codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

The Hague, The Netherlands, 24 – 28 April 2006

ACTION REQUIRED AS A RESULT OF CHANGES IN ACCEPTABLE DAILY INTAKE (ADI) STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS

1. This document summarizes actions required by the Codex Committee on Food Additives and Contaminants as a result of changes in the Acceptable Daily Intake (ADI) status of food additives or other toxicological recommendations concerning additives, natural food constituents and contaminants as proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 65th Meeting (Geneva, 7-16 June 2005).[1]

2. At its 65th Meeting, JECFA recommended changes to existing ADIs and/or established new or temporary ADIs or gave other toxicological recommendations for food additives and ingredients as contained in the attached Table 1. The CCFAC should decide and agree on any action which might be required concerning these changes.

3. At its 65th Meeting, JECFA also evaluated a large number of flavouring agents using the Procedure for the Safety Evaluation of Flavouring Agents. For the majority of flavours JECFA concluded that these substances were of "no safety concern" based on current intake, or previously established ADIs were maintained, and these substances are not included in the attached Table 1.

4. For a number of flavours only anticipated poundage data were provided for the safety assessment according to the procedure. JECFA made the safety assessment conditional, and requested that use level or poundage data will be made available before the end of 2007, otherwise the safety evaluations for these compounds will be revoked. These flavours are attached in Table 2. No actions are required by CCFAC, but the Committee is requested to take note of the data request.

[1] See the Summary and Conclusions of the 65th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, (Unnumbered, Agenda Item 4a) for additional details.

Table 1. Food additives evaluated toxicologically at the 65th JECFA meeting

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFAC
901	Beeswax	No safety concern at the predicted dietary exposure (less than 650 mg/person/day), based on the long history of use and lack of toxicity observed with the major components of beeswax.	Consider the draft food additive provision for beeswax in food category 14.1.4 in Tables 1 and 2 of the GSFA.
902	Candelilla wax	No safety concern at the predicted dietary exposure (less than 650 mg/person/day).	Consider the draft food additive provision for candelilla wax in food category 14.1.4 in Tables 1 and 2 of the GSFA.
-	Phospholipase A1 from *Fusarium venenatum* expressed in *Aspergillus oryzae*	The information provided on the enzyme phospholipase A1 was too limited to assess its safety.	No action.
1204	Pullulan	ADI 'not specified'[2]	Consider requesting proposals for inclusion in the GSFA.
999	Quillaia extract Type 1	The previous ADI established for quillaia extract type 1 was converted to an ADI based on saponin content using the lower end of the specified saponin range, and established as a **group ADI for quillaia extract type 1 and quillaia extract type 2 of 0-1 mg saponins/kg bw**.	Consider whether to revise the food additive provision, to express the maximum level base on saponins and whether it is necessary to revise the INS number to reflect the two types of quillaia extract.

[2] 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.

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFAC
999	Quillaia extract Type 2	The previous ADI established for quillaia extract type 1 was converted to an ADI based on saponin content using the lower end of the specified saponin range, and established as a **group ADI for quillaia extract type 1 and quillaia extract type 2 of 0-1 mg saponins/kg bw**.	

Table 2. Flavouring agents which were assessed as of 'no safety concern' on a conditional basis

A. Flavouring agents evaluated at the 65th JECFA meeting

No.	1. Flavouring agent
1483	2-Methyl-3-(1-oxopropoxy)-4H-pyran-4-one
1527	4-Allylphenol
1528	2-Methoxy-6-(2-propenyl)phenol
1532	Eugenyl isovalerate
1538	cis-3-Hexenyl anthranilate
1539	Citronellyl anthranilate
1546	Ethyl N-methylanthranilate
1547	Ethyl N-ethylanthranilate
1548	Isobutyl N-methylanthranilate
1549	Methyl N-formylanthranilate
1550	Methyl N-acetylanthranilate
1551	Methyl N,N-dimethylanthranilate
1552	N-Benzoylanthranilic acid
1553	Trimethyloxazole
1554	2,5-Dimethyl-4-ethyloxazole
1555	2-Ethyl-4,5-dimethyloxazole
1556	2-Isobutyl-4,5-dimethyloxazole
1557	2-Methyl-4,5-benzo-oxazole
1558	2,4-Dimethyl-3-oxazoline
1561	Butyl isothiocyanate
1562	Benzyl isothiocyanate
1563	Phenethyl isothiocyanate
1569	4,5-Dimethyl-2-propyloxazole
1570	4,5-Epoxy-(E)-2-decenal
1571	beta-Ionone epoxide
1573	Epoxyoxophorone
1579	Ethylamine
1580	Propylamine
1581	Isopropylamine
1583	Isobutylamine
1584	sec-Butylamine
1585	Pentylamine
1586	2-Methylbutylamine
1588	Hexylamine
1590	2-(4-Hydroxyphenyl)ethylamine
1591	1-Amino-2-propanol
1593	Butyramide
1594	1,6-Hexalactam
1595	2-Isopropyl-N,2,3-trimethylbutyramide
1596	N-Ethyl (E)-2,(Z)-6-nonadienamide
1597	N-Cyclopropyl (E)-2,(Z)-6-nonadienamide
1598	N-Isobutyl (E,E)-2,4-decadienamide
1602	(+/-)-N,N-Dimethyl menthyl succinamide
1603	1-Pyrroline
1604	2-Acetyl-1-pyrroline
1605	2-Propionylpyrroline
1606	Isopentylidene isopentylamine
1608	2-Methylpiperidine
1611	Triethylamine
1612	Tripropylamine
1613	N,N-Dimethylphenethylamine
1614	Trimethylamine oxide
1615	Piperazine

B. Flavouring agents evaluated at the 59th (2002), 61st (2003) and 63rd (2004) meetings

No.	Flavouring agent	Year	Note
963	Ethyl cyclohexanecarboxylate	2002	a
986	10-Hydroxymethylene-2-pinene	2002	a
1063	2,5-Dimethyl-3-furanthiol	2002	b
1065	Propyl 2-methyl-3-furyl disulfide	2002	a
1066	Bis(2-methyl-3-furyl) disulfide	2002	b
1067	Bis(2,5-dimethyl-3-furyl) disulfide	2002	b
1068	Bis(2-methyl-3-furyl) tetrasulfide	2002	a
1070	2,5-Dimethyl-3-furan thioisovalerate	2002	a
1077	Furfuryl isopropyl sulfide	2002	b
1082	2-Methyl-3,5- or 6-(furfurylthio)pyrazine	2002	b
1085	3-[(2-Methyl-3-furyl)thio]-4-heptanone	2002	a
1086	2,6-Dimethyl-3-[(2-methyl-3-furyl)thio]-4-heptanone	2002	a
1087	4-[(2-Methyl-3-furyl)thio]-5-nonanone	2002	a
1089	2-Methyl-3-thioacetoxy-4,5-dihydrofuran	2002	a
1157	4-Hydroxy-4-methyl-5-hexenoic acid gamma lactone	2003	a
1158	(+/-) 3-Methyl-gamma-decalactone	2003	a
1159	4-Hydroxy-4-methyl-7-cis-decenoic acid gamma lactone	2003	a
1160	Tuberose lactone	2003	a
1161	Dihydromintlactone	2003	a
1162	Mintlactone	2003	b
1163	Dehydromenthofurolactone	2003	b
1164	(+/-)-(2,6,6,-Trimethyl-2-hydroxycyclohexylidene)acetic acid gamma-lactone	2003	a
1167	2-(4-Methyl-2-hydroxyphenyl)propionic acid-gamma-lactone	2003	a
1174	2,4-Hexadien-1-ol	2003	a
1176	(E,E)-2,4-Hexadienoic acid	2003	a
1180	(E,E)-2,4-Octadien-1-ol	2003	a
1183	2,4-Nonadien-1-ol	2003	a
1188	(E,Z)-2,6-Nonadien-1-ol acetate	2003	a
1189	(E,E)-2,4-Decadien-1-ol	2003	a
1191	Methyl (E)-2-(Z)-4-decadienoate	2003	a
1193	Ethyl 2,4,7-decatrienoate	2003	a
1199	(+/-)-2-Methyl-1-butanol	2003	a
1217	2-Methyl-2-octenal	2003	a
1218	4-Ethyloctanoic acid	2003	a
1226	8-Ocimenyl acetate	2003	a
1228	3,7,11-Trimethyl-2,6,10-dodecatrienal	2003	a
1229	12-Methyltridecanal	2003	a
1232	1-Ethoxy-3-methyl-2-butene	2003	b
1236	2,2,6-Trimethyl-6-vinyltetrahydropyran	2003	b
1239	Cycloionone	2003	a
1245	2,4-Dimethylanisole	2003	a
1248	1,2-Dimethoxybenzene	2003	a
1265	4-Propenyl-2,6-dimethoxyphenol	2003	a
1289	erythro- and threo-3-Mercapto-2-methylbutan-1-ol	2003	b
1290	(±)-2-Mercaptomethylpentan-1-ol	2003	b
1292	3-Mercapto-2-methylpentanal	2003	b
1293	4-Mercapto-4-methyl-2-pentanone	2003	b
1296	spiro[2,4-Dithia-1-methyl-8-oxabicyclo(3.3.0)octane-3,3'-(1'-oxa-2'-methyl)-cyclopentane]	2003	a
1299	2,3,5-Trithiahexane	2003	b
1300	Diisopropyl trisulfide	2003	b
1311	2-(2-Methylpropyl)pyridine	2004	a
1319	2-Propionylpyrrole	2004	b

No.	Flavouring agent	Year	Note
1322	2-Propylpyridine	2004	a
1334	4-Methylbiphenyl	2004	b
1342	delta-3-Carene	2004	a
1343	alpha-Farnesene	2004	a
1344	1-Methyl-1,3-cyclohexadiene	2004	a
1367	trans-2-Octen-1-yl acetate	2004	b
1368	trans-2-Octen-1-yl butanoate	2004	b
1369	Cis-2-Nonen-1-ol	2004	b
1370	(E)-2-Octen-1-ol	2004	a
1371	(E)-2-Butenoic acid	2004	a
1372	(E)-2-Decenoic acid	2004	a
1373	(E)-2-Heptenoic acid	2004	a
1374	(Z)-2-Hexen-1-ol	2004	a
1375	trans-2-Hexenyl butyrate	2004	a
1376	(E)-2-Hexenyl formate	2004	a
1377	trans-2-Hexenyl isovalerate	2004	a
1378	trans-2-Hexenyl propionate	2004	a
1379	trans-2-Hexenyl pentanoate	2004	a
1380	(E)-2-Nonenoic acid	2004	a
1381	(E)-2-Hexenyl hexanoate	2004	a
1382	(Z)-3- & (E)-2-Hexenyl propionate	2004	a
1384	2-Undecen-1-ol	2004	a
1407	Dihydronootkatone	2004	b
1409	beta-Ionyl acetate	2004	a
1410	alpha-Isomethylionyl acetate	2004	a
1411	3-(l-Menthoxy)-2-methylpropane-1,2-diol	2004	a
1412	Bornyl butyrate	2004	a
1413	D,L-Menthol(+/-)-propylene glycol carbonate	2004	a
1414	L-Monomenthyl glutarate	2004	a
1415	L-Menthyl methyl ether	2004	a
1416	p-Menthane-3,8-diol	2004	a
1435	Taurine	2004	a
1438	L-Arginine	2004	a
1439	L-Lysine	2004	a
1447	Tetrahydrofurfuryl cinnamate	2004	a
1457	(+/-)-2-(5-Methyl-5-vinyl-tetrahydrofuran-2-yl)propionaldehyde	2004	a
1475	Ethyl 2-ethyl-3-phenylpropanoate	2004	a
1478	2-Oxo-3-phenylpropionic acid	2004	a

[a]Flavourings where only anticipated poundage data were available
[b]Flavourings where the MSDI derived from anticipated poundage data from the US was greater than the MSDI derived from recorded poundage data of the EU.