CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



Agenda Item 7

CX/FA 13/45/15 November 2012

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fifth Session

Beijing, China, 18-22 March 2013

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 76TH JECFA MEETING

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the following Specifications for the Identity and Purity of Food Additives arising from the 76th JECFA Meeting (see Annex) are invited to do so **no later than 31 January 2013** as follows: Secretariat, Codex Committee on Food Additives, China National Center for Food Safety Risk Assessment (CFSA), Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing 100022, China, (E-mail: <u>secretariat@ccfa.cc</u>), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (E-mail: <u>Codex@fao.org</u>).

BACKGROUND

1. Specifications for 115 food additives (8) and flavourings (107) were discussed and prepared or revised at the 76th JECFA meeting (Geneva, Switzerland, 5 -14 June 2012) and the resulting monographs are available (in English only) on JECFA Online Edition of: "Combined Compendium of Food Additive Specifications" <u>http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en</u>. Monographs resulting from the 76th JECFA meeting will be published as FAO JECFA Monographs 13, FAO, Rome, 2012. The publication will be available to download as pdf-document at the FAO JECFA website at: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/

2. These specifications cover:

	Food Additives	Flavourings
New:	5	107
Revised:	3	-
Maintained	-	36
Revised – not republished	-	-
Full:	8	105
Tentative:	-	2
Withdrawn:	1	

3. The Committee is being asked to review these specifications, in particular those designated as "Full" (see first part of the Annex), with a view to recommending their adoption by the Commission as Codex Specifications, taking into account comments received.

4. The specifications for mineral oil (medium and low viscosity) were withdrawn, since the temporary ADI for low viscosity oils (Class II and III) has been withdrawn. For the remaining mineral oils of medium viscosity (Class I), which enjoy a separate ADI, new specifications were prepared.

5. From the 107 of the new flavourings reviewed during the 76th JECFA meeting 105 flavourings were given full specifications. Those are listed in second part of the Annex.

6. The full specifications prepared for the flavourings with JECFA Nos 2093, 2137, 2147-2150, 2152, 2156, and 2158-2160 include a statement made by the 76th JECFA that additional data are required to complete evaluation., and that the evaluation of No. 2151 is temporary pending receipt of additional toxicological data. The CCFA may consider whether or not to adopt the specifications for these flavourings.

7. In the flavouring specifications that have been assigned a tentative status (JECFA Nos. 2153, 2154), the outstanding information which is to be submitted to the JECFA Secretariat is defined. The CCFA is invited to note these requests for information and data.

8. The specifications for the flavourings with JECFA Nos 1491-1494, 1497, 1499, 1503-1505, 1507-1511, 1513-1517, 1520-1526, 1495-1496, 1498, 1500-1502, 1506, 1512 and 1518-1519 were maintained at the 76th JECFA meeting. <u>These have been adopted already in 2006 by the Commission as Codex</u> <u>specifications</u>. The safety evaluation of these flavourings is not yet completed.

Annex

SPECIFICATIONS AND ACTIONS RESULTING FROM THE 76^{TH} JECFA MEETING

(at Step 3)

FOOD ADDITIVES

SPECIFICATIONS DESIGNATED AS *FULL* (FAO JECFA Monographs 11, Rome, 2011):¹

Ethyl cellulose (R) (INS 462)

Magnesium dihydrogen diphosphate (N) (INS 450(ix))

Mineral oil (medium viscosity) (N)

Modified starches (R)

3-Phytase from Aspergillus niger expressed in Aspergillus niger (N)

Serine protease (chymotrypsin) from Nocardiopsis prasina expressed in Bacillus licheniformis (N)

Serine protease (trypsin) from Fusarium oxysporum expressed in Fusarium venenatum (N)

Titanium dioxide (R) (INS 171)

SPECIFICATIONS WITHDRAWN:

Mineral oil (medium and low viscosity)

The 76th JECFA noted that the temporary group ADI for mineral oil (medium and low viscosity) classes II and III (INS 905f, g) had been established in 1995 and extended on a number of occasions. As data supporting the establishment of a full ADI had not been made available, the previously established temporary group ADI was withdrawn.

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⁽N) new specifications; (R) revised specifications; (T) tentative specifications;

FLAVOURINGS

NEW AND FULL SPECIFICATIONS PREPARED BY THE 76th JECFA

JECFA No.	Flavouring
2043	2-Aminoacetophenone
2077	(2E,6E/Z,8E)-N-(2-Methylpropyl)-2,6,8-decatrienamide
2078	(2S,5R)-N-[4-(2-Amino-2-oxoethyl)phenyl]-5- methyl-2-(propan-2-yl)cyclohexanecarboxamide
2079	(1R,2S,5R)-N-(4-Methoxyphenyl)-5-methyl-2-(1- methylethyl)cyclohexanecarboxamide
2080	N-Cyclopropyl-5-methyl-2-isopropylcyclohexanecarboxamide
2081	N-(2-Methylcyclohexyl)-2,3,4,5,6-Pentafluorobenzamide
2082	3[(4-Amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide
2133	3,6-Dimethyl-2,3,3a,4,5,7ahexahydrobenzofuran
2134	Ethyl linalyl ether
2135	Linalool oxide pyranoid
2137	Nerolidol oxide
2138	Methyl hexyl ether
2139	Myrcenyl methyl ether
2142	Digeranyl ether
2136	Isoamyl phenethyl ether
2140	5-Isopropyl-2,6-diethyl-2- methyltetrahydro-2H-pyran
2141	Butil β-naphthyl ether
2103	(E)-Ethyl 3-(2-furyl)acrylate
2104	Di-2-furylmethane
2105	2-Methylbenzofuran
2163	trans-2-Nonenyl acetate
2164	N Propyl sorbate
2165	cis-2-Octenol
2166	trans-2-Tridecenol
2167	Ethyl 2-hexenoate (mixture of isomers)
2120	L-Ornithine (as the monochlorohydrate)
2121	L-Alanyl-L-glutamine
2122	L-Methionylglycine
2123	Glutamyl-valyl-glycine
2118	L-Isoleucine
2119	L-Threonine
2143	Ethyl α-ethyl- β-methyl- β-phenylglycidate
2144	Methyl β-phenylglycidate
2145	d-8-p-Menthene-1,2-epoxide
2146	I-8-p-Menthene-1,2-epoxide
2099	5-Methylfurfuryl alcohol
2100	Furfural propyleneglycol acetal
2101	Furfuryl formate
2102	Furfuryl decanoate
2177	cis-3-Nonen-1-ol
2178	trans-3-Nonen-1-ol

JECFA No.	Flavouring
2179	cis,cis-3,6-Nonadienyl acetate
2180	trans-3-Hexenyl acetate
2181	<i>cis</i> -3-Hexenoic acid
2182	cis-3-Nonenyl acetate
2183	cis-6-Nonenyl acetate
2184	(Z)-5-Octenyl acetate
2185	(E)-4-Undecenal
2161	3-(1-((3,5-Dimethylisoxazol-4-yl)methyl)-1Hpyrazol-4-yl)-1-(3-hydroxybenzyl)-imidazolidine-2,4-dione
2162	3-(1-((3,5-Dimethylisoxazol-4-yl)methyl)-1Hpyrazol-4-yl)-1-(3-hydroxybenzyl)-5,5-dimethylimidazolidine- 2,4-dione
2170	3',7-Dihydroxy-4-methoxyflavan
2171	Trilobatin
2172	(±)-Eriodictyol
2125	Isopropenylpyrazine
2126	5-Ethyl-2,3-dimethylpyrazine
2127	2-Methyl-5-vinylpyrazine
2128	A ixture of 2,5-dimethyl-6,7-dihydro-5Hcyclopentapyrazine'and 2,7-dimethyl-6,7- dihydro-5H- cyclopentapyrazine
2065	2-Ethoxy-3-isopropylpyrazine
2130	3,5- and 3,6-Dimethyl-2-isobutylpyrazine
2131	2-Ethoxy-3-ethylpyrazine 2
2132	-Ethyl-3-methylthiopyrazine
2155	2-Acetyl-4-isopropylpyridine
2157	6-Methoxyquinoline
2173	3-Methylhexanal
2174	6-Methylheptanal
2175	6-Methyloctanal
2176	3,7-Dimethyloctanal
2086	1-(Methylthio)-3-octanone
2089	4-Methyl-2-propyl-1,3-oxathiane
2083	3-Pentanethiol
2084	4-Mercapto-3-methyl-2-butanol
2085	Ethyl 2-mercapto-2-methylpropionate
2087	1,1-Propanedithiol
2088	1-Methyldithio-2-propanone
2106	2-Pentylthiophene
2107	2-Acetyl-5-methylthiophene
2108	2-Pentylthiazole
2109	4,5-Dimethyl-2-isobutylthiazole
2110	3,4-Dimethylthiophene
2111	2-Thienylmethanol
2112	1-(2-Thienyl)ethanethiol
2113	5-Ethyl-2-methylthiazole
2114	2-Ethyl-2,5-dihydro-4-methylthiazole
2115	4-Methyl-3-thiazoline

JECFA No.	Flavouring
2116	2-Ethyl-4,6-dimethyldihydro-1,3,5-dithiazine
2117	4-Amino-5,6-dimethylthieno[2,3-d]pyrimidin-2(1H)-one hydrochloride
2090	5-Methylfurfuryl mercaptan
2091	2-Methyl-3-furyl methylthiomethyl disulfide
2092	2-Methyl-3-furyl 2-methyl-3-tetrahydrofuryl disulfide
2094	Methyl 3-(furfurylthio)propionate
2095	3-[(2-Methyl-3-furyl)thio]butanal
2096	1-(2-FurfuryIthio)-propanone
2097	2-Methyl-4,5-dihydrofuran-3-thiol
2098	2-Methyltetrahydrofuran-3-thiol acetate

FLAVOURINGS WITH NEW AND FULL SPECIFICATIONS FOR WHICH ADDITIONAL DATA ARE REQUIRED TO COMPLETE THE EVALUATION

JECFA No.	Flavouring
2147	2,3-Epoxyoctanal
2148	2,3-Epoxyheptanal
2149	2,3-Epoxydecanal
2150	1-Ethyl-2-pyrrolecarboxaldehyde
2151	2,4-Dimethylpyridine
2152	1-Methyl-1H-pyrrole-2-carboxaldehyde
2156	2-Methoxypyridine
2158	1-(2-Hydroxyphenyl)-3-(pyridine-4-yl)propan-1-one
2159	1-(2-Hydroxy-4-isobutoxyphenyl)-3- (pyridine-2-yl)propan-1-one N
2160	1-(2-Hydroxy-4-methoxyphenyl)-3-(pyridine-2-yl)propan-1-one
2093	2-Tetrahydrofurfuryl 2-mercaptopropionate

FLAVOURINGS WERE GIVEN NEW AND TENTATIVE SPECIFICATIONS BY THE 76th JECFA

JECFA No.	Flavouring
2153	2-Acetyl-4-isopropenylpyridine
2154	4-Acetyl-2-isopropenylpyridine