

# 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 10(b)

CX/FAC 04/36/12  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

#### Thirty-sixth Session

Rotterdam, The Netherlands, 22 - 26 March 2004

#### SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 61<sup>st</sup> 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 15 February 2004** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: [info@codexalimentarius.nl](mailto: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](mailto:Codex@fao.org) - *preferably* -).

#### BACKGROUND

1. Specifications for 268 food additives and flavouring agents were discussed and prepared at the 61<sup>st</sup> JECFA meeting (Rome, June 2003) and are published in Addendum 11 to the "Compendium of Food Additive Specifications" (FAO Food and Nutrition Paper 52-Add. 11 – distributed under separate cover). These specifications cover:

	<u>Food additives</u>	<u>Flavouring agents</u>
Total:	23	245
New (Revised):	7 (14)	139 (106)
Full:	15 (1 maintained)	225
Tentative:	8 (1 maintained)	20

Additionally, the 61<sup>st</sup> JECFA established new specifications, also published in Addendum 11, for a water-treatment agent (sodium dichloroisocyanurate) and a nutritional source of iron (ferrous glycinate (processed with citric acid)). The Committee will not be asked to consider these two substances.

2. Revised limits for arsenic and lead for 39 additives were also established and published in Addendum 11. The functional uses of these additives include absorbent, antioxidant, antifoaming, carrier solvent, clouding agent, colour retention, emulsifier, and sequestrant applications. The Commission has previously adopted the complete specifications of 33 of these 39 additives as Codex Advisory Specifications. The Committee is being asked to review the newly established or revised limits for arsenic and lead for the 33 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. 11.

**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 by the 35th 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 15 additives given full specifications at the 61<sup>st</sup> JECFA are listed in the Annex. A separate list of the additives for which specifications were designated tentative is also given in Annex.
6. Limits for lead and arsenic for 39 additives were established or revised at the 61st 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 (33, see 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 245 flavouring agent specifications established during the 61st JECFA, 20 are designated as tentative (see Annex) and will be assigned to Category IV or V. This leaves 225 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 245 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***Sunday 21 March 2004, 08:30 – 10:30 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. 11) arising from the 61st JECFA Meeting
  - A. Additives (uses other than as flavouring agents)
  - B. Revision of limits for heavy metals 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 61st JECFA, Rome June 2003)
    - i. *Working definition of “flavouring agent”*
    - ii. *Compendium of food additive specifications and Guide to specifications*
    - iii. *Safety evaluation of natural flavouring complexes*
    - iv. *Chemical and Technical Assessments*
    - v. *Specifications of purity for flavouring agents*
    - vi. *Residual solvents*

## VII. Other Business

**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 61st JECFA (FNP 52 - ADD. 11, Rome, 2003) FOR THE FOLLOWING ADDITIVES:**

*alpha*-Amylase from *Bacillus licheniformis* containing a genetically engineered *alpha*-amylase gene from *B. licheniformis*

Curcumin

*beta*-Carotene from *Blakeslea trispora*

Laccase from *Myceliophthora thermophila* expressed in *Aspergillus oryzae*

Magnesium silicate

Natamycin

Neotame

Polyvinyl alcohol

Quillaia extract (Type 1)

Quillaia extract (Type 2)

Sucrose esters

D-Tagatose

Talc

*mixed* Xylanase, *beta*-glucanase enzyme preparation, produced by a strain of *Humicola insolens*

Xylanase from *Thermomyces lanuginosus* expressed in *Fusarium venenatum*

**SPECIFICATIONS DESIGNATED AS TENTATIVE AT THE 61st JECFA (FNP 52 - ADD. 11, Rome, 2003) FOR THE FOLLOWING ADDITIVES:**

Annatto extract (solvent-extracted bixin)

Annatto extract (solvent-extracted norbixin)

Annatto extract (oil-processed bixin suspension)

Annatto extract (aqueous-processed bixin)

Annatto extract (alkali-processed norbixin)

Annatto extract (alkali-processed norbixin, not acid-precipitated)

Monomagnesium phosphate

Trisodium diphosphate

**REVISION OF HEAVY METALS LIMITS FOR CERTAIN ADDITIVES AT THE 61st JECFA (SEE FNP 52 - ADD. 11):**

<b>Additive name</b>	<b>INS</b>	<b>As</b>	<b>Pb</b>	<b>Additive name</b>	<b>INS</b>	<b>As</b>	<b>Pb</b>
Activated carbon		3	5	Octyl gallate	0311	-	2
Aluminium potassium sulfate	0522	-	5	Polydimethyl siloxane	0900	-	1
Aluminium sulfate (anhydrous)	0520	-	5	Potassium lactate (solution)	0326	-	2
Ascorbic acid	0300	-	2	Potassium polyphosphates	0452 (ii)	3	4
Ascorbyl palmitate	0304 (i)	-	2	Propyl gallate	0310	-	2
Bone phosphate	0542	3	2	Sodium aluminium phosphate, acidic	0541 (i)	3	2
Butylated hydroxyanisole (BHA)	0320	-	2	Sodium erythorbate	0316	-	2
Calcium ascorbate	0302	-	2	Sodium lactate (solution)	0325	-	2
Calcium disodium ethylenediaminetetraacetate	0385	-	2	Stannous chloride	0512	-	2
Cupric sulfate	0519	-	10	Sucrose acetate isobutyrate	0444	-	2
Dilauryl thiodipropionate	0389		2	Tertiary butylhydroquinone	0319	-	2
Disodium ethylenediaminetetraacetate	0386	-	2	Thiodipropionic acid	0388	-	2
Dodecyl gallate	0312	-	2	Tocopherol concentrate mixed	0307 b	-	2
Erythorbic acid	0315		2	Tocopherol concentrate, d-alpha	0307 a	-	2
Ethyl protocatechuate	-		2	Tocopherol, dl-alpha	0307 c	-	2
Ferrous lactate	0585	-	1	Triethyl citrate	1505	-	2
Isopropyl citrate mixture	0384	-	2				
Lecithin	0322	-	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 61st JECFA (SEE FNP 52-ADD. 11):**

42, 54, 56, 57, 60, 61, 62, 65, 66, 71, 73, 95, 98, 101, 104, 107, 110, 112, 117, 119, 124, 170, 180, 205, 212, 237, 244, 272, 302, 303, 322, 323, 325, 329, 332, 337, 338, 346, 348, 349, 358, 360, 384, 385, 396, 397, 409, 410, 417, 419, 422, 423, 435, 443, 465, 468, 470, 473, 479, 480, 488, 489, 495, 502, 519, 548, 556, 559, 568, 569, 571, 583, 586, 590, 592, 603, 604, 625, 668, 669, 704, 735, 737, 918, 923, 924, 937, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1164, 1165, 1166, 1167, 1168, 1169, 1170, 1171, 1172, 1173, 1174, 1175, 1176, 1177, 1178, 1179, 1180, 1181, 1182, 1183, 1184, 1185, 1186, 1187, 1188, 1189, 1190, 1191, 1192, 1193, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1202, 1204, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1213, 1214, 1215, 1216, 1217, 1219, 1220, 1221, 1222, 1223, 1224, 1225, 1226, 1227, 1228, 1229, 1230, 1231, 1232, 1233, 1234, 1235, 1236, 1237, 1238, 1239, 1240, 1241, 1242, 1243, 1244, 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1253, 1254, 1255, 1256, 1257, 1258, 1259, 1260, 1261, 1262, 1264, 1265, 1266, 1267, 1268, 1269, 1270, 1271, 1272, 1274, 1275, 1276, 1277, 1278, 1279, 1280, 1281, 1282, 1283, 1284, 1285, 1286, 1287, 1288, 1289, 1290, 1292, 1293, 1294, 1295, 1297, 1298, 1299, 1300 (**Total 225**)

**JECFA NUMBERS FOR FLAVOURING AGENTS GIVEN TENTATIVE SPECIFICATIONS (including those for which an existing tentative designation was maintained) BY THE 61st JECFA (SEE FNP 52-ADD. 11):**

53, 55, 68, 399, 471, 504, 557, 570, 605, 615, 628, 631.2, 632.2, 633.2, 1203, 1218, 1263, 1273, 1291, 1296  
**(Total 20)**

**SPECIFICATIONS WITHDRAWN BY THE 61st JECFA:**

None