

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 13

CX/FAC 05/37/17
March 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 63rd JECFA MEETING

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 4 April 2005** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - *preferably*).

BACKGROUND

1. Specifications for 217 food additives and flavouring agents were discussed and prepared at the 63rd JECFA meeting (Geneva, June 2004) and are published in Addendum 12 to the “Compendium of Food Additive Specifications” (FAO Food and Nutrition Paper 52-Add. 12 – distributed under separate cover). The Compendium is also available on the JECFA website: http://www.fao.org/es/ESN/jecfa/whatisnew_en.stm. These specifications cover:

	<u>Food additives</u>	<u>Flavouring agents</u>
Total:	20	197
New (Revised):	10 (9)	176 (18)
Full:	16	192
Tentative:	3	5 (3 maintained)

2. Limits for arsenic, lead, cadmium, and mercury for 83 additives were revised or established, as necessary, and published in Addendum 12. The Commission has previously adopted the complete specifications of 71 of these 83 additives as Codex Advisory Specifications. The Committee is being asked to review the revised or newly established limits for arsenic, lead, cadmium, and mercury for the 71 additives in order to recommend their adoption by the Commission as revised Codex Specifications, taking into account comments received.

3. Comments are also invited on the Principles Governing the Establishment and Revision of Specifications, which are elaborated in Section A of Food and Nutrition Paper 52 - Add. 12.

AD HOC WORKING GROUP**Consideration of Specifications**

4. Comments will be considered at a meeting of the *ad hoc* Working Group on Specifications, which was established at the 36th Session of the Committee. The Provisional Agenda is included in the Annex (below). The specifications will be classified into Categories I, II, III, IV, or V, according to the established procedures. An explanation of the five categories is provided in the Annex.
5. The 17 additives given full specifications at the 63rd JECFA are listed in the Annex. A separate list of the additives for which specifications were designated tentative is also given in the Annex.
6. Limits for arsenic, lead, cadmium, and mercury for 83 additives were revised or established, as necessary, at the 63rd JECFA, in accordance with the procedure and principles elaborated at the 53rd JECFA (Rome, June 1999) and stated in FAO Food and Nutrition Paper 52 – Add. 7. Only the limits for those additives (71, see the Annex) whose complete specifications are already adopted as Codex Advisory Specifications will be open for discussion and classified as either Category I or III. Those placed in Category I will be recommended for endorsement by the Committee as revisions to their existing Codex Specifications.
7. Of the 197 flavouring agent specifications reviewed during the 63rd JECFA, 5 are designated as tentative (see Annex) and will be assigned to Category IV or V. This leaves 192 for consideration during the session. To avoid protracted discussions, the Working Group will be asked to identify only those specifications that it considers unsuitable for recommendation as Codex Specifications (i.e., Category I). The JECFA numbers for all 197 substances are included in the Annex.

Consideration of Principles

8. The Working Group will also have the opportunity to comment on the Principles Governing the Establishment and Revision of Specifications. See item VI of the Provisional Agenda in the Annex.

AD HOC WORKING GROUP ON SPECIFICATIONS

Saturday 23 April 2005, 10:30-12:30 hours

PROVISIONAL AGENDA

- I. Introductions
- II. Approval of the Agenda
- III. Comments from the Codex and JECFA Secretariats
- IV. Comments by the Working Group Chairman
- V. Review of Category Definitions (see below)
- VI. Review of Comments Submitted on the Specifications for the Identity and Purity of Food Additives (FAO FNP 52 - Add. 12) arising from the 63rd JECFA Meeting
 - A. Additives (uses other than as flavouring agents)
 - B. Revision of limits for heavy metals and arsenic for certain additives
 - C. Specifications for certain flavouring agents
 - D. Principles governing the establishment and revision of specifications (see also Annex 3 of “Summary and Conclusions” of the 63rd JECFA, Geneva, June 2004)
 - i. *Flavour complexes derived from natural sources*
 - ii. *Determination of carotenoids*
 - iii. *Revision of heavy metals and arsenic specifications*
- VII. Other Business
- VIII. Reestablishment of the Working Group

SPECIFICATIONS CATEGORIES

- I. Specifications that are suitable for submission to the Commission for final adoption as Codex Specifications;
- II. Specifications that will be suitable for submission to the Commission for final adoption as Codex Specifications after editorial changes have been made;
- III. Specifications that require substantive changes before they are considered suitable as Codex Specifications and which should be held at Step 2 of the Specifications Procedures pending further advice from JECFA;
- IV. Specifications that have been revised by recent sessions of JECFA or that may be revised at the forthcoming session;
- V. Specifications that are incomplete and have been designated by JECFA as tentative (and, therefore, are not to be considered for adoption as Codex Specifications).

SPECIFICATIONS DESIGNATED AS FULL AT THE 63rd JECFA (FNP 52 - ADD. 12, Geneva, 2004) FOR THE FOLLOWING ADDITIVES:

Acetic acid
Aluminium lakes of colouring matters – General specifications
Aluminium powder
Benzoyl peroxide
Hexose oxidase from <i>Chondrus crispus</i> expressed in <i>Hansenula polymorpha</i>
Hydrogen peroxide
1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)
Hydroxypropyl cellulose
Hydroxypropylmethyl cellulose

Iron oxides
Lutein from <i>Tagetes erecta</i>
Octanoic acid
Polyvinyl alcohol
Titanium dioxide
Xylanase (resistant to xylanase inhibitor) from <i>Bacillus subtilis</i> containing a modified xylanase gene from <i>Bacillus subtilis</i>
Xylanase from <i>Bacillus subtilis</i> expressed in <i>Bacillus subtilis</i>
Zeaxanthin (Synthetic)

SPECIFICATIONS DESIGNATED AS TENTATIVE AT THE 63rd JECFA (FNP 52 - ADD. 12, Geneva, 2004) FOR THE FOLLOWING ADDITIVES:

Magnesium sulfate
Steviol glycosides

Zeaxanthin-rich extract from <i>Tagetes erecta</i>
--

REVISION OF ARSENIC and HEAVY METALS LIMITS (mg/kg) FOR CERTAIN ADDITIVES (THE 63rd JECFA; SEE FNP 52 - ADD. 12):

Additive name	INS	As	Pb	Cd	Hg
Aluminium ammonium sulfate	523	-	3	-	-
Ammonium chloride	510	-	2	-	-
Ammonium hydrogen carbonate	503 (ii)	-	2	-	-
Azodicarbonamide	927 a	-	2	-	-
Bees wax	901	-	2	-	-
Benzoic acid	210	-	2	-	-
Benzyl alcohol	-	-	2	-	-
Butan-1,3-diol	-	-	2	-	-
Butan-1-ol	-	-	2	-	-
Butan-2-ol	-	-	2	-	-
Butyl <i>p</i> -hydroxybenzoate	-	-	2	-	-
Calcium acetate	263	-	2	-	-
Calcium benzoate	213	-	2	-	-
Calcium carbonate	170	3	3	-	-
Calcium chloride	509	-	2	-	-
Calcium cyclamate	952	-	1	-	-
Calcium hydrogen phosphate	341 (ii)	3	4	-	-
Calcium sulfate	516	-	2	-	-
Candelilla wax	902	-	2	-	-
Castor oil	1503	-	2	-	-
Chlorine	925	-	2	-	1

Additive name	INS	As	Pb	Cd	Hg
Citranaxanthin	-	-	2	-	-
Cyclodextrin, beta-	459	-	1	-	-
Cyclohexane	-	-	2	-	-
Dammar gum	-	-	2	-	-
Diethyl tartrate	-	-	2	-	-
Diethylene glycol monoethyl ether	-	-	2	-	-
Dimethyl dicarbonate	242	-	2	-	-
Ferric ammonium citrate	-	-	2	-	-
Glycerol	422	-	2	-	-
Glycerol diacetate	-	-	2	-	-
Heptanes	-	-	2	-	-
Hexamethylene tetramine	239	-	2	-	-
Isoamyl acetate	-	-	2	-	-
Isobutanol	-	-	2	-	-
Isopropyl acetate	-	-	2	-	-
Lactic acid	270	-	2	-	-
Light petroleum	-	-	2	-	-
Lysozyme hydrochloride	1105	-	2	-	-
Magnesium chloride	511	-	2	-	-
Magnesium hydrogen phosphate	343 (ii)	3	4	-	-
Magnesium lactate	329	-	2	-	-

Methanol	-	2	-	-
Mineral oil (high viscosity)	905d	-	1	-
Monoglyceride citrate		-	2	-
Potassium acetate	261	-	2	-
Potassium benzoate	212	-	2	-
Potassium bromate	924 a	-	2	-
Potassium chloride	508	-	2	-
Potassium dihydrogen phosphate	340 (i)	3	4	-
Potassium iodate	917	-	2	-
Potassium nitrate	252	-	2	-
Potassium nitrite	249	-	2	-
Potassium sodium L(+) tartrate	337	-	2	-
Potassium sulfate	515 (i)	-	2	-
Propylene glycol	1520	-	2	-
Sodium benzoate	211	-	2	-

Sodium carboxymethyl cellulose	466	-	2	-
Sodium cyclamate	952	-	1	-
Sodium diacetate	262 (ii)	-	2	-
Sodium nitrate	251	-	2	-
Sodium nitrite	250	-	2	-
Sodium percarbonate		-	2	-
Sodium thiocyanate		-	2	-
Sorbic acid	200	-	2	-
Sucralose	955	-	1	-
Tannic acid	181	-	2	-
Toluene		-	2	-
Triacetin	1518	-	2	-
Trichlorotrifluoroethane, 1,1,2-		-	2	-
Urea	927 b	-	2	-

JECFA NUMBERS FOR FLAVOURING AGENTS GIVEN FULL SPECIFICATIONS (including those for which an existing specification was maintained or a tentative designation removed) BY THE 63rd JECFA (SEE FNP 52 - ADD. 12):

53, 55, 68, 399, 471, 504, 557, 570, 605, 615, 628, 919, 1203, 1218, 1263, 1273, 1291, 1296, 1301 – 1325, 1327 – 1416, 1418 – 1432, 1434, 1435, 1437 – 1478 (Total 192).

JECFA NUMBERS FOR FLAVOURING AGENTS GIVEN TENTATIVE SPECIFICATIONS (including those for which an existing tentative designation was maintained) BY THE 63rd JECFA (SEE FNP 52 - ADD. 12):

631.2, 632.2, 633.2, 1326, 1479 (Total 5).

SPECIFICATIONS WITHDRAWN BY THE 63rd JECFA:

None.