



**Food and Agriculture
Organization
of the United Nations**

**World Health
Organization**



**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Fifty-ninth meeting
Geneva, 4-13 June 2002**

SUMMARY AND CONCLUSIONS

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Geneva, Switzerland, from 4 to 13 June 2002. The purpose of the meeting was to evaluate certain food additives.

Dr J.-C. Larsen, Head of Division, Division of Gene Technology and Biochemistry, Institute of Food Safety and Nutrition, Danish Veterinary and Food Administration, Søborg, Denmark, served as Chairman and Mrs I. Meyland, Senior Scientific Adviser, Institute of Food Research and Nutrition, Danish Veterinary and Food Administration, Søborg, Denmark, served as Vice-Chairman.

Dr M. Luetzow, Food Quality and Standards Service, Food and Nutrition Division, Food and Agriculture Organization of the United Nations, and Dr J.L. Herrman, International Programme on Chemical Safety, World Health Organization, served as joint secretaries.

The present meeting was the fifty-ninth in a series of similar meetings. The tasks before the Committee were (a) to elaborate further principles for evaluating the safety of food additives and contaminants; (b) to evaluate certain food additives and flavouring agents; and (c) to review and prepare specifications for selected food additives and flavouring agents.

The report of the meeting will appear 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 (ADIs) and other toxicological recommendations. Information on specifications for the identity and purity of certain food additives examined by the Committee will also be included.

The participants in the meeting are listed in Annex 1. Further information required or desired is listed in Annex 2. Items of a general nature that contain information that the Committee would like to disseminate quickly are included in Annex 3.

Toxicological monographs or monograph addenda on most of the substances that were considered will be published in WHO Food Additives Series No. 50.

New and revised specifications for the identity and purity of the compounds will be published in FAO Food and Nutrition Paper Series 52, Addendum 10.

Corrected version (04 July 2002) – corrections are on page 4, where several entries for acidity regulators have been either deleted or corrected.

Acceptable daily intakes (ADIs), other recommendations, and information on specifications

1. Food additives evaluated toxicologically

Food additive	Specifications ^a	Acceptable daily intake (ADI) and other toxicological recommendations
Alitame	R	Evaluation postponed pending receipt of a final report of a 90-day study of tolerance in diabetics
Cross-linked sodium carboxymethyl cellulose	N	Included in the group ADI 'not specified' ^b with other modified celluloses
Mineral oils (low-and medium-viscosity)		
Class I ^c	R	0-10 mg/kg bw
Class II ^d and Class III ^e	R	0-0.01 mg/kg bw (group ADI) (temporary) ^f
Nitrate	S	0-3.7 mg/kg bw (expressed as nitrate ion)
Nitrite	S	0-0.07 mg/kg bw (expressed as nitrite ion)
Salatrim (short- and long-chain acyltriglyceride molecules)	R	Adequate information was not available to evaluate its safety and nutritional effects

^aN, new specifications prepared; R, existing specifications revised; S, existing specifications were not considered.

^bADI 'not specified' is used to refer to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological and other) and the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effects and from its acceptable background levels in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of good manufacturing practice, i.e. it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal food of inferior quality or adulterated food, and it should not create a nutritional imbalance.

^cIncluding P70(H) oil.

^dIncluding N70(H) and N70(A) oils.

^eIncluding P15(H), N15(H), and N10(A) oils

^fSee Annex II.

2. Food additive considered for specifications only

Food Additive	Specifications ^a
Amyloglucosidase from <i>Aspergillus niger</i> , var.	R

^aR, existing specifications revised.

3. Revision of heavy metals limits for food additives

At its fifty-fifth meeting, the Committee began its implementation of a systematic five-year programme to replace the outdated test for heavy metals (as lead) in all existing food additive specifications with appropriate limits for individual metals of concern.

At the present meeting, the heavy metals and arsenic limits of 52 colours and 44 acidity regulators were reviewed.

Comments on the Committee's new proposed limits are invited. If alternative values and supporting data are not received by the deadline for submission of data for the sixty-first meeting (30 November 2002), the proposed metal limits will be adopted and supersede the existing limits, replacing those published in FAO Food and Nutrition Paper 52 and its addenda 1 to 9.

Category	Food additive	INS	As	Pb	Cd	Hg
Colour	Allura red AC	0129	-	2	-	-
Colour	Aluminum powder	0173	3	20	-	-
Colour	Amaranth	0123	-	2	-	-
Colour	Annatto extracts(Oil & alkali extracted)	0160 b	3	2	-	1
Colour	Annatto extracts(Solvent extracted)	0160 b	3	2	-	1
Colour	beta Apo-8'-carotenal	0160 e	-	2	-	-
Colour	beta-Apo-8'-carotenic acid ethyl ester	0160 f	-	2	-	-
Colour	Azorubine	0122	-	2	-	-
Colour	Beet red	0162	3	2	-	-
Colour	Blackcurrant extract	0163 ii	-	2	-	-
Colour	Brilliant Black BN	0151	-	2	-	-
Colour	Brilliant Blue FCF	0133	-	2	-	-
Colour	Brown FK	0154	-	2	-	-
Colour	Brown HT	0155	-	2	-	-
Colour	Canthaxanthin	0161 g	-	2	-	-
Colour	Caramel colours	0150 a,b,c,d	1	2	-	-
Colour	Carmines	0120	-	5	-	-
Colour	beta-Carotene, Synthetic	0160 a(i)	-	2	-	-
Colour	beta-Carotene from <i>Blakeslea trispora</i>	0160 a	-	2	-	-
Colour	Carotenes (Algae)	0160 a(ii)	-	5	-	-
Colour	Carotenes, (Vegetable)	0160 a(ii)	-	5	-	-
Colour	Carthamus red	-	-	5	-	-
Colour	Carthamus yellow	-	-	5	-	-
Colour	Chlorophyllins, Copper complexes	0141 ii	3	5	-	-
Colour	Chlorophylls	0140	3	5	-	-
Colour	Chlorophylls, copper complexes	0141 i	3	5	-	-
Colour	Cochineal extract	0120	-	5	-	-
Colour	Curcumin	0100	-	2	-	-
Colour	Erythrosine	0127	-	2	-	-
Colour	Fast Green FCF	0143	-	2	-	-
Colour	Fast Red E	-	-	2	-	-
Colour	Grape skin extract	0163 ii	3	2	-	-
Colour	Green S	0142	-	2	-	-
Colour	Indigotine	0132	-	2	-	-
Colour	Iron oxides	0172	3	10	10	1
Colour	Lithol rubine BK	0180	-	2	-	-
Colour	Mixed carotenoids	-	-	5	-	-
Colour	Paprika Oleoresin	0160 c	3	2	-	-
Colour	Patent Blue V	0131	-	2	-	-
Colour	Ponceau 4R	0124	-	2	-	-
Colour	Quinoline Yellow	0104	-	2	-	-
Colour	Red 2G	0128	-	2	-	-
Colour	Riboflavin	0101 i	-	2	-	-
Colour	Riboflavin 5'-phosphate sodium	0101 ii	-	2	-	-
Colour	Riboflavin from <i>Bacillus subtilis</i>	0101 l	-	1	-	-
Colour	Saffron	-	3	2	-	-

Category	Food additive	INS	As	Pb	Cd	Hg
Colour	Sunset Yellow FCF	0110	-	2	-	-
Colour	Tagetes Extract	-	-	2	-	-
Colour	Tartrazine	0102	-	2	-	-
Colour	Titanium dioxide	0171	3	10	-	1
Colour	Turmeric oleoresin	0100 ii	3	2	-	-
Colour	Vegetable carbon	0153	3	2	-	-
Acidity regulator	Acetic acid, glacial	0260	-	2	-	-
Acidity regulator	Ammonia solution	0527	-	2	-	-
Acidity regulator	Ammonium carbonate	0503 i	-	2	-	-
Acidity regulator	Ammonium dihydrogen phosphate	0342 i	3	4	-	-
Acidity regulator	Calcium citrates	0333	-	2	-	-
Acidity regulator	Calcium dihydrogen phosphate	0341 i	3	4	-	-
Acidity regulator	Calcium DL malate	0352 ii	-	2	-	-
Acidity regulator	Calcium hydroxide	0526	-	2	-	-
Acidity regulator	Calcium lactate	0327	-	2	-	-
Acidity regulator	Calcium oxide	0529	-	2	-	-
Acidity regulator	Di ammonium hydrogen phosphate	0342 ii	3	4	-	-
Acidity regulator	Dicalcium pyrophosphate	0450 vi	3	4	-	-
Acidity regulator	Dipotassium hydrogen phosphate	0340 ii	3	4	-	-
Acidity regulator	Disodium hydrogen phosphate	0339 ii	3	4	-	-
Acidity regulator	Disodium pyrophosphate	0450 i	3	4	-	-
Acidity regulator	Hydrochloric acid	0507	-	1	-	-
Acidity regulator	Magnesium hydroxide carbonate	0504 ii	-	2	-	-
Acidity regulator	Magnesium hydroxide	0528	-	2	-	-
Acidity regulator	Magnesium DL lactate	0329	-	2	-	-
Acidity regulator	Phosphoric acid	0338	3	4	-	-
Acidity regulator	Potassium carbonate	0501 i	-	2	-	-
Acidity regulator	Potassium dihydrogen citrate	0332	-	2	-	-
Acidity regulator	Potassium hydrogen carbonate	0501 ii	-	2	-	-
Acidity regulator	Potassium hydroxide	0525	-	2	-	-
Acidity regulator	Sodium acetate	0262 I	-	2	-	-
Acidity regulator	Sodium carbonate	0500 I	-	2	-	-
Acidity regulator	Sodium dihydrogen citrate	0331 i	-	2	-	-
Acidity regulator	Sodium dihydrogen phosphate	0339 i	3	4	-	-
Acidity regulator	Sodium DL malate	0350 ii	-	2	-	-
Acidity regulator	Sodium fumarate	0365	-	2	-	-
Acidity regulator	Sodium hydrogen carbonate	0500 ii	-	2	-	-
Acidity regulator	Sodium hydrogen DL-malate	0350 i	-	2	-	-
Acidity regulator	Sodium hydroxide	0524	-	2	-	-
Acidity regulator	Sodium sesquicarbonate	0500 iii	-	2	-	-
Acidity regulator	Sulfuric acid	0513	-	2	-	-
Acidity regulator	Triammonium citrate	0380	-	2	-	-
Acidity regulator	Tripotassium citrate	0332 ii	-	2	-	-
Acidity regulator	Tripotassium phosphate	0340 iii	3	4	-	-
Acidity regulator	Trisodium citrate	0331 iii	-	2	-	-
Acidity regulator	Trisodium phosphate	0339 iii	3	4	-	-

4. Flavouring agents evaluated using the Procedure for the Safety Evaluation of Flavouring Agents

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

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Cyclohexanecarboxylic acid	961	N	No safety concern
Methyl cyclohexanecarboxylate	962	N	No safety concern
Ethyl cyclohexanecarboxylate	963	N	No safety concern
Cyclohexaneethyl acetate	964	N	No safety concern
Cyclohexaneacetic acid	965	N	No safety concern
Ethyl cyclohexanepropionate	966	N	No safety concern
2,2,3-Trimethylcyclopent-3-en-1-yl acetaldehyde	967	N	No safety concern
cis-5-Isopropenyl-cis-2-methylcyclopentan-1-carboxaldehyde	968	N	No safety concern
Campholene acetate	969	N	No safety concern
<i>alpha</i> -Campholenic alcohol	970	N	No safety concern
p-Menth-1-en-9-al	971	N	No safety concern
1-p-Menthen-9-yl acetate	972	N	No safety concern
p-Mentha-1,8-dien-7-al	973	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
1,2,5,6-Tetrahydrocuminic acid	976	N	No safety concern
2,6,6-Trimethylcyclohexa-1,3-dienyl methanal	977	N	No safety concern
2,6,6-Trimethyl-1-cyclohexen-1-acetaldehyde	978	N	No safety concern
2,6,6-Trimethyl-1&2-cyclohexen-1-carboxaldehyde	979	N	No safety concern
2-Formyl-6,6-dimethylbicyclo[3.1.1]hept-2-ene (Myrtenal)	980	N	No safety concern
Myrtenol	981	N	No safety concern
Myrtenyl acetate	982	N	No safety concern
6,6-Myrtenyl formate	983	N	No safety concern
Santalol (<i>alpha</i> & <i>beta</i>)	984	N	No safety concern
Santalyl acetate (<i>alpha</i> and <i>beta</i>)	985	N	No safety concern
10-Hydroxymethylene-2-pinene	986	N	No safety concern

^aN, new specifications prepared

B. Phenethyl alcohol, aldehyde, acid, and related acetals and esters

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Phenethyl alcohol	987	N	No safety concern
Phenethyl formate	988	N	No safety concern
Phenethyl acetate	989	N	No safety concern
Phenethyl propionate	990	N	No safety concern
Phenethyl butyrate	991	N	No safety concern
Phenethyl isobutyrate	992	N	No safety concern
Phenethyl 2-methylbutyrate	993	N	No safety concern
Phenethyl isovalerate	994	N	No safety concern
Phenethyl hexanoate	995	N	No safety concern
Phenethyl octanoate	996	N	No safety concern
Phenethyl tiglate	997	N	No safety concern
Phenethyl senecioate	998	N	No safety concern
Phenethyl phenylacetate	999	N	No safety concern
Acetaldehyde phenethyl propyl acetal	1000	N	No safety concern
Acetaldehyde butyl phenethyl acetal	1001	N	No safety concern
Phenylacetaldehyde	1002	N	No safety concern
Phenylacetaldehyde dimethyl acetal	1003	N	No safety concern
Phenylacetaldehyde glyceryl acetal	1004	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Phenylacetaldehyde 2,3-butylene glycol acetal	1005	N	No safety concern
Phenylacetaldehyde diisobutyl acetal	1006	N	No safety concern
Phenylacetic acid	1007	N	No safety concern
Methyl phenylacetate	1008	N	No safety concern
Ethyl phenylacetate	1009	N	No safety concern
Propyl phenylacetate	1010	N	No safety concern
Isopropyl phenylacetate	1011	N	No safety concern
Butyl phenylacetate	1012	N	No safety concern
Isobutyl phenylacetate	1013	N	No safety concern
Isoamyl phenylacetate	1014	N	No safety concern
Hexyl phenylacetate	1015	N	No safety concern
3-Hexenyl phenylacetate	1016	N	No safety concern
Octyl phenylacetate	1017	N	No safety concern
Rhodinyl phenylacetate	1018	N	No safety concern
Linalyl phenylacetate	1019	N	No safety concern
Geranyl phenylacetate	1020	N	No safety concern
Citronellyl phenylacetate	1021	N	No safety concern
Santalyl phenylacetate (<i>alpha</i> and <i>beta</i>)	1022	N	No safety concern
p-Tolylacetaldehyde	1023	N	No safety concern
p-Isopropylphenylacetaldehyde	1024	N	No safety concern
Methyl p-tert-butylphenylacetate	1025	N	No safety concern
Phenoxyacetic acid	1026	N	No safety concern
Ethyl (p-tolyloxy)acetate	1027	N	No safety concern
2-Phenoxyethyl isobutyrate	1028	N	No safety concern
Sodium 2-(4-methoxyphenoxy)propanoate	1029	N	No safety concern

^aN, new specifications prepared

C. Sulfur-containing heterocyclic compounds

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Thiamine hydrochloride	1030	N	No safety concern
4-Methyl-5-thiazoleethanol	1031	N	No safety concern
Thiazole	1032	N	No safety concern
2-(1-Methylpropyl)thiazole	1033	N	No safety concern
2-Isobutylthiazole	1034	N	No safety concern
4,5-Dimethylthiazole	1035	N	No safety concern
2,4,5-Trimethylthiazole	1036	N	No safety concern
2-Isopropyl-4-methylthiazole	1037	N	No safety concern
4-Methyl-5-vinylthiazole	1038	N	No safety concern
2,4-Dimethyl-5-vinylthiazole	1039	N	No safety concern
Benzothiazole	1040	N	No safety concern
2-Acetylthiazole	1041	N	No safety concern
2-Propionylthiazole	1042	N	No safety concern
4-Methylthiazole	1043	N	No safety concern
2-Ethyl-4-methylthiazole	1044	N	No safety concern
4,5-Dimethyl-2-isobutyl-3-thiazoline	1045	N	No safety concern
2-Isobutyl-4,6-dimethyldihydro-1,3,5-dithiazine and 4-isobutyl-2,6-dimethyldihydro-1,3,5-dithiazine (mixture)	1046	N	No safety concern
2-Isopropyl-4,6-dimethyl and 4-Isopropyl-2,6-dimethyldihydro-1,3,5-dithiazine (mixture)	1047	N	No safety concern
2,4,6-Triisobutyl-5,6-dihydro-4H-1,3,5-dithiazine	1048	N	No safety concern
2,4,6-Trimethyldihydro-4H-1,3,5-dithiazine	1049	N	No safety concern
5-Methyl-2-thiophenecarboxaldehyde	1050	N	No safety concern
3-Acetyl-2,5-dimethylthiophene	1051	N	No safety concern
2-Thienylmercaptan	1052	N	No safety concern
2-Thienyl disulfide	1053	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
4-Methyl-5-thiazoleethanol acetate	1054	N	No safety concern
2,4-Dimethyl-5-acetylthiazole	1055	N	No safety concern
2-Ethoxythiazole	1056	N	No safety concern
2-Methyl-5-methoxythiazole	1057	N	No safety concern
4,5-Dimethyl-2-ethyl-3-thiazoline	1058	N	No safety concern
2-(2-Butyl)-4,5-dimethyl-3-thiazoline	1059	N	No safety concern

^aN, new specifications prepared

D. Sulfur-substituted furan derivatives used as flavouring agents

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
2-Methyl-3-furanthiol	1060	N	No safety concern
2-Methyl-3-(methylthio)furan	1061	N	No safety concern
2-Methyl-5-(methylthio)furan	1062	N	No safety concern
2,5-Dimethyl-3-furanthiol	1063	N	No safety concern
Methyl 2-methyl-3-furyl disulfide	1064	N	No safety concern
Propyl 2-methyl-3-furyl disulfide	1065	N	No safety concern
Bis(2-methyl-3-furyl) disulfide	1066	N	No safety concern
Bis(2,5-dimethyl-3-furyl) disulfide	1067	N	No safety concern
Bis(2-methyl-3-furyl) tetrasulfide	1068	N	No safety concern
2-Ethanoic acid, S-(2-methyl-3-furanyl) ester	1069	N	No safety concern
2,5-Dimethyl-3-furan thioisovalerate	1070	N	No safety concern
2,5-Dimethyl-3-thiofuroylfuran	1071	N	No safety concern
Furfuryl mercaptan	1072	N	No safety concern
S-Furfuryl thioformate	1073	N	No safety concern
S-Furfuryl thioacetate	1074	N	No safety concern
S-Furfuryl thiopropionate	1075	N	No safety concern
Furfuryl methyl sulfide	1076	N	No safety concern
Furfuryl isopropyl sulfide	1077	N	No safety concern
Methyl furfuryl disulfide	1078	N	No safety concern
Propyl furfuryl disulfide	1079	N	No safety concern
2,2'-(Thiodimethylene)difuran	1080	N	No safety concern
2,2'-(Dithiodimethylene)difuran	1081	N	No safety concern
2-Methyl-3-, 5- or 6-(furfurylthio)pyrazine	1082	N	No safety concern
S-Methyl thiofuroate	1083	N	No safety concern
4-((2-Furanmethyl)thio)-2-pentanone	1084	N	No safety concern
3-[(2-Methyl-3-furyl)thio]-4-heptanone	1085	N	No safety concern
2,6-Dimethyl-3-[(2-methyl-3-furyl)thio]-4-heptanone	1086	N	No safety concern
4-[(2-Methyl-3-furyl)thio]-5-nonanone	1087	N	No safety concern
Ethyl 3-(furfurylthio)propionate	1088	N	No safety concern
2-Methyl-3-thioacetoxo-4,5-dihydrofuran	1089	N	No safety concern
2-Methyl-3-tetrahydrofuranthiol	1090	N	No safety concern
2,5-Dimethyl-3-tetrahydrofuranthiol, <i>cis</i> and <i>trans</i> isomers	1091	N	No safety concern
2,5-Dimethyl-3-thioacetoxo-tetrahydrofuran, <i>cis</i> and <i>trans</i> isomers	1092	N	No safety concern

^aN, new specifications prepared

E. Alicyclic Ketones, Secondary Alcohols and related esters

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Cyclohexyl acetate	1093	N	No safety concern
Cyclohexyl butyrate	1094	N	No safety concern
Cyclohexyl formate	1095	N	No safety concern
Cyclohexyl isovalerate	1096	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Cyclohexyl propionate	1097	N	No safety concern
<i>cis</i> and <i>trans</i> -p-1(7)8-Menthadien-2-yl acetate	1098	N	No safety concern
3,3,5-Trimethyl cyclohexanol	1099	N	No safety concern
Cyclohexanone	1100	N	No safety concern
Cyclopentanone	1101	N	No safety concern
2-Methylcyclohexanone	1102	N	No safety concern
3-Methylcyclohexanone	1103	N	No safety concern
4-Methylcyclohexanone	1104	N	No safety concern
1-Methyl-1-cyclopenten-3-one	1105	N	No safety concern
2-Hexylidene cyclopentanone	1106	N	No safety concern
3-Methyl-2-cyclohexen-1-one	1107	N	No safety concern
2,2,6-Trimethylcyclohexanone	1108	N	No safety concern
2- <i>sec</i> -Butylcyclohexanone	1109	N	No safety concern
4-Isopropyl-2-cyclohexenone	1110	N	No safety concern
Tetramethylethylcyclohexenone (mixture of isomers)	1111	N	No safety concern
Isophorone	1112	N	No safety concern
3-Methyl-5-propyl-2-cyclohexen-1-one	1113	N	No safety concern
3-Methyl-2-(2-pentenyl)-2-cyclopenten-1-one	1114	N	No safety concern
Isojasmone	1115	N	No safety concern
(<i>E</i>)-2-(2-Octenyl)cyclopentanone	1116	N	No safety concern
2-(3,7-Dimethyl-2,6-octadienyl)cyclopentanone	1117	N	No safety concern

^aN, new specifications prepared

F. Aliphatic secondary alcohols, ketones and related esters

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
3-Decanone	1118	N	No safety concern
5-Methyl-5-hexen-2-one	1119	N	No safety concern
6-Methyl-5-hepten-2-one	1120	N	No safety concern
3,4,5,6-Tetrahydropseudoionone	1121	N	No safety concern
6,10-Dimethyl-5,9-undecadien-2-one	1122	N	No safety concern
2,6,10-Trimethyl-2,6,10-pentadecatrien-14-one	1123	N	No safety concern
3-Penten-2-one	1124	N	No safety concern
4-Hexen-3-one	1125	N	No safety concern
2-Hepten-4-one	1126	N	No safety concern
3-Hepten-2-one	1127	N	No safety concern
3-Octen-2-one	1128	N	No safety concern
2-Octen-4-one	1129	N	No safety concern
3-Decen-2-one	1130	N	No safety concern
4-Methyl-3-penten-2-one	1131	N	No safety concern
5-Methyl-3-hexen-2-one	1132	N	No safety concern
5-Methyl-2-hepten-4-one	1133	N	No safety concern
6-Methyl-3,5-heptadien-2-one	1134	N	No safety concern
(<i>E</i>)-7-Methyl-3-octen-2-one	1135	N	No safety concern
3-Nonen-2-one	1136	N	No safety concern
(<i>E</i>) & (<i>Z</i>)-4,8-Dimethyl-3,7-nonadien-2-one	1137	N	No safety concern
(<i>E</i>)-6-Methyl-3-hepten-2-one	1138	N	No safety concern
(<i>E,E</i>)-3,5-Octadien-2-one	1139	N	No safety concern
3-Octen-2-ol	1140	N	No safety concern
(<i>E</i>)-2-Octen-4-ol	1141	N	No safety concern
2-Pentyl butyrate	1142	N	No safety concern
(+/-)Heptan-3-yl acetate	1143	N	No safety concern
(+/-)Heptan-2-yl butyrate	1144	N	No safety concern
(+/-)Nonan-3-yl acetate	1145	N	No safety concern
2-Pentyl acetate	1146	N	No safety concern
1-Penten-3-one	1147	N	No safety concern
1-Octen-3-one	1148	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
2-Pentyl-1-buten-3-one	1149	N	No safety concern
1-Penten-3-ol	1150	N	No safety concern
1-Hexen-3-ol	1151	N	No safety concern
1-Octen-3-ol	1152	N	No safety concern
1-Decen-3-ol	1153	N	No safety concern
(E,R)-3,7-Dimethyl-1,5,7-octatrien-3-ol	1154	N	No safety concern
6-Undecanone	1155	N	No safety concern
2-Methylheptan-3-one	1156	N	No safety concern

^aN, new specifications prepared

5. Flavouring agents considered for specifications only

No.	Flavouring agent	Specifications ^a	No.	Flavouring agent	Specifications ^a
111	Lauric acid	R	814	<i>alpha</i> -Methylphenethyl butyrate	R
113	Myristic acid	R	817	4- (p-Tolyl)-2-butanone	R
115	Palmitic acid	R	847	Benzyl 2,3-dimethylcrotonate	R
116	Stearic acid	R	861	Glyceryl tribenzoate	S
182	Isoamyl laurate	R	862	Propylene glycol dibenzoate	S
310	Isopropyl isovalerate	R	866	Tolualdehydes (mixed o,m,p)	R
390	<i>gamma</i> -Ionone	R	870	Butyl p-hydroxybenzoate	S
455	Butyl sulfide	R	872	Anisyl formate	R
476	Ethyl 3-methylthiopropionate	R	910	3-Oxohexanoic acid diglyceride	R
483	Ethyl thioacetate	R	911	3-Oxooctanoic acid glyceride	R
490	Allyl thiopropionate	R	914	3-Oxodecanoic acid glyceride	R
492	Methylthio 2-(acetyloxy)propionate	R	915	3-Oxododecanoic acid glyceride	R
493	Methylthio 2-(propionyloxy)propionate	R	916	3-Oxotetradecanoic acid glyceride	R
540	1,6-Hexanedithiol	R	917	3-Oxohexadecanoic acid glyceride	R
542	1,9-Nonanedithiol	R	918	Glyceryl monostearate	R,T
551	2-Mercaptopropionic acid	R	919	Glyceryl monooleate	R,T
553	Ethyl 3-mercaptopropionate	R	921	Glyceryl tripropanoate	S
564	Dimethyl disulfide	R	922	Tributylin	S
566	Propyl disulfide	R	923	Glycerol 5-hydroxydecanoate	S,T
601	Ethyl 3-hydroxyhexanoate	R	924	Glycerol 5-hydroxy-dodecanoate	S,T
602	Ethyl 3-oxohexanoate	R	926	Propylene glycol stearate	R
606	Levulinic acid	R	937	Pyruvaldehyde	S,T
608	Butyl levulinate	R	943	Acetaldehyde ethyl <i>cis</i> -3-hexenyl acetal	R
609	1,4-Nonanediol diacetate	R	954	Ethyl vanillin propylene glycol acetal	R
614	Diethyl malonate	R	955	4-Hydroxybenzyl alcohol	N
616	Dimethyl succinate	R	956	4-Hydroxybenzaldehyde	N
617	Diethyl succinate	R	957	4-Hydroxybenzoic acid	N
622	Diethyl tartrate	R	958	2-Hydroxybenzoic acid	N
624	Diethyl sebacate	R	959	4-Hydroxy-3-methoxy benzoic acid	N
625	Dibutyl sebacate	R	960	Vanillin <i>erythro</i> - & <i>threo</i> -butan-2,3-diol acetal	N
626	Ethylene brassylate	R			
627	Aconitic acid	R			
642	3-Phenylpropyl hexanoate	R			
678	<i>alpha</i> -Amylcinnamyl isovalerate	R			
729	Dihydroxyacetophenone	R			
745	5-Methylfurfural	R			
752	2-Phenyl-3-carbethoxyfuran	R			

^aR, existing specifications revised; S, existing specifications were maintained; T, the existing, new, or revised specifications are tentative and new information is required.

6. Evaluation of secondary components of flavouring agents

The Committee had previously considered the procedure for evaluating flavouring agents for which the minimum assay figures were below 95%; it has followed the general principle that specifications should be designated as tentative if less than 95% of the material in the commercial product consisted of the named compound and known secondary components, which need to be taken into account during the safety evaluation.

At the present meeting, the Committee considered information on the presence of known secondary components in all 51 substances evaluated from its forty-sixth through fifty-fifth meetings for which the minimum assay was less than 95%, in order to assess whether these were covered by the existing safety evaluations of the named compounds.

In most cases, the secondary components of known chemical identity were found to be normal metabolites of the named compound, or to have chemical structures that are sufficiently similar that they fit within the same group evaluations. In two cases, the secondary components were not closely related to the named compound: the safety of the secondary component in 2,3-pentadione (No 410) was assessed by reference to its likely metabolism, and that of 6-hydroxy-3,7-dimethyloctanoic acid lactone (No. 237) was evaluated by reference to the no-observed-effect level (NOEL) for a similar compound.

In the light of all the available data on secondary components present in materials of commerce containing less than 95% of the named compound, the Committee concluded that the secondary components do not raise safety concerns and confirmed its conclusions that the flavouring agents listed below do not present any safety concern at the current estimated levels of intake.

The specifications for the 51 flavouring agents will be reviewed at a future meeting.

No.	Flavouring agent	No.	Flavouring agent
42	Isoamyl formate	323	<i>cis</i> -5-Octenal
53	Citronellyl formate	325	<i>cis</i> -6-Nonenal
54	Geranyl formate	332	Linoleic acid
55	Neryl formate	346	Methyl linoleate & Methyl linolenate
56	Rhodinyl formate	348	2,6-Dimethyl-6-hepten-1-ol
57	Citronellyl acetate	349	2,6-Dimethyl-5-heptenal
60	Rhodinyl acetate	358	Linalyl formate
61	Citronellyl propionate	360	Linalyl propionate
62	Geranyl propionate	384	<i>beta</i> -Damascone
65	Citronellyl butyrate	385	<i>alpha</i> -Damascone
66	Geranyl butyrate	399	Methyl- <i>beta</i> -ionone
68	Rhodinyl butyrate	410	2,3-Pentadione
71	Citronellyl isobutyrate	419	Ethyl cyclopentenolone
73	Neryl isobutyrate	435	p-Menth-1-en-3-one
95	Heptanal	592	Citronellyloxyacetaldehyde
98	Octanal	604	3-(Hydroxymethyl)-2-heptanone
101	Nonanal	625	Dibutyl sebacate
104	Decanal	668	Linalyl cinnamate
107	Undecanal	978	2,6,6-Trimethyl-1-cyclohexene-1-acetaldehyde
110	Lauric aldehyde	1005	Phenylacetaldehyde
112	Myristaldehyde		2,3-butylene glycol acetal
117	Propyl formate	1046	A mixture of 2-Isobutyl-4,6-dimethyl and 4-isobutyl-2,6-dimethyldihydro-1,3,5-dithiazine
119	n-Amyl formate	1047	A mixture of 2-Isopropyl-4,6-dimethyl and 4-isopropyl-2,6-dimethyldihydro-1,3,5-dithiazine
124	Isobutyl formate	1069	2-Ethanoic acid, S-(2-methyl-3-furanyl) ester
170	n-Amyl heptanoate	1086	2,6-Dimethyl-3-[(2-methyl-3-furyl)thio]-4-heptanone
180	Methyl laurate	1092	2,5-Dimethyl-3-thioacetoxy-tetrahydrofuran, <i>cis</i> and <i>trans</i> isomers
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	<i>cis</i> -5-Octen-1-ol		

No.	Flavouring agent
1109	2-sec-Butylcyclohexanone
1128	3-Octen-2-one
1135	(E)-7-Methyl-3-octen-2-one

No.	Flavouring agent
1137	(E) & (Z)-4,8-Dimethyl-3,7-nonadien-2-one
1154	(E,R)-3,7-Dimethyl-1,5,7-octatrien-3-ol

7. Substances requiring confirmation of use as flavouring agents

The evaluation of 18 flavouring agents could not be completed at the fifty-seventh meeting of JECFA that was held in Rome in June 2001, pending information on whether they were in current use as flavouring agents. The Committee received information from the flavour industry on these substances, and concluded that flavour uses have been established for 16 of them. The conclusions of the Committee are summarized in the following table.

No.	Flavouring agent	Evaluation based on current intake as a flavouring agent
850	Benzoic acid ^a	No safety concern
861	Glyceryl tribenzoate	No safety concern
862	Propylene glycol dibenzoate	No safety concern
870	Butyl- <i>para</i> -hydroxybenzoate	No safety concern
909	Glycerol ^b	Evaluation not finalized, pending development of definition of 'flavouring agent'
914	3-Oxodecanoic acid glyceride	No safety concern
915	3-Oxododecanoic acid glyceride	No safety concern
916	3-Oxotetradecanoic acid glyceride	No safety concern
917	3-Oxohexadecanoic acid glyceride	No safety concern
918	Glyceryl monostearate ^c	No safety concern
919	Glyceryl monooleate ^c	No safety concern
920	Triacetin ^d	No safety concern
921	Glyceryl tripropionate (Tripropionin)	No safety concern
922	Tributylin	No safety concern
923	Glycerol 5-hydroxydecanoate	No safety concern
924	Glycerol 5-hydroxydodecanoate	No safety concern
925	Propylene glycol ^e	Evaluation not finalized, pending development of definition of 'flavouring agent'
926	Propylene glycol stearate ^f	No safety concern

Annex 1

Fifty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Geneva, 4-13 June 2002

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Annex 2

Further information required or desired

Mineral oils (low- and medium-viscosity), Class II and Class III

Information on the relevance to humans of the response of Fischer 344 and Sprague-Dawley rats to these materials is required for evaluation in 2006. In order for the data to be applicable to as wide a range of mineral oils as possible, the Committee suggested that commercial mineral oils of the lowest viscosity be used in such studies. Further studies might be required, depending on the outcome of these studies.

Aluminium powder, Iron oxides and Titanium dioxide

Due to the high levels of heavy metals set in the present specifications there is a need to reconsider the specifications for these inorganic colours. The Committee maintained the existing limits and decided to call for data on the raw materials, manufacturing methods and analytical data on impurities for review at a future meeting.

Annex 3

General considerations

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

1. **Modification of the agenda**

Annatto extracts, ethyl carbamate, methylmercury, and sodium dichloroisocyanurate (NaDCC) were removed from the agenda because data necessary for their evaluation were not available. The evaluation of curcumin was deferred until 2003 because the temporary acceptable daily intake (ADI) had been extended to that time at the fifty-seventh meeting of the Committee. Gum Arabic was removed from the agenda because no new information on differences in the origin, manufacturing, quality and use patterns for gum Arabic from *Acacia senegal* and from *Acacia seyal* was provided.

Nitrite was added to the agenda because the pivotal observed toxic effects of nitrate, which was evaluated at the present meeting, are consequent on its conversion to nitrite in vivo. The Committee also considered (1) the safety of the secondary components of a large number of flavouring agents for which the minimum assay values were below 95% and (2) flavouring agents requiring confirmation of flavour use, neither of which was on the original agenda.

2. **Project to update principles and methods of risk assessment of chemicals in food**

The Committee was informed of progress being made on the Project, which has been initiated by FAO and WHO. General principles and methods for the assessment of food additives, contaminants, residues of veterinary drugs and pesticides, and food ingredients that have been developed through the years and published in Environmental Health Criteria Nos. 70¹ and 104² and in reports of the Joint FAO/WHO Expert Committee on Food Additives and the Joint FAO/WHO Meeting on Pesticide Residues will be updated and consolidated, and the utility of new assessment procedures will be considered.

The final product will contain an historical background, and the activity will be placed in the context of the risk analysis paradigm. A framework for incorporation of new principles and methods will be developed. The Project will focus on:

- chemical characterization (including contaminants and natural constituents) and development of specifications for food additives, pesticides, and veterinary drugs;
- maximum residue levels for pesticides and veterinary drugs;
- exposure assessment (including acute and chronic intake, deterministic and probabilistic approaches, and cumulative and aggregate exposure);
- toxicological test procedures and evaluation (including general issues and specific toxicological endpoints);
- human data (clinical studies, epidemiological studies including biomarkers, potentially susceptible populations, allergenicity, intolerance, and diet-toxicity interactions);
- evaluations (including such issues as threshold of toxicological concern, potency estimates, margins of safety, benchmark dose, acute reference dose, special considerations for contaminants, uncertainty and variability, scientific criteria for re-evaluation);

¹ *Principles for the safety assessment of food additives and contaminants in food*. Geneva, World Health Organization, 1987 (WHO Environmental Health Criteria, No. 70).

² *Principles for the toxicological assessment of pesticide residues in food*. Geneva, World Health Organization, 1990 (WHO Environmental Health Criteria, No. 104).

- principles related to specific substances (e.g., flavouring agents and substances consumed in large amounts); and
- Glossary (nomenclature and terminology).

The Committee emphasized the importance of this activity to its work, and encouraged FAO and WHO to proceed with it in a timely manner. It recommended that:

- a prescriptive approach should not be taken, so that there will be maximum flexibility in evaluating chemicals and in incorporating new methods of assessment;
- the intended audience, including risk managers and potential submitters of data, should be clearly defined and kept in mind during all stages of the Project;
- new testing procedures and methods of assessment should be validated before they are used; and
- harmonization and cooperation with risk assessment activities of other international and national organizations should be considered, as appropriate.

3. Procedure for evaluating flavouring agents that are members of groups that have been evaluated previously by the Committee

The Committee has evaluated a large number of flavouring agents using the Procedure for the Safety Evaluation of Flavouring Agents. To facilitate their evaluations, the substances have been grouped according to their chemical structure. A number of flavouring agents in development and additional ones in commerce fit into the groups of flavouring agents that have already been evaluated, and the Committee concluded that these flavouring agents should be evaluated, and the evaluations documented, in a manner consistent with the previous practices and procedures of the Committee. Past evaluations should serve as the basis for evaluating new or additional flavouring agents and, if a substantial body of new data was available, the previous evaluation might need to be reconsidered. The Committee recommended that the *Guidelines for the preparation of working papers (monographs) on flavouring agents*, available at www.who.int/pcs, be updated accordingly.

4. Consideration of guidelines

The Committee confirmed that detailed guidelines for the preparation of working papers were required and should be revised regularly on the basis of comments provided by the Committee. At its present meeting, the Committee considered several guidelines that had been prepared by the Joint Secretariat and made comments and suggestions for improvement.

Comprehensive intake assessments of food additives are a more recent task of the Committee. Therefore at the current meeting specific attention was paid to the *Guidelines for the preparation of working papers on the intake of food additives*. The Committee suggested that intake from dietary sources other than food additives and exposure to non-dietary sources might also be of relevance. The terms for intake assessment used in working papers should be standardized within the Committee and harmonized with those developed by OECD/IPCS (as summarized in the *Glossary of exposure assessment-related terms* which is available at <http://www.ipcsharmonize.org/index.html>).

A draft guideline for working procedures to be followed by the Committee when elaborating specifications for food additives was considered and substantial changes and amendments were suggested to the Secretariat.

5. Risk analysis principles and exposure assessment

The Codex Committee on Food Additives and Contaminants, at its Thirty-fourth Session, asked the Joint FAO/WHO Expert Committee on Food Additives to review and comment on papers that it had prepared on *Application of risk analysis principles for food additives and contaminants* and *Draft principles for exposure assessment of contaminants and toxins in food*. The Committee reviewed these papers and provided comments to CCFAC in the form of letters from the chairman and vice-chairman of the present Committee to the chairman of the Codex Committee. These letters are available on the FAO and WHO web sites.