ANNEX 1: SUMMARY OF RECOMMENDATIONS FROM THE 69TH JECFA

Toxicological recommendations and information on specifications

1. Food additives and ingredients evaluated toxicologically or assessed for dietary exposure

Food additive	Specifications[a]	Acceptable daily intake (ADI) and other toxicological recommendations
Asparaginase from *Aspergillus niger* expressed in *A. niger*	N	**ADI "not specified"[b]** when used in the applications specified and in accordance with good manufacturing practice.
Ethyl lauroyl arginate	N	**ADI of 0–4 mg/kg bw for Ethyl-N[α]-lauroyl-L-arginate HCl** based on a NOAEL of 442 mg/kg bw per day in two reproductive toxicity studies and a safety factor of 100. The Committee noted that some of the estimates of high exposure (greater than 95th percentile) exceeded the ADI, but recognized that these estimates were highly conservative and that actual intakes were likely to be within the ADI.
Calcium lignosulfonate (40-65) The suffix (40-65) reflects the weight-average molecular weight range (40 000–65 000) to distinguish it from other calcium lignosulfonates in commerce	N	**ADI of 0–20 mg/kg bw** based on a NOEL of 2000 mg/kg bw per day from a 90-day toxicity study and a safety factor of 100. The maximum potential dietary exposure to calcium lignosulfonate (40–65) was low and not expected to exceed 7 mg/kg bw per day from use as a carrier of fat-soluble vitamins and carotenoids in food and supplements.
Paprika extract Since the source material and the manufacturing process differ for paprika preparations used as a spice and as a food colour, the name "paprika extract" was adopted for use as a food colour, leaving the term "paprika oleoresin" for use as a spice.	N,T	The Committee did **not allocate an ADI**. Concern was expressed as to whether the material tested in the 90-day and long-term studies was representative of all commercial production of paprika extract used as food colour. The fact that the material tested contained less than 0.01% capsaicin and the fact that the Committee did not receive adequate data to establish a limit for capsaicin in the specifications for paprika extract added to this concern. New tentative specifications were prepared, pending receipt of additional information on paprika extract used as food colour, including concentrations of capsaicin (to differentiate from materials used as flavours) and additional information about the composition of batches of extract produced by a variety of manufacturers.
Phospholipase C expressed in *Pichia pastoris*	N	**ADI "not specified"[b]** when used in the applications specified and in accordance with good manufacturing practice.

Food additive	Specifications[a]	Acceptable daily intake (ADI) and other toxicological recommendations
Phytosterols, phytostanols and their esters	N	**Group ADI of 0–40 mg/kg bw for phytosterols, phytostanols and their esters, expressed as the sum of phytosterols and phytostanols in their free form**, based on an overall NOAEL of 4200 mg/kg bw per day to which a safety factor of 100 was applied. The overall NOAEL was identified using the combined evidence from several studies of short-term (90 day) toxicity. The Committee considered the margin between this overall NOAEL and the lowest LOAEL from the 90 day toxicity studies of 9000 mg/kg bw per day as adequate for this overall NOAEL to be used as the basis for establishing an ADI. This conclusion is supported by the results of the available studies of reproductive toxicity, Based on available data the Committee concluded that dietary exposure to phytosterols and -stanols would typically be within the ADI.
Polydimethylsiloxane (PDMS)	R	**Temporary ADI of 0–0.8 mg/kg bw for PDMS,** based on the previous ADI and **applying an additional safety factor of 2.** The previously established ADI of 0–1.5 mg/kg bw was withdrawn. Results of studies to elucidate the mechanism and relevance of ocular toxicity observed in the submitted toxicology studies, as well as data on actual use levels in foods should be provided before the end of 2010. The temporary ADI applies to PDMS that meets the revised specifications prepared.
Steviol glycosides	R	**ADI of 0–4 mg/kg bw expressed as steviol**, based on a NOEL of 970 mg/kg bw per day from a long-term experimental study with stevioside (383 mg/kg bw per day expressed as steviol) and a safety factor of 100. The results of the new studies presented to the Committee showed no adverse effects of steviol glycosides when taken at doses of about 4 mg/kg bw per day, expressed as steviol, for up to 16 weeks by individuals with type 2 diabetes mellitus and individuals with normal or low-normal blood pressure for 4 weeks. Some estimates of high-percentile dietary exposure to steviol glycosides exceeded the ADI, particularly when assuming complete replacement of caloric sweeteners with steviol glycosides. The Committee recognized that these estimates were highly conservative and that actual intakes were likely to be within the ADI.
Sulfites Dietary exposure assessment		The main contributors to total dietary exposure to sulfites differ between countries owing to differing patterns of use of sulfites in foods and of consumption of foods to which sulfites may be added. Thus dried fruit, sausages and nonalcoholic beverages were the main contributors of sulfites in some countries, while in other countries these foods are generally produced without the use of sulfites. In countries where wine is regularly consumed, it was one of the main contributors to dietary exposure in adults. Dietary exposure in high regular consumers of wine (97.5^{th} percentile) was shown to exceed the ADI for sulfites (0-0.7 mg/kg bw) based either on MLs in Codex GSFA, on MLs in national legislation or on the average concentration determined analytically (about 100 mg/l).

		In children and teenagers, a significant contribution to mean exposure to sulfites could come from fruit juices and soft drinks (including cordial), sausages, various forms of processed potatoes, dried fruit and nuts. Other significant contributions to dietary exposure in the adult population come from dried fruit, sausages and beer. The Committee provided recommendation on further relevant actions to be considered by countries and the Codex Alimentarius Commission (see Annex 2).

[a] N: new specifications prepared; R: existing specifications revised; S: existing specifications maintained; T: tentative specifications.

[b] ADI '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.

2. Food additives, including flavouring agents, considered for specifications only

Food Additive	Specifications[a]
Canthaxanthin	R
Carob bean gum and carob bean gum (clarified)	R
Chlorophyllin, copper complexes sodium and potassium salts	R
Carbohydrase from *Aspergillus niger var.*	W
Estragole	W
Fast Green FCF	R
Guar gum and guar gum (clarified)	R
Iron oxides	R
Isomalt	R
Monomagnesium phosphate	N
Patent Blue V	R
Sunset Yellow FCF	R
Trisodium diphosphate	N

[a] N: New specifications prepared; R: Existing specifications revised; T: tentative specifications; W: Existing specifications withdrawn.

3. Flavouring agents

3.1. Flavourings evaluated by the Procedure for the Safety Evaluation of Flavouring Agents

3.1.1 Aliphatic, linear α,β-unsaturated aldehydes, acids and related alcohols, acetals and esters

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural Class I			
(Z)-2-Penten-1-ol	1793	N	No safety concern
(E)-2-Decen-1-ol	1794	N	No safety concern
(Z)-Pent-2-enyl hexanoate	1795	N	No safety concern
(E)-2-Hexenyl octanoate	1796	N	No safety concern
trans-2-Hexenyl 2-methylbutyrate	1797	N	No safety concern
Hept-trans-2-en-1-yl acetate	1798	N	No safety concern
(E,Z)-Hept-2-en-1-yl isovalerate	1799	N	No safety concern
trans-2-Hexenal glyceryl acetal	1800	N	No safety concern
trans-2-Hexenal propylene glycol acetal	1801	N	No safety concern
cis- and trans-1-Methoxy-1-decene	1802	N	No safety concern
(E)-Tetradec-2-enal	1803	N	No safety concern
(E)-2-Pentenoic acid	1804	N	No safety concern
(E)-2-Octenoic acid	1805	N	No safety concern
Ethyl trans-2-butenoate	1806	N	No safety concern
Hexyl 2-butenoate	1807	N	No safety concern
Ethyl trans-2-hexenoate	1808	N	No safety concern
(E,Z)-Methyl 2-hexenoate	1809	N	No safety concern
Hexyl trans-2-hexenoate	1810	N	No safety concern
Methyl trans-2-octenoate	1811	N	No safety concern
Ethyl trans-2-octenoate	1812	N	No safety concern
(E,Z)-Methyl 2-nonenoate	1813	N	No safety concern
Ethyl trans-2-decenoate	1814	N	No safety concern

[a]N: new specifications prepared

3.1.2 Aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, and related esters

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural class I			
Ethyl (E)-2-methyl-2-pentenoate	1815	N	No safety concern
2-Methylbutyl 3-methyl-2-butenoate	1816	N	No safety concern
(+/-)(E,Z)-5-(2,2-Dimethylcyclopropyl)-3-methyl-2-pentenal	1817	N	No safety concern
(E,Z)-4-Methylpent-2-enoic acid	1818	N	No safety concern
(+/-)-4-Ethyloctanal	1819	N	No safety concern
(E)-Geranyl 2-methylbutyrate	1820	N	No safety concern
(E)-Geranyl valerate	1821	N	No safety concern
(E)-Geranyl tiglate	1822	N	No safety concern
(E)-Citronellyl 2-methylbut-2-enoate	1823	N	No safety concern
(E)-Ethyl tiglate	1824	N	No safety concern
(E,Z)-Geranic acid	1825	N	No safety concern
Prenyl formate	1826	N	No safety concern
Prenyl acetate	1827	N	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Prenyl isobutyrate	1828	N	No safety concern
Prenyl caproate	1829	N	No safety concern
(+/-)-Dihydrofarnesol	1830	N	No safety concern
(E,Z)-3,7,11-Trimethyldodeca-2,6,10-trienyl acetate	1831	N	No safety concern
(E,Z)-Phytol	1832	N	No safety concern
(E,Z)-Phytyl acetate	1833	N	No safety concern
Structural class II			
Methyl 2-methyl-2-propenoate	1834	N	No safety concern

[a]N: new specifications prepared

3.1.3 Aliphatic secondary alcohols, ketones and related esters

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural class I			
Isopropenyl acetate	1835	N	No safety concern
1-Octen-3-yl acetate	1836	N	No safety concern
1-Octen-3-yl butyrate	1837	N	No safety concern
6-Methyl-5-hepten-2-yl acetate	1838	N	No safety concern
3-(Hydroxymethyl)-2-octanone	1839	N	No safety concern
(+/-)-[R-(E)]-5-Isopropyl-8-methylnona-6,8-dien-2-one	1840	N	No safety concern
(+/-)-cis- and trans-4,8-Dimethyl-3,7-nonadien-2-ol	1841	N	No safety concern
2,4-Dimethyl-4-nonanol	1850	N	No safety concern
Structural class II			
(+/-)-1-Hepten-3-ol	1842	N	No safety concern
(E, Z)-4-Octen-3-one	1843	N	No safety concern
(E)-2-Nonen-4-one	1844	N	No safety concern
(E)-5-Nonen-2-one	1845	N	No safety concern
(Z)-3-Hexenyl 2-oxopropionate	1846	N	No safety concern
(+/-)-cis- and trans-4,8-Dimethyl-3,7-nonadien-2-yl acetate	1847	N	No safety concern
(E)-1,5-Octadien-3-one	1848	N	No safety concern
10-Undecen-2-one	1849	N	No safety concern
8-Nonen-2-one	1851	N	No safety concern

[a]N: new specifications prepared.

3.1.4 Substances structurally related to menthol

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural Class I			
Menthyl valerate	1852	N	No safety concern
2-(l-Menthoxy)ethanol	1853	N	No safety concern
l-Menthyl acetoacetate	1854	N	No safety concern
l-Menthyl (R,S)-3-hydroxybutyrate	1855	N	No safety concern
8-p-Menthene-1,2-diol	1860	N	No safety concern
Structural Class II			
l-Piperitone	1856	N	No safety concern
2,6,6-Trimethylcyclohex-2-ene-1,4-dione	1857	N	No safety concern
Menthyl pyrrolidone carboxylate	1858	N	No safety concern
3,9-Dimethyl-6-(1-methylethyl)-1,4-dioxaspiro[4.5]decan-2-one	1859	N	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
d-2,8-p-Menthadien-1-ol	1861	N	No safety concern

[a]N: new specifications prepared.

3.1.5 Monocyclic and bicyclic secondary alcohols, ketones and related esters

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural Class I			
Dehydronootkatone	1862	N	No safety concern
Isobornyl isobutyrate	1863	N	No safety concern
l-Bornyl acetate	1864	N	No safety concern
Thujyl alcohol	1865	N	No safety concern
Structural class II			
Vetiverol	1866	N	No safety concern
Vetiveryl acetate	1867	N	No safety concern
3-Pinanone	1868	N	No safety concern
Isobornyl 2-methylbutyrate	1869	N	No safety concern
Verbenone	1870	N	No safety concern

[a]N: new specifications prepared.

3.1.6 Aliphatic acyclic primary alcohols with aliphatic linear saturated carboxylic acids

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural class I			
Methyl hexanoate	1871	N	No safety concern
Hexyl heptanoate	1872	N	No safety concern
Hexyl nonanoate	1873	N	No safety concern
Hexyl decanoate	1874	N	No safety concern
Heptyl heptanoate	1875	N	No safety concern
Dodecyl propionate	1876	N	No safety concern
Dodecyl butyrate	1877	N	No safety concern

[a]N: new specifications prepared.

3.1.7 Hydroxy- and alkoxy- substituted benzyl derivatives

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural class I			
4-Hydroxy-3,5-dimethoxy benzaldehyde	1878	N	No safety concern
Vanillin 3-(l-menthoxy)propane-1,2-diol acetal	1879	N	No safety concern
Sodium 4-methoxybenzoyloxyacetate	1880	N	No safety concern
Vanillin propylene glycol acetal	1882	N	No safety concern
4-Methoxybenzoyloxyacetic acid	1883	N	No safety concern
Structural class III			
Divanillin	1881	N	No safety concern

[a]N: new specifications prepared.

3.1.8 Miscellaneous nitrogen-containing substances

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Structural class II			
Methyl isothiocyanate	1884	N	No safety concern
Ethyl isothiocyanate	1885	N	No safety concern
Isobutyl isothiocyanate	1886	N	No safety concern
Isoamyl isothiocyanate	1887	N	No safety concern
Isopropyl isothiocyanate	1888	N	No safety concern
3-Butenyl isothiocyanate	1889	N	No safety concern
2-Butyl isothiocyanate	1890	N	No safety concern
4-(Methylthio)butyl isothiocyanate	1892	N	No safety concern
4-Pentenyl isothiocyanate	1893	N	No safety concern
5-Hexenyl isothiocyanate	1894	N	No safety concern
5-(Methylthio)pentyl isothiocyanate	1896	N	No safety concern
6-(Methylthio)hexyl isothiocyanate	1897	N	No safety concern
Structural class III			
Amyl isothiocyanate	1891	N	No safety concern
Hexyl isothiocyanate	1895	N	No safety concern

[a]N: new specifications prepared.

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

The Committee concluded that the Procedure could not be applied to this group, because of the unresolved toxicological concerns. Studies that would assist in the safety evaluation include investigations of the influence of the nature and position of ring substitution on metabolism and on covalent binding to macromolecules. Depending on the findings, additional studies might include assays related to the mutagenic and carcinogenic potential of representative members of this group.

Flavouring agent	JECFA No.	Specifications[a]
Structural Class II		
2-Methylfuran	1487	S
2,5-Dimethylfuran	1488	S
2-Ethylfuran	1489	S
2-Butylfuran	1490	S
2-Pentylfuran	1491	S
2-Heptylfuran	1492	S
2-Decylfuran	1493	S
3-Methyl-2-(3-methylbut-2-enyl)-furan	1494	S
3-(2-Furyl)acrolein	1497	S
3-(5-Methyl-2-furyl)prop-2-enal	1499	S
2-Furyl methyl ketone	1503	S
2-Acetyl-5-methylfuran	1504	S
2-Acetyl-3,5-dimethylfuran	1505	S
2-Butyrylfuran	1507	S
(2-Furyl)-2-propanone	1508	S
2-Pentanoylfuran	1509	S
1-(2-Furyl)butan-3-one	1510	S
4-(2-Furyl)-3-buten-2-one	1511	S
Ethyl 3-(2-furyl)propanoate	1513	S
Isobutyl 3-(2-furan)propionate	1514	S
Isoamyl 3-(2-furan)propionate	1515	S

Flavouring agent	JECFA No.	Specifications[a]
Isoamyl 4-(2-furan)butyrate	1516	S
Phenethyl 2-furoate	1517	S
Furfuryl methyl ether	1520	S
Ethyl furfuryl ether	1521	S
Difurfuryl ether	1522	S
2,5-Dimethyl-3-furanthiol acetate	1523	S
Furfuryl 2-methyl-3-furyl disulfide	1524	S
3-[(2-Methyl-3-furyl)thio]-2-butanone	1525	S
O-Ethyl S-(2-furylmethyl)thiocarbonate	1526	S
Structural Class III		
2,3-Dimethylbenzofuran	1495	S
2,4-Difurfurylfuran	1496	S
2-Methyl-3(2-furyl)acrolein	1498	S
3-(5-Methyl-2-furyl)-butanal	1500	S
2-Furfurylidene-butyraldehyde	1501	S
2-Phenyl-3-(2-furyl)prop-2-enal	1502	S
3-Acetyl-2,5-dimethylfuran	1506	S
Pentyl 2-furyl ketone	1512	S
Propyl 2-furanacrylate	1518	S
2,5-Dimethyl-3-oxo-(2H)-fur-4-yl butyrate	1519	S

[a]S: Specifications maintained. The specifications monographs will include a statement that the safety evaluation has not been completed.

3.1.10 Alkoxy-substituted allylbenzenes present in foods, essential oils, and used as flavouring agents

The Committee concluded that the data reviewed on the six alkoxy-substituted allylbenzenes provide evidence of toxicity and carcinogenicity to rodents given high doses for several of these substances. A mechanistic understanding of these effects and their implications for human risk have yet to be fully explored, and will have a significant impact on the assessment of health risks from alkoxy-substituted allylbenzenes at the concentrations at which they occur in food.

Flavouring agent	No.	Specifications[a]
Apiole	1787	N
Elemicin	1788	N
Estragole	1789	N
Methyl eugenol	1790	N
Myristicin	1791	N
Safrole	1792	N

[a]N: new specifications prepared. The specifications monographs will include a statement that the safety evaluation has not been completed.

3.2 Re-evaluation of safety of certain flavourings

At the fifty-ninth, sixty-first, sixty-third and sixty-fifth meetings of the Committee, only "anticipated" annual volumes of productions were provided for some flavouring agents and used in the MSDI calculation. These volumes were used for expedience in completing a safety evaluation, but the conclusions of the Committee were made conditional pending the submission of actual poundage data.

Actual production volumes were subsequently submitted for all 143 requested flavouring agents and were evaluated by the Committee. The two flavouring substances requiring a re-evaluation were No. 1414, l-monomenthyl glutarate and No. 1595, 2-isopropyl-N,2,3-trimethylbutyramide.

The Committee concluded that the Procedure could not be applied to 2-isopropyl-*N*,2,3-trimethylbutyramide, because of evidence of clastogenicity in the presence, but not in the absence, of metabolic activation.

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
Ethyl cyclohexanecarboxylate	963	S	No safety concern
10-Hydroxymethylene-2-pinene	986	S	No safety concern
2,5-Dimethyl-3-furanthiol	1063	S	No safety concern
Propyl 2-methyl-3-furyl disulfide	1065	S	No safety concern
Bis(2-methyl-3-furyl) disulfide	1066	S	No safety concern
Bis(2,5-dimethyl-3-furyl) disulfide	1067	S	No safety concern
Bis(2-methyl-3-furyl) tetrasulfide	1068	S	No safety concern
2,5-Dimethyl-3-furan thioisovalerate	1070	S	No safety concern
Furfuryl isopropyl sulfide	1077	S	No safety concern
2-Methyl-3,5- or 6-(furfurylthio)pyrazine	1082	S	No safety concern
3-[(2-Methyl-3-furyl)thio]-4-heptanone	1085	S	No safety concern
2,6-Dimethyl-3-[(2-methyl-3-furyl)thio]-4-heptanone	1086	S	No safety concern
4-[(2-Methyl-3-furyl)thio]-5-nonanone	1087	S	No safety concern
2-Methyl-3-thioacetoxy-4,5-dihydrofuran	1089	S	No safety concern
4-Hydroxy-4-methyl-5-hexenoic acid gamma-lactone	1157	S	No safety concern
(+/-) 3-Methyl-gamma-decalactone	1158	S	No safety concern
4-Hydroxy-4-methyl-7-cis-decenoic acid gamma-lactone	1159	S	No safety concern
Tuberose lactone	1160	S	No safety concern
Dihydromintlactone	1161	S	No safety concern
Mintlactone	1162	S	No safety concern
Dehydromenthofurolactone	1163	S	No safety concern
(+/-)-(2,6,6-Trimethyl-2-hydroxycyclohexylidene) acetic acid gamma-lactone	1164	S	No safety concern
2-(4-Methyl-2-hydroxyphenyl)propionic acid gamma-lactone	1167	S	No safety concern
2,4-Hexadien-1-ol	1174	S	No safety concern
(E,E)-2,4-Hexadienoic acid	1176	S	No safety concern
(E,E)-2,4-Octadien-1-ol	1180	S	No safety concern
2,4-Nonadien-1-ol	1183	S	No safety concern
(E,Z)-2,6-Nonadien-1-ol acetate	1188	S	No safety concern
(E,E)-2,4-Decadien-1-ol	1189	S	No safety concern
Methyl (E)-2-(Z)-4-decadienoate	1191	S	No safety concern
Ethyl 2,4,7-decatrienoate	1193	S	No safety concern
(+/-) 2-Methyl-1-butanol	1199	S	No safety concern
2-Methyl-2-octenal	1217	S	No safety concern
4-Ethyloctanoic acid	1218	S	No safety concern
8-Ocimenyl acetate	1226	S	No safety concern
3,7,11-Trimethyl-2,6,10-dodecatrienal	1228	S	No safety concern
12-Methyltridecanal	1229	S	No safety concern
1-Ethoxy-3-methyl-2-butene	1232	S	No safety concern
2,2,6-Trimethyl-6-vinyltetrahydropyran	1236	S	No safety concern
Cycloionone	1239	S	No safety concern
2,4-Dimethylanisole	1245	S	No safety concern
1,2-Dimethoxybenzene	1248	S	No safety concern
4-Propenyl-2,6-dimethoxyphenol	1265	S	No safety concern
erythro and threo-Mercapto-2-methylbutan-1-ol	1289	S	No safety concern
(±)2-Mercapto-2-methylpentan-1-ol	1290	S	No safety concern
3-Mercapto-2-methylpentanal	1292	S	No safety concern
4-Mercapto-4-methyl-2-pentanone	1293	S	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
spiro[2,4-Dithia-1-methyl-8-oxabicyclo(3.3.0)octane-3,3'-(1'-oxa-2'-methyl)-cyclopentane]	1296	S	No safety concern
2,3,5-Trithiahexane	1299	S	No safety concern
Diisopropyl trisulfide	1300	S	No safety concern
2-(2-Methylpropyl)pyridine	1311	S	No safety concern
2-Propionylpyrrole	1319	S	No safety concern
2-Propylpyridine	1322	S	No safety concern
4-Methylbiphenyl	1334	S	No safety concern
delta-3-Carene	1342	S	No safety concern
Farnesene (alpha and beta)	1343	S	No safety concern
1-Methyl-1,3-cyclohexadiene	1344	S	No safety concern
trans-2-Octen-1-yl acetate	1367	S	No safety concern
trans-2-Octen-1-yl butanoate	1368	S	No safety concern
cis-2-Nonen-1-ol	1369	S	No safety concern
(E)-2-Octen-1-ol	1370	S	No safety concern
(E)-2-Butenoic acid	1371	S	No safety concern
(E)-2-Decenoic acid	1372	S	No safety concern
(E)-2-Heptenoic acid	1373	S	No safety concern
(Z)-2-Hexen-1-ol	1374	S	No safety concern
trans-2-Hexenyl butyrate	1375	S	No safety concern
(E)-2-Hexenyl formate	1376	S	No safety concern
trans-2-Hexenyl isovalerate	1377	S	No safety concern
trans-2-Hexenyl propionate	1378	S	No safety concern
trans-2-Hexenyl pentanoate	1379	S	No safety concern
(E)-2-Nonenoic acid	1380	S	No safety concern
(E)-2-Hexenyl hexanoate	1381	S	No safety concern
(Z)-3- & (E)-2-Hexenyl propionate	1382	S	No safety concern
2-Undecen-1-ol	1384	S	No safety concern
Dihydronootkatone	1407	S	No safety concern
beta-Ionyl acetate	1409	S	No safety concern
alpha-Isomethylionyl acetate	1410	S	No safety concern
3-(l-Menthoxy)-2-methylpropane-1,2-diol	1411	S	No safety concern
Bornyl butyrate	1412	S	No safety concern
d,l-Menthol-(±)-propylene glycol carbonate	1413	S	No safety concern
l-Monomenthyl glutarate	1414	S	No safety concern
l-Menthyl methyl ether	1415	S	No safety concern
p-Menthane-3,8-diol	1416	S	No safety concern
Taurine	1435	S	No safety concern
L-Arginine	1438	S	No safety concern
L-Lysine	1439	S	No safety concern
Tetrahydrofurfuryl cinnamate	1447	S	No safety concern
(±)-2-(5-Methyl-5-vinyltetrahydrofuran-2-yl)propionaldehyde	1457	S	No safety concern
Ethyl 2-ethyl-3-phenylpropanoate	1475	S	No safety concern
2-Oxo-3-phenylpropionic acid and	1478	S	No safety concern
Sodium 2-Oxo-3-phenylpropionate	1479	S	No safety concern
2-Methyl-3-(1-oxopropoxy)-4H-pyran-4-one	1483	S	No safety concern
4-Allylphenol	1527	S	No safety concern
2-Methoxy-6-(2-propenyl)phenol	1528	S	No safety concern
Eugenyl isovalerate	1532	S	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusions based on current estimated intake
cis-3-Hexenyl anthranilate	1538	S	No safety concern
Citronellyl anthranilate	1539	S	No safety concern
Ethyl N-methylanthranilate	1546	S	No safety concern
Ethyl N-ethylanthranilate	1547	S	No safety concern
Isobutyl N-methylanthranilate	1548	S	No safety concern
Methyl N-formylanthranilate	1549	S	No safety concern
Methyl N-acetylanthranilate	1550	S	No safety concern
Methyl N,N-dimethylanthranilate	1551	S	No safety concern
N-Benzoylanthranilic acid	1552	S	No safety concern
Trimethyloxazole	1553	S	No safety concern
2,5-Dimethyl-4-ethyloxazole	1554	S	No safety concern
2-Ethyl-4,5-dimethyloxazole	1555	S	No safety concern
2-Isobutyl-4,5-dimethyloxazole	1556	S	No safety concern
2-Methyl-4,5-benzo-oxazole	1557	S	No safety concern
2,4-Dimethyl-3-oxazoline	1558	S	No safety concern
Butyl isothiocyanate	1561	S	No safety concern
Benzyl isothiocyanate	1562	S	No safety concern
Phenethyl isothiocyanate	1563	S	No safety concern
4,5-Dimethyl-2-propyloxazole	1569	S	No safety concern
4,5-Epoxy-(E)-2-decenal	1570	S	No safety concern
beta-Ionone epoxide	1571	S	No safety concern
Epoxyoxophorone	1573	S	No safety concern
Ethylamine	1579	S	No safety concern
Propylamine	1580	S	No safety concern
Isopropylamine	1581	S	No safety concern
Isobutylamine	1583	S	No safety concern
sec-Butylamine	1584	S	No safety concern
Pentylamine	1585	S	No safety concern
2-Methylbutylamine	1586	S	No safety concern
Hexylamine	1588	S	No safety concern
2-(4-Hydroxyphenyl)ethylamine	1590	S	No safety concern
1-Amino-2-propanol	1591	S	No safety concern
Butyramide	1593	S	No safety concern
1,6-Hexalactam	1594	S	No safety concern
2-Isopropyl-N,2,3-trimethylbutyramidee	1595	S	**Further information is needed**
N-Ethyl (E)-2,(Z)-6-nonadienamide	1596	S	No safety concern
N-Cyclopropyl (E)-2,(Z)-6-nonadienamide	1597	S	No safety concern
N-Isobutyl (E,E)-2,4-decadienamide	1598	S	No safety concern
(±)-N,N-Dimethyl menthyl succinamide	1602	S	No safety concern
1-Pyrroline	1603	S	No safety concern
2-Acetyl-1-pyrroline	1604	S	No safety concern
2-Propionylpyrroline	1605	S	No safety concern
Isopentylidene isopentylamine	1606	S	No safety concern
2-Methylpiperidine	1608	S	No safety concern
Triethylamine	1611	S	No safety concern
Tripropylamine	1612	S	No safety concern
N,N-Dimethylphenethylamine	1613	S	No safety concern
Trimethylamine oxide	1614	S	No safety concern
Piperazine	1615	S	No safety concern

ANNEX 2: RECOMMENDATIONS AND FURTHER INFORMATION REQUIRED

Paprika extract

Data on the composition and capsaicin content of batches of paprika extract for use as a colour produced by a variety of manufacturers. Information as to whether the material used in the toxicological tests submitted was representative of all the products in commerce. If not, additional toxicological data on representative material would be needed for the evaluation of paprika extract for use as a colour.

The Committee recommended that the specifications for paprika oleoresin be revised at a future meeting in order to allow the differentiation of paprika extract used as a colour from paprika oleoresin used as a flavour.

Polydimethylsiloxane

Results of studies to elucidate the mechanism and relevance of the ocular toxicity observed in the experimental studies and data on actual use levels in foods should be provided before the end of 2010.

Sulfites – dietary exposure assessment and maximum levels (MLs) in foods

Countries that have not yet done so could consider collecting data on the current use of sulfites in food and beverages available on their markets and investigating whether dietary exposure in some subpopulations exceeds the ADI. On the basis of this investigation, individual countries and the food industry could consider the possibility of taking one or more of the following measures to reduce dietary exposure to sulfites so that the ADI is not exceeded in the population:

(1) align national legislation with Codex MLs where these are lower;
(2) take action to effectively enforce national MLs;
(3) encourage research on alternative methods of preservation, particularly on applications in which the use of sulfites is responsible for a significant contribution;
(4) take action so that the use of sulfites is reduced in foods where safe alternative solutions are available.

Codex Alimentarius Commission codes of practices for certain groups of food commodities, such as fruit juice, dried fruit and processed meat, could be amended to include suggestions to help countries and the food industry in the implementation of a reduction of the use of sulfites in food.

Furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers (JECFA Nos, Structural Class II: 1487, 1488, 1489, 1490, 1491, 1492, 1493, 1494, 1497, 1499, 1503, 1504, 1505, 1507, 1508, 1509, 1510, 1511, 1513, 1514, 1515, 1516, 1517, 1520, 1521, 1522, 1523, 1524, 1525, 1526; Structural Class III: 1495, 1496, 1498, 1500, 1501, 1502, 1506, 1512, 1518, 1519)

The Committee concluded that the Procedure could not be applied to this group of flavouring agents, because of the unresolved toxicological concerns. Studies that would assist in the safety evaluation include investigations of the influence of the nature and position of ring substitution on metabolism and on covalent binding to macromolecules. Depending on the findings, additional studies might include assays related to the mutagenic and carcinogenic potential of representative members of this group of flavours.

Alkoxy-substituted allylbenzenes present in foods, essential oils, and used as flavouring agents (Apiole JECFA No. 1787, Elemicin No. 1788, Estragole No. 1789, Methyl eugenol No. 1790, Myristicin No 1791, Safrole No 1792)

There is evidence of toxicity and carcinogenicity to rodents given high doses for several of these substances. A mechanistic understanding of these effects and their implications for human risk have yet to be fully explored, and will have a significant impact on the assessment of health risks from alkoxy-

substituted allylbenzenes at the concentrations at which they occur in food. Further research is needed to assess the potential risk to human health from low-level dietary exposure to alkoxy-substituted allylbenzenes present in foods and essential oils and used as flavouring agents.

2-isopropyl-N,2,3-trimethylbutyramide (JECFA No. 1595)

The Committee concluded that the Procedure could not be applied to 2-isopropyl-N,2,3-trimethylbutyramide, because of because of evidence of clastogenicity in the presence, but not in the absence, of metabolic activation. Information that would assist in resolving the concerns would include data on the potential of this compound to form reactive metabolites and on whether clastogenicity is also expressed in vivo, as well as additional information on the effects found in the kidney (tubular nephrosis, tubular dilatation with granular casts and hyaline droplet formation) at relatively low doses.

CORRIGENDA

COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS
FAO FOOD AND NUTRITION PAPER 52, Addendum 9, ROME, 2001.

Page 129, Flavouring agent **2-Ethyl-6-methyl pyrazine** (JECFA No. 769): The entry on Assay minium % is corrected to exclude the presence of the 2,3-isomer as follows: 95 (sum of 2,5- and 2,6-isomers).

COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS
FAO FOOD AND NUTRITION PAPER 52, Addendum 11, ROME, 2003.

Page 120, the name of flavouring agent with JECFA No. 1290 is corrected to **(+/-)2-Mercapto-2-methylpentan-1-ol**.

COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS
FAO FOOD AND NUTRITION PAPER 52, Addendum 12, ROME, 2004.

Page 89, Flavouring agent **DL-(3-Amino-3-carboxypropyl)dimethylsulfonium chloride** (JECFA No. 1427: the Chemical Abstract Services number is corrected to 3493-12-7, to reflect the DL-form of the substance, and the missing letter l in sulfonium is added.

COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS
FAO FOOD AND NUTRITION PAPER 52, Addendum 13, ROME, 2005.

Page 59, Flavouring agent **2,5-Dimethyl-3-oxo-(2H)-fur-4-yl butyrate** (JECFA No. 1519): the entry on Secondary Components is modified to indicate the concentration ranges as follows: SC: 1-3% 4-Hydroxy-2,5-dimethyl-3(2H)-furanone and 1-3% Butyric acid

Page 59, Flavouring agent **Furfuryl 2-methyl-3-furyl disulfide** (JECFA No. 1524): the entry on Secondary Components is modified to indicate the concentration range as follows: SC: 6-7% Di-(2-methyl-3-furyl) disulfide.

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COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS

Joint FAO/WHO Expert Committee on Food Additives

69th meeting 2008

This document contains food additive specifications monographs, analytical methods and other information, prepared at the sixty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which was held in Rome, Italy, from 17 to 26 June 2008. The specifications monographs provide information on the identity and purity of food additives used directly in foods or in food production. The main three objectives of these specifications are to identify the food additive that has been subjected to testing for safety, to ensure that the additive is of the quality required for use in food or in processing, and to reflect and encourage good manufacturing practice. This publication and other documents produced by JECFA contain information that is useful to all those who work with or are interested in food additives and their safe use in food.

ISBN 978-92-5-106065-0 ISSN 1817-7077

TC/M/I0345E/1/9.08/1000