

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 11

CX/FA 07/39/17

December 2006

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Thirty-ninth Session

Beijing, China, 24-28 April 2007

### SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 67<sup>th</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 28 February 2007** as follows: Secretariat, Codex Committee on Food Additives, National Institute of Nutrition and Food Safety, China CDC, 7 Panjiayuan Nanli, Chaoyang District, Beijing 100021, China (Telefax: + 86 10 67711813, E-mail: [secretariat@ccfa.cc](mailto:secretariat@ccfa.cc) *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org) - *preferably*).

## BACKGROUND

1. Specifications for 24 food additives were discussed and prepared or reviewed at the 67<sup>th</sup> JECFA meeting (Rome, June 2006) and the resulting monographs are published in FAO JECFA Monographs 3, FAO, Rome, 2006 and available on JECFA website at FAO as follows: <http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en> and on: <ftp://ftp.fao.org/docrep/fao/009/a0675e/a0675e00.pdf> (in English only)
2. These specifications, including “General specifications and considerations for enzyme preparations used in food processing”, cover:

New:	4
Revised:	15
Revised – not republished	2
Full:	14
Tentative:	5
Withdrawn:	3
3. The Committee is being asked to review these specifications, in particular those designated as “Full”, with a view to recommending their adoption by the Commission as Codex Specifications, taking into account comments received.
4. A recent review comparing Codex specifications with existing JECFA specifications has been carried out. As a result JECFA specifications for 11 substances were identified to differ significantly from the adopted Codex specifications. A list of these substances is shown in Annex 3 to this document together with an indication of the actual difference and explanations for the changes.

5. The 11 substances can be grouped in the following way:
- |  |   |
|--|---|
| Substances for which JECFA has withdrawn the specifications:   | 6 |
| Substances for which JECFA has revised the criteria for inorganic impurities:                              | 3 |
| Substance for which JECFA has revised the specification and introduced a new criterion for safety reasons: | 1 |
| Substance for which JECFA has revised the specification and designated them as tentative:                  | 1 |
6. The Committee is being asked to review the Codex status for the specifications for these substances and to recommend to the Commission what action should be taken, taking into account comments received.

## **AD HOC WORKING GROUP**

### **Consideration of Specifications**

7. Comments on the specifications resulting from the 67<sup>th</sup> JECFA will be considered at a meeting of the *ad hoc* Working Group on Specifications, which was established at the 38<sup>th</sup> Session of the Committee. The Provisional Agenda is included in the Annex 1 of this document. 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 Annex 1.
8. The 14 additives given full (new and revised) specifications at the 67<sup>th</sup> JECFA are listed in Annex 2. Separate lists of the additives for which specifications were designated as tentative (5), withdrawn (2) or revised without being republished are also given in the Annex.
9. Comments on the General specifications and considerations for enzyme preparations used in food processing will be considered and classified into one of the categories (see item VI A of the Provisional Agenda).

### **Consideration of JECFA Specifications that are different from adopted Codex Specifications**

10. Comments on the substances listed in Annex 3 together with an indication of actual changes made by JECFA and the reasons for the changes will also be considered in order to prepare recommendations to the Committee for actions to be taken on the individual substances.

**Annex 1****AD HOC WORKING GROUP ON SPECIFICATIONS****Monday 23 April 2007, 14:00-16:00 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 Compendium of Food Additives Specifications (FAO JECFA Monographs 3, Rome, 2006) arising from the 67<sup>th</sup> JECFA Meeting
  - A. Specifications for additives
  - B. General specifications and considerations for enzyme preparations used in food processing (see also Annex 3 of “Summary and Conclusions” of the 67<sup>th</sup> JECFA, Rome, June 2007)
- VII. Substances for which adopted Codex Specifications differs from existing JECFA 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).

## Annex 2

SPECIFICATIONS RESULTING FROM THE 67<sup>th</sup> JECFA**SPECIFICATIONS DESIGNATED AS FULL AT THE 67<sup>th</sup> JECFA (FAO JECFA Monographs 3, Rome, 2006):<sup>1</sup>**

Annatto extracts (alkali-processed norbixin, acid-precipitated) (R)  
 Annatto extracts (alkali-processed norbixin, not acid-precipitated) (R)  
 Annatto extracts (aqueous-processed bixin) (R)  
 Annatto extracts (solvent extracted bixin) (R)  
 Annatto extracts (solvent extracted norbixin) (R)  
 Calcium DL-malate (R)  
 Lycopene (synthetic) (N)  
 Lycopene from *Blakeslea trispora* (N)  
 DL-malic acid (R)  
 Sodium hydrogen DL-malate (R)  
 Sodium DL-malate (R)  
 Titanium dioxide (R)  
 Zeaxanthin (synthetic) (R)  
 General specifications and considerations for enzyme preparations used in food processing (R)

**SPECIFICATIONS DESIGNATED AS TENTATIVE AT THE 67<sup>th</sup> JECFA (FAO JECFA Monographs 3, Rome, 2006):**

Annatto extracts (oil-processed bixin) (R)  
 Carob bean gum (R)  
 Carob bean gum (clarified) (N)  
 Guar gum (R)  
 Guar gum (clarified) (N)

**SPECIFICATIONS WITHDRAWN BY THE 67<sup>th</sup> JECFA:**

Butyl-p-hydroxybenzoate  
 Propyl-p-hydroxybenzoate  
 Ethylene oxide

**SPECIFICATIONS REVISED WITHOUT BEING REPUBLISHED:**

Acetylated oxidized starch	(corrected specifications are included in the specifications monograph for modified starches in the JECFA on-line database for food additives).
Maltitol	(corrected specifications are published in FAO JECFA Monographs 1 (2005)).

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<sup>1</sup> (N) new specification; (R) revised specification.

**SUBSTANCES FOR WHICH ADOPTED CODEX SPECIFICATIONS DIFFERS FROM EXISTING JECFA SPECIFICATIONS**

<b>Food Additive</b>	<b>INS No.</b>	<b>Year of adoption</b>	<b>Differences between the adopted Codex Specifications and the existing JECFA Specifications</b>	<b>Possible recommendation for action</b>
Butyl p-hydroxybenzoate		1981 (2005)	Withdrawn at 67 <sup>th</sup> JECFA (June 2006) In view of the adverse effects in male rats, butyl paraben (butyl- p-hydroxybenzoate) should be excluded from the group ADI for the parabens used in food. Subsequently the specs were withdrawn.	A. Withdraw the Codex Specifications B. Maintain the Codex Specifications C. Add the substance to the priority list for JECFA for revision of specifications
Turmeric	100 (ii)	1983	Withdrawn by 49 <sup>th</sup> JECFA (June 1997) The specifications for turmeric as a food colour were on the agenda for revision. However, as the use of this substance was considered to be as a spice and not as a food colour, the Committee decided to withdraw the existing specifications.	A. Withdraw the Codex Specifications B. Maintain the Codex Specifications C. Add the substance to the priority list for JECFA for revision of specifications
Propyl p-hydroxybenzoate	216	1999	Withdrawn by 67 <sup>th</sup> JECFA (June 2006) In view of the adverse effects in male rats, propyl paraben (propyl- p-hydroxybenzoate) should be excluded from the group ADI for the parabens used in food. Subsequently the specs were withdrawn.	A. Withdraw the Codex Specifications B. Maintain the Codex Specifications C. Add the substance to the priority list for JECFA for revision of specifications
Calcium hydrogen sulphite	227	1979	Withdrawn by the 53 <sup>rd</sup> JECFA (June 1999). No information was received on actual uses of calcium hydrogen sulfite in food, and all existing data indicated that the substance is not used as a food additive. The Committee therefore decided to withdraw the existing specifications.	A. Withdraw the Codex Specifications B. Maintain the Codex Specifications C. Add the substance to the priority list for JECFA for revision of specifications
Aluminium sodium sulfate	521	1981	Withdrawn by 55 <sup>th</sup> JECFA (June 2000) As no responses to call for data for aluminium sodium sulfate the existing specifications were withdrawn	A. Withdraw the Codex Specifications B. Maintain the Codex Specifications C. Add the substance to the priority list for JECFA for revision of specifications
Paraffin wax	905 c (ii)	1993	Withdrawn by 44 <sup>th</sup> JECFA (February 1995). The previous ADI "not specified" was withdrawn because toxicological effects were observed at all dose levels. The existing specifications were subsequently withdrawn.	A. Withdraw the Codex Specifications B. Maintain the Codex Specifications C. Add the substance to the priority list for JECFA for revision of specifications

Food Additive	INS No.	Year of adoption	Differences between the adopted Codex Specifications and the existing JECFA Specifications	Possible recommendation for action
Sodium L(+)-tartrate	335	1995	While editing the FAO JECFA Monographs 1 the criteria for inorganic impurities were brought in line with the same criteria included in other specifications for tartrates. In addition one of two identity tests for tartrate included in the specifications were deleted.	C. Add the substance to the priority list for JECFA for revision of specifications D. Adoption as Codex Specifications
Pentapotassium triphosphate	451 (ii)	1989	Revised criteria for inorganic impurities (63 <sup>rd</sup> JECFA) (2004). This substance was not included in the list adopted by CCFAC/CAC.	C. Add the substance to the priority list for JECFA for revision of specifications D. Adoption as Codex Specifications
Insoluble polyvinylpyrrolidone	1202	1991	Revised criteria for inorganic impurities (63 <sup>rd</sup> JECFA) (2004). This substance was not included in the list adopted by CCFAC/CAC.	C. Add the substance to the priority list for JECFA for revision of specifications D. Adoption as Codex Specifications
Polyvinylpyrrolidone	1201	1983	Specifications adopted as Codex Specifications were revised at the 30 <sup>th</sup> JECFA (1986) and a new criterion with a limit for Hydrazine was included for safety reasons. The 20 <sup>th</sup> CCFAC (1988) placed specs in Category III ( <i>review method of assay and compare with method for Insoluble PVP in FNP 34</i> ). However, this substance was not subsequently put on the agenda for JECFA for consideration of the request from CCFAC.	C. Add the substance to the priority list for JECFA for revision of specifications E. Reconsider specification prepared by 30 <sup>th</sup> JECFA and the decision of 20 <sup>th</sup> CCFAC to place it in Category III
Sucrose esters of fatty acids	473	1991, 2001	The specifications for Sucrose esters of fatty acids (adopted as Codex Specifications) were revised by the 65 <sup>th</sup> JECFA and designated as tentative requesting further information. The tentative specifications will be withdrawn unless the requested information is received before the end of year 2006 (The substance is on the Agenda of the 68 <sup>th</sup> JECFA 2007)	A. Withdraw the Codex Specifications F. Postpone decision awaiting the result of 68 <sup>th</sup> JECFA'