CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 3(b)** **CX/FA 20/52/4 Rev.1**

**December 2019**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD ADDITIVES**

**Fifty-first Session**

# PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 87th JECFA MEETING

Codex members and Observers wishing to submit comments at Step 3 on the proposed draft Specifications for the Identity and Purity of Food Additives arising from the 87th JECFA Meeting (Annex 1) should do so as instructed in CL 2019/118-FA available on the Codex webpage/Circular Letters 2019: http://www.codexalimentarius.org/circular-letters/en/.

## BACKGROUND

1. New specifications for food additives were prepared at the 87th JECFA (JECFA87) meeting (Rome, 4-13 June 2019).

2. Full specifications for 11 food additives were developed or revised, specifications for 9 flavourings were revised.

3. Full specifications for 11 additives: brilliant black (Black PN) (INS 151), carotenal, beta-apo-8'- (INS 160e), carotenes, *beta-,* synthetic (INS 160a(i)), carotenes, *beta-, Blakeslea trispora* (INS 160a(iii)), β-carotene-rich extract from *Dunaliella salina* (INS 160a(iv)), citric and fatty acid esters of glycerol (CITREM) (INS 472c), metatartaric acid (INS 353), yeast mannoproteins (INS 455), potassium polyaspartate (INS 456), rosemary extract (INS 392) and steviol glycosides (applies to steviol glycosides from *Stevia rebaudiana* Bertoni (steviol glycosides from Stevia) (INS 960a), rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)) and enzyme modified steviol glycosides).

4. Tentative specifications for 4 food additives were developed: black carrot extract (INS 163(vi)), cassia gum (INS 427), gellan gum (INS 418) and steviol glycoside (applies to enzyme modified glucosylated steviol glycosides).

5. JECFA87 had been requested to evaluate the different forms and ways of production for steviol glycosides and has recommended that all steviol glycosides be included in a modular monograph titled “Steviol glycosides”. This modular monograph or framework was adopted for developing specifications for steviol glycosides by four different methods of production. Specifications for steviol glycosides produced by different production methods were included as annexes, as follows:

- Annex 1: Steviol Glycosides from *Stevia rebaudiana* Bertoni (revised from the specifications monograph for Steviol glycosides from *Stevia rebaudiana* Bertoni (INS 960a) prepared at the 84th JECFA).
- Annex 2: Steviol Glycosides from Fermentation (specifications for Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)) prepared at the 82nd JECFA were revised to include other steviol glycosides from *Saccharomyces cerevisiae* and *Yarrowia lipolytica*).
- Annex 3: Enzyme Modified Steviol Glycosides (new specifications).
- Annex 4: Enzyme Modified Glucosylated Steviol Glycosides (new specifications, tentative pending further information concerning the analytical methods).

6. JECFA87 recognized that steviol glycosides could be produced via a new method or the modification or combination of the methods currently described in the annexes of the specifications monograph. If the final product meets the current specification of ≥95% steviol glycosides, JECFA will evaluate possible impurities from the method of manufacture. When appropriate, the modifications will be introduced into the relevant annex; alternatively, a new annex would be added.

7. CCFA52 is requested to take note that the specifications for steviol glycosides are listed both under full and tentative.

8. The full specifications to be discussed and considered by CCFA52 for adoption are listed in Annex 1, whereas other specifications for food additives which were designated as tentative or maintained by the 87th JECFA are listed in Annex 2. In addition, a list of errata is also reprinted in Annex 2 and presented for information to CCFA52.

9. The specification monographs is available (in English only) on the JECFA Online Edition of: "Combined Compendium of Food Additive Specifications" www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/ as FAO JECFA Monographs 23, FAO, Rome, 2019. 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/

**RECOMMENDATIONS**

10. CCFA52 is requested to review the specifications designated as "Full" for the food additives listed in Annex 1 with a view to recommending their adoption by CAC43 as Codex Specifications, taking into account comments received.

**Annex 1**

**PROPOSED DRAFT SPECIFICATIONS RESULTING FROM THE 87TH JECFA MEETING**

**(at Step 3)**

**FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS *FULL* (FAO JECFA Monographs 23, Rome, 2019:[1]**

Brilliant black (Black PN) (INS 151) (R)

Carotenal, beta-apo-8'- (INS 160e) (R)

Carotenes, *beta*-, *Blakeslea trispora* (INS 160a(iii)) (R)

β-carotene-rich extract from *Dunaliella salina* (INS 160a(iv)) (R)

Carotenes, beta-, synthetic (INS 160a(i)) (R)

Citric and fatty acid esters of glycerol (CITREM) (INS 472c) (R)

Metatartaric acid (INS 353) (R)

Yeast mannoproteins (INS 455) (R)

Potassium polyaspartate (INS 456) (N)

Rosemary extract (INS 392) (R)

Steviol glycosides (R, N)[2]

**Flavouring agents considered for revision of specifications only[1]**

| Flavouring agent | JECFA No. | Specifications |
|---|---|---|
| Methyl propionate | 141 | R |
| Ethyl oleate | 345 | R |
| alpha-Methyl-beta-hydroxypropyl alpha-methyl-beta-mercaptopropyl sulphide | 547 | R |
| Vanillin | 889 | R |
| Ethyl vanillin | 893 | R |
| 2,2,3-Trimethylcyclopent-3-en-1-yl acetaldehyde | 967 | R |
| alpha- and beta-Cyclocitral (50:50 mixture) | 979 | R |
| Sodium 2-(4-methoxyphenoxy)propanoate | 1029 | R |
| 2,2,6-Trimethyl-6-vinyltetrahydropyran | 1236 | R |

[1] (M) existing specifications maintained; (N) new specifications; (R) revised specifications; (T) tentative specifications.

[2] A framework was adopted for developing specifications for steviol glycosides by four different methods of production. Specifications for steviol glycosides produced by different production methods were included as annexes, as below:

- Annex 1: Steviol Glycosides from *Stevia rebaudiana* Bertoni (**revised** from the specifications monograph for Steviol glycosides from *Stevia rebaudiana* Bertoni prepared at the 84th meeting of JECFA (INS 960a)).
- Annex 2: Steviol Glycosides from Fermentation (specifications for Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)) prepared at the 82nd JECFA were **revised** to include other steviol glycosides from *Saccharomyces cerevisiae* and *Yarrowia lipolytica*).
- Annex 3: Enzyme Modified Steviol Glycosides (new specifications).
- Annex 4: Enzyme Modified Glucosylated Steviol Glycosides (**new** specifications, **tentative** pending further information concerning the analytical methods).

**Annex 2**

**OTHER SPECIFICATIONS RESULTING FROM THE 87th JECFA MEETING**

**(for information only)**

**SPECIFICATIONS DESIGNATED AS *TENTATIVE* (FAO JECFA Monographs 23, Rome, 2019):[1]**

Black Carrot Extract (INS 163(vi)) (N, T)[3]

Cassia gum (INS 427) (R, T)[4]

Gellan gum (INS 418) (R, T)

Stevial glycoside (R, T)[2]

[3] For the spray-dried powder form of black carrot extract. The specifications were made tentative pending further information on the material of commerce, including a full characterization of the proteins, carbohydrates, lipids, fibre, minerals and non-anthocyanin polyphenol components in five lots each of the liquid and powder forms of black carrot extract

[4] At the eighty-sixth meeting, the Committee updated the specifications for cassia gum by including the high-performance liquid chromatographic method received and removed their tentative status. Based on comments received about the method performance, the present Committee reviewed the method again and noted that additional investigations were required. Therefore, the Committee decided to make the specifications tentative until ongoing investigations are completed.

**Corrigenda**

The following requests for corrections, reported to the JECFA secretariats, were evaluated by the 87th JECFA meeting and found to be necessary.

- *The following corrections will be made only in the online database for specifications:*

| Food additive | Original text | New text | Additional information |
|---|---|---|---|
| Copper sulfate (INS 519) | CAS: 7758-98-7 | CAS: 7758-99-8 | Original CAS number is for anhydrous form; however, the specifications are for the pentahydrate |
| Magnesium dihydrogen diphosphate (INS 450(ix)) | METHOD OF ASSAY<br>The determination of phosphorus contains the following formula<br>$P_2O_5$, %w/w = P% × 4.983 | METHOD OF ASSAY<br>The determination of phosphorus contains the following formula<br>$P_2O_5$, %w/w = P% × 2.2921 | Original formula did not account for the presence of two phosphorus atoms per molecule |
| Basic methacrylate copolymer (INS 1205)<br>Will also be applied to anionic methacrylate copolymer (INS 1207) and neutral methacrylate copolymer (INS 1206) | In section Definition:<br>"Basic methacrylate copolymer is used as a coating and glazing agent for food supplements and foods for special medical purposes." | Sentence deleted. | Deletion requested by CCFA51[5]; sentence provided only marginal information |
| 2-Acetyl-1-pyrroline (JECFA No. 1604) | CAS: 99583-29-6 | CAS: 85213-22-5 | Correction to CAS number |

- *The following name was missing from the List of participants in the meeting report of the eighty-sixth meeting of JECFA (WHO Technical Report Series, No. 1014, 2019):*

  Dr E. Dessipri, European Directorate for the Quality of Medicines & HealthCare, Council of Europe, Strasbourg, France (*Member*)

- *The following participants were indicated as not attending the eighty-sixth meeting, but actually participated in the meeting by video conference:*

  Dr M. DiNovi, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, Maryland, USA (*WHO Temporary Adviser*)

  Dr J.R. Srinivasan, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, Maryland, USA (*FAO Expert*)

[5] REP19/FA, para. 17