	Citronellal	106-23-0	2307
1221.	3,7-Dimethyl-6-octenoic acid	502-47-6	3142
1222.	Rhodinol	6812-78-8	2980
1223.	Geraniol	106-24-1	2507
1224.	Nerol	106-25-2	2770
1225.	Citral	5392-40-5	2303
1226.	8-Ocimenyl acetate	999999-91-4	3886
1227.	2,6-Dimethyl-10-methylene-2,6,11-dodecatrienal	60066-88-8	3141
1228.	3,7,11-Trimethyl-2,6,10-dodecatrienal	19317-11-4	4019

# Group 3: Aliphatic branched-chain unsaturated alcohols, aldehydes, acids, and related esters

JECFA No.	NAME	CAS No.	FEMA No.
1229.	12-Methyltridecanal	75853-49-5	4005
1230.	Farnesol		

# **Group 4: Aliphatic and aromatic ethers**

JECFA	NAME	CAS	FEMA
No.		No.	No.
1231.	sec-Butyl ethyl ether	2679-87-0	3131
1232.	1-Ethoxy-3-methyl-2-butene	22094-00-4	3777
1233.	1,4-Cineole	470-67-7	3658
1234.	Eucalyptol	470-82-6	2465
1235.	Nerol oxide	1786-08-9	3661
1236.	2,2,6-Trimethyl-6-vinyltetrahydropyran	7392-19-0	3735
1237.	Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran	16409-43-1	3236
1238.	Theaspirane	36431-72-8	3774
1239.	Cycloionone	5552-30-7	3822
1240.	1,5,5,9-Tetramethyl-13-oxatricyclo(8.3.0.0(4,9))tridecane	3738-00-9	3471
1241.	Anisole	100-66-3	2097
1242.	o-Methylanisole	578-58-5	2680
1243.	p-Methylanisole	104-93-8	2681
1244.	p-Propylanisole	104-45-0	2930
1245.	2,4-Dimethylanisole	6738-23-4	3828
1246.	1-Methyl-3-methoxy-4-isopropylbenzene	1076-56-8	3436
1247.	Carvacryl ethyl ether	4732-13-2	2246
1248.	1,2-Dimethoxybenzene	91-16-7	3799
1249.	m-Dimethoxybenzene	151-10-0	2385
1250.	p-Dimethoxybenzene	150-78-7	2386
1251.	3,4-Dimethoxy-1-vinylbenzene	6380-23-0	3138
1252.	Benzyl ethyl ether	539-30-0	2144
1253.	Benzyl butyl ether	588-67-0	2139
1254.	Methyl phenethyl ether	3558-60-9	3198
1255.	Diphenyl ether	101-84-8	3667
1256.	Dibenzyl ether	103-50-4	2371
1257.	β-Naphthyl methyl ether	93-04-9	
1258.	β-Naphthyl ethyl ether	93-18-5	2768
1259.	β-Naphthyl isobutyl ether	2173-57-1	3719

# **Group 5: Hydroxypropenylbenzenes**

JECFA	NAME	CAS	FEMA
No.		No.	No.
1260.	Isoeugenol	97-54-1	2468
1261.	Isoeugenyl formate	7774-96-1	2474
1262.	Isoeugenyl acetate	93-29-8	2470
1263.	Isoeugenyl phenylacetate	120-24-1	2477
1264.	Propenylguaethol	94-86-0	2922
1265.	4-Propenyl-2,6-dimethoxyphenol	20675-95-0	3728
1266.	Isoeugenyl methyl ether	93-16-3	2476
1267.	Isoeugenyl ethyl ether	7784-67-0	2472
1268.	Isoeugenyl benzyl ether	120-11-6	3698

Group 6: Linear and branched-chain aliphatic unsaturated, unconjugated alcohols, aldehydes, acids and related esters (see report of the fifty first meeting)

JECFA	NAME	CAS	FEMA
No.		No.	No.
1269.	Isoprenyl acetate	5205-07-2	3991
1270.	4-Pentenyl acetate	1576-85-8	4011
1271.	3-Hexenal	4440-65-7	3923
1272.	3-Hexenyl formate	2315-09-5	3353
1273.	Ethyl 5-hexenoate	54653-25-7	3976
1274.	cis-3-Hexenyl propionate	33467-74-2	3933
1275.	cis-3-Hexenyl isobutyrate	41519-23-7	3929
1276.	(Z)-3-Hexenyl (E)-2-butenoate	65405-80-3	3982
1277.	cis-3-Hexenyl tiglate	67883-79-8	3931
1278.	cis-3-Hexenyl valerate	35852-46-1	3936
1279.	3-Hexenyl 2-hexenoate	53398-87-1	3928
1280.	(Z)-4-Hepten-1-ol	6191-71-5	3841
1281.	Ethyl cis-4-heptenoate	39924-27-1	3975
1282.	(Z)-5-Octenyl propionate	196109-18-9	3890
1283.	(Z,Z)-3,6-Nonadien-1-ol	53046-97-2	3885
1284.	(E)-3,(Z)-6-Nonadien-1-ol	56805-23-3	3884
1285.	(E,Z)-3,6-Nonadien-1-ol acetate	211323-05-6	3953
1286.	9-Decenal	39770-05-3	3912
1287.	4-Decenoic acid	26303-90-2	3914
1288.	cis-4-Decenyl acetate	67452-27-1	3967

Group 7: Simple aliphatic and aromatic sulfides and thiols (see report of the fifty third meeting)

JECFA	NAME	CAS	FEMA
No.		No.	No.
1289.	erythro and threo-3-Mercapto-2-methylbutan-1-ol	Pending	3993
1290.	(+/-)2-Mercapto-2-methylpentan-1-ol	258823-39-1	3995
1291.	3-Mercapto-2-methylpentan-1-ol (racemic)	227456-27-1	3996
1292.	3-Mercapto-2-methylpentanal	227456-28-2	3994
1293.	4-Mercapto-4-methyl-2-pentanone	19872-52-7	3997
1294.	(+/-) Ethyl 3-mercaptobutyrate	156472-94-5	3977
1295.	Ethyl 4-(acetylthio)butyrate	104228-51-5	3974
1296.	spiro(2,4-Dithia-1-methyl-8-oxabicyclo(3.3.0)octane-3,3'-(1'-oxa-2'-methyl)-cyclopentane)	38325-25-6	3270
1297.	2-(Methylthio)ethanol	5271-38-5	4004
1298.	Ethyl 5-(methylthio)valerate	233665-98-0	3978
1299.	2,3,5-Trithiahexane	42474-44-2	4021
1300.	Diisopropyl trisulfide	5943-34-0	3968

# 7. Food additives for which information is needed on suggested limits for individual heavy metals (e.g. lead), with supporting analytical data

Food additive	Category	INS No.
Activated carbon	Adsorbant	-
Aluminium potasssium sulfate	Firming agent	0522
Aluminium sodium sulfate	Firming agent	0521
Aluminium sulfate (anhydrous)	Firming agent	0520
Ascorbic acid	Antioxidant	0300
Ascorbyl palmitate	Antioxidant	0304
Ascorbyl stearate	Antioxidant	0305
Bone phosphate	Emulsifier	0542
Butylated hydroxyanisole (BHA)	Antioxidant	0320

Food additive	Category	INS No.
Butylated hydroxytoluene (BHT)	Antioxidant	0321
Calcium ascorbate	Antioxidant	0302
Calcium disodium EDTA	Sequestrant	0385
Cupric sulfate	Colour retention agent	0519
Diatomaceous earth	Filter aid	-
Dilauryl thiopropionate	Antioxidant	0389
Disodium ethylene diamine tetracetate	Sequestrant	0386
Dodecyl gallate	Antioxidant	0312
Erythorbic acid	Antioxidant	0315
Ethyl protocatechuate	Antioxidant	-
Ferrous lactate	Colour retention agent	0585
Guaiac resin	Antioxidant	0314
Isopropyl citrate mixture	Antioxidant	0384
Lecithin	Antioxidant	0322
Octyl gallate	Antioxidant	0311
Polydimethylsiloxane	Antifoaming agent	0900
Polyethylene glycols	Carrier solvent	1521
Potassium lactate (solution)	Antioxidant	0326
Potassium polyphosphates	Emulsifier	0452 (ii)
Propyl gallate	Antioxidant	0310
Salts of fatty acids, Ca, K, Na,	Emulsifier	0470
Sodium aluminium phosphate, acidic	Raising agent	0541 (i)
Sodium aluminium phosphate, basic	Emulsifier	0541 (ii)
Sodium ascorbate	Antioxidant	0301
Sodium caseinate	Emulsifier	-
Sodium erythorbate	Antioxidant	0316
Sodium lactate (solution)	Antioxidant synergist	0325
Stannous chloride	Antioxidant	0512
Sucrose acetate isobutyrate	Clouding agent	0444
Tertiary butylhydroquinone	Antioxidant	0319
Thiodipropionic acid	Antioxidant	0388
Tocopherol Concentrate, d-alpha	Antioxidant	0307 a
Tocopherol concentrate, mixed	Antioxidant	0307 b
Tocopherol, dl	Antioxidant	0307 c
Triethyl citrate	Carrier solvent	1505

## 8. Flavouring agents for which minimum assay values are below 95%

At its fifty-ninth meeting, the Committee concluded that the secondary components of the following flavouring agents do not raise safety concerns. The sixty-first meeting will consider possible revisions of the specifications of these flavouring agents.

JECFA	NAME
No.	
42	Isoamyl formate
53	Citronellyl formate
54	Geranyl formate
55	Neryl formate
56	Rhodinyl formate
57	Citronellyl acetate
60	Rhodinyl acetate
61	Citronellyl propionate
62	Geranyl propionate

JECFA	NAME
No.	
65	Citronellyl butyrate
66	Geranyl butyrate
68	Rhodinyl butyrate
71	Citronellyl isobutyrate
73	Neryl isobutyrate
95	Heptanal
98	Octanal
101	Nonanal
104	Decanal

JECFA	NAME
No.	
107	Undecanal
110	Lauric aldehyde
112	Myristaldehyde
117	Propyl formate
119	n-Amyl formate
124	Isobutyl formate
170	n-Amyl heptanoate
180	Methyl laurate
205	Methyl 2-methylbutyrate
212	2-Methylbutyl 2-methylbutyrate
237	6-Hydroxy-3,7-dimethyloctanoic acid
	lactone
272	3,7-Dimethyl-1-octanol
302	2,6-Dimethyl-4-heptanone
303	2,6-Dimethyl-4-heptanol
322	cis-5-Octen-1-ol
323	cis-5-Octenal
325	cis-6-Nonenal

JECFA	NAME	
No.		
332	Linoleic Acid	
346	Methyl linoleate & Methyl linolenate	
	(mixture)	
348	2,6-Dimethyl-6-hepen-1-ol	
349	2,6-Dimethyl-5-heptenal	
358	Linalyl formate	
360	Linalyl propionate	
384	beta-Damascone	
385	alpha-Damascone	
399	Methyl-beta-ionone	
410	2,3-Pentadione	
419	Ethyl cyclopentenolone	
435	p-Menth-1-en-3-one (Piperitone)	
592	Citronellyloxyacetaldehyde	
604	3-(Hydroxymethyl)-2-heptanone	
625	Dibutyl sebacate	
668	Linalyl cinnamate	

# 9. Revision of tentative specifications for flavouring agents

The following flavouring agents presently have tentative specifications. The sixty-first meeting will either remove the 'tentative' designation or withdraw the specifications.

JECFA	NAME	Data requested
No.		
237	6-Hydroxy-3,7-dimethyloctanoic acid lactone	MP
244	3-Heptyldihydro-5-methyl-2 (3H)-furanone	A, SG
329	9-Undecenal	A
337	Methyl cis-4-octenoate	A, RI, SG
338	Ethyl cis-4-octenoate	RI, SG
396	Dehydrodihydroionone	RI, SG
397	Dehydrodihydroionol	RI, SG
409	3-Hydroxy-2-pentanone	A, RI, SG
417	2,3-Undecadione	A, RI, SG
422	3-Ethyl-2-hydroxy-4-methylcyclopent-2-en-1-one	ID, RI, SG
423	5-Ethyl-2-hydroxy-3-methylcyclopent-2-en-1-one	ID, RI, SG
443	1-Menthol ethylene glycol	A
465	2-Methylthioacetaldehyde	SG
468	4-(Methylthio)butanal	BP, RI, SG
470	2-(Methylthio)methyl-2-butenal	SG
471	2,8-Dithianon-4-ene-4-carboxaldehyde	BP, ID
473	Methylthiomethyl butyrate	BP, ID
479	Methylthiomethyl hexanoate	BP, ID, RI
480	Ethyl 3-(methylthio) butyrate	BP, ID, RI
488	S-Methyl 4-methylpentane-thioate	BP, RI
489	S-Methyl hexanethioate	BP, ID, RI
495	1-Methylthio-2-propanone	BP, ID, SG
502	Di(butan-3-one-1-yl) sulfide	RI, SG
504	S-Methyl benzothioate	BP,RI, SG
519	2-Ethylhexanethiol	BP, RI
548	4-Methoxy-2-methyl-2-butanethiol	RI, SG
556	3-Mercaptohexyl hexanoate	A
557	1-Mercapto-2-propanone	A, BP, RI range

JECFA No.	NAME	Data requested
559	2-Keto-4-butanethiol	ID, RI, SG
568	Allyl dimethyl sulfide	ID, SG
569	Methyl 1-propenyl disulfide	A, ID, SG
570	Propenyl propyl disulfide	ID, SG
571	Methyl 3-methyl-1-butenyl disulfide	BP, ID
583	Methyl ethyl trisulfide	BP, ID, SG
586	Allyl methyl trisulfide	A, ID, SG
590	Methyl 2-hydroxy-4-methyl pentanoate	SG
603	Ethyl 2,4-dioxohexanoate	ID, RI, SG
605	1,3-Nonanediol acetate (mixed esters)	BP
615	Butyl ethyl malonate	A, BP, RI
628	Ethyl aconitate (mixed esters)	ID
631.2	3-Methyl-2-oxobutanoic acid sodium salt	A(m)
632.2	3-Methyl-2-oxopentanoic acid sodium salt	A(m)
633.2	4-Methyl-2-oxopentanoic acid sodium salt	A(m)
669	Terpinyl cinnamate	A, ID, SG
704	p-Tolyl laurate	A, BP, ID, RI, SG
735	2-Phenylphenol	ID
737	2,3,6-Trimethylphenol	BP
909	Glycerol	[F]
918	Glyceryl monostearate	MP range
919	Glyceryl monooleate	BP, RI, SG
923	Glycerol 5-hydroxydecanoate	(A) specificity
924	Glycerol 5-hydroxydodecanoate	(A) specificity
925	Propylene glycol	[F]
937	Pyruvaldehyde	A(m)

A=assay minimum, A(e)=equivalence factor for assay\*, A(m)=details of assay method, BP=boiling point, ID=identity test, RI=refractive index, SG=specific gravity; [F]: information on functional use as a flavour

#### References

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- 2. Evaluation of certain food additives and contaminants (Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 896, 2000.
- 3. Toxicological evaluation of certain food additives. WHO Food Additives Series, No. 17, 1982.
- 4. Evaluation of certain food additives and contaminants (Forty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 859, 1995.
- 5. Evaluation of certain food additives (Fifty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 891, 2000.
- 6. Toxicological evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 35, 1996.
- 7. Compendium of food additive specifications, addendum 6. FAO Food and Nutrition Paper, No. 52, Add. 6, 1998.
- 8. Evaluation of certain food additives and contaminants (Fifty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 909, in press.
- 9. Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 48, 2002.
- Compendium of food additive specifications, addendum 9. FAO Food and Nutrition Paper, No. 52, Add. 9, 2001.
- 11. Evaluation of certain food additives and contaminants (Fifty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 901, 2001.
- 12. Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 46, 2001.
- 13. Compendium of food additive specifications, addendum 8. FAO Food and Nutrition Paper, No. 52, Add. 8, 2000.
- 14. Toxicological evaluation of certain food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers, and thickening agents. FAO Nutrition Meetings Report Series, No. 53A, 1974; WHO Food Additives Series, No. 5, 1974.
- 15. Compendium of food additive specifications (Joint FAO/WHO Expert Committee on Food Additives (JECFA)). Combined specifications from 1st through the 37th meetings, 1956-1990. Rome, Food and Agriculture Organization of the United Nations, 1992 (2 volumes).
- 16. Evaluation of certain food additives and contaminants (Forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 884, 1999.
- 17. Compendium of food additives specifications, addendum 7. FAO Food and Nutrition Paper, No. 52, Add. 7, 1999.
- 18. Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 44, 2000.

#### **ANNEX 2**

#### **GUIDELINES FOR THE PREPARATION OF DATA SHEETS**

Description of the physical and chemical characteristics of the additive should be given.

Raw material(s) used in commercial production of the additive should be listed. This section may be subdivided according to the different processes for manufacturing the additive.

Method of Manufacture by which raw material(s) is converted into a finished commercial food additive should be described. It is acknowledged that some of these data may be trade secrets. Therefore, such a data is held in strict confidence.

Impurities including intermediates should be listed and levels given:

- substances in raw materials which remain in the additive
- by-products from the method(s) of manufacture
- residues of processing aids used in the manufacture

Functional use(s) should be indicated by describing the technological purpose for using the additive and the levels of use on a commodity basis.

Estimate(s) of daily intake by humans to the additive through the food chain should be provided. The calculations and assumptions made in deriving each estimate are to be given.

Reactions and fate in food should be described. If no detailed data are available, statements on the general chemical reactivity of the additive may be reported.

Effects on nutrients, both adverse and beneficial effects resulting from use of the additive should be indicated.

#### **ANNEX 3**

#### JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

#### **BACKGROUND**

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) was established in the mid-1950s by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to assess chemical additives in food on an international basis. The first meeting was held in 1956 in response to recommendations made at an FAO/WHO Conference on Food Additives that met in Geneva in 1955.

In the early 1960s the Codex Alimentarius Commission (CAC), which is an international intergovernmental body, was established. The primary aims of the CAC are to protect the health of the consumer and facilitate international trade in food. At the time that the CAC was formed it was decided that JECFA would provide expert advice to Codex on matters relating to food additives. A system was established whereby the Codex Committee on Food Additives, a general subject committee, identified food additives that should receive priority attention, which were then referred to JECFA for assessment before being considered for inclusion in Codex Food Standards.

This system is still in place, but it has been expanded to include food contaminants and residues of veterinary drugs in food to provide advice to the presently-existing Codex Committee on Food Additives and Contaminants (CCFAC) and Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). JECFA also provides scientific advice directly to FAO and WHO Member States, and requests for assessment may come directly from them. JECFA is <u>not</u> a component of the CAC.

Specialists invited to serve as Members of JECFA are independent scientists who serve in their individual capacities as experts, and <u>not</u> as representatives of their governments or employers. The goal is to establish safe levels of intake and to develop specifications for identity and purity (food additives) or maximum residue limits when veterinary drugs are used in accordance with good practice in the use of veterinary drugs.

Through mid-2002, a total of fifty-nine meetings of JECFA have been held. The reports are published in the WHO Technical Report Series. The toxicological evaluations, that summarize the data that serve as the basis for the safety assessments, are published in the WHO Food Additives Series. The specifications and residues evaluations are published in the FAO Food and Nutrition Papers. All of the specifications that had been prepared from the first through the thirty-seventh meetings have been consolidated in a Compendium of Food Additives Specifications, which was published by FAO in 1992. From the thirty-ninth meeting onwards the specifications have been published in nine addenda to the Compendium. The second edition of the Compendium is in preparation.

A *Summary of Evaluations* performed by the Joint FAO/WHO Expert Committee on Food Additives, a comprehensive document that summarizes all JECFA evaluations from the first through recent meetings, is available free of charge on the Internet in a searchable format at <a href="http://www.who.int/pcs/">http://www.fao.org/es/esn/jecfa</a> or <a href="http://www.tao.org/es/esn/jecfa">http://www.tao.org/es/esn/jecfa</a> or <a href="http://jecfa.ilsi.org/">http://jecfa.ilsi.org/</a>.