



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx COMMITTEE ON FOOD ADDITIVES

#### Fifty-third Session

#### PROPOSED DRAFT SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 92<sup>ND</sup> AND 95<sup>TH</sup> JECFA MEETINGS RESPECTIVELY

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 92<sup>nd</sup> and 95<sup>th</sup> JECFA Meetings (Annexes 1 and 2) should do so as instructed in CL 2023/5/OCS-FA available on the Codex webpage/Circular Letters 2023: <http://www.codexalimentarius.org/circular-letters/en/>.

#### BACKGROUND

##### A. Proposed draft specifications for identity and purity of food additives arising from the 92<sup>nd</sup> JECFA meeting

1. New specifications for seven food additives were prepared at the 92<sup>nd</sup> JECFA (JECFA92) meeting (virtual, 7-18 June 2021).
2. New specifications for five food additives were developed and the specifications for two additives were revised.
3. Full specifications for six food additives were developed: Benzoic acid, its salts and derivatives<sup>1</sup>, Collagenase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*,  $\beta$ -Glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*, Phospholipase A2 from *Streptomyces violaceoruber* expressed in *S. violaceoruber*, Riboflavin from *Ashbya gossypii* (INS 101(iv)), Ribonuclease P from *Penicillium citrinum*.
4. Revised specifications for Modified starches were developed.
5. The full specifications to be discussed and considered by CCFA53 for adoption are listed in Annex 1.
6. The specification monographs are available (in English only) on the JECFA Online Edition of: "Combined Compendium of Food Additive Specifications" <https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/> as FAO JECFA Monographs 27, FAO, Rome, 2022. The publication is further available to download as pdf-document at the FAO JECFA website at: <https://www.fao.org/food-safety/resources/publications/en/>.

##### B. Proposed draft specifications for identity and purity of food additives arising from the 95<sup>th</sup> JECFA meeting

7. New specifications for food additives were prepared at the 95<sup>th</sup> JECFA (JECFA95) meeting (virtual, 6–17 and 22 June 2022).
8. Full specifications for one food additive were developed and specifications for one food additive were revised; new specifications for two flavourings were developed.
9. The Committee recommended the enzyme preparations would conform to the following format wherever possible: [principal enzyme activity (activities)] from [name of donor organism(s)] expressed in [systematic name of production organism], for example, "α-amylase from *Bacillus licheniformis* expressed in *Bacillus subtilis*". Furthermore, the Committee decided that an identification system would be used for all enzyme preparations. The identifier would consist of two parts: the JECFA meeting number followed by the number of agenda point of the substance, that is, JECFAXX-Y (e.g. JECFA95-1).
10. Full specifications for one food additive were developed: Lipase from *Thermomyces lanuginosus* and *Fusarium Oxysporum* expressed in *Aspergillus oryzae* (JECFA95-7).

<sup>1</sup> Benzoic acid, its salts and derivatives is the reporting basis for BENZOATES which includes benzoic acid (INS 210), sodium benzoate (INS 211), potassium benzoate (INS 212) and calcium benzoate (INS 213)

11. Revised specifications for one additive were developed: Spirulina extract (INS 134).
12. Full specifications for two flavourings were developed: Trans-4-tert-butylcyclohexanol (2263), Caryophylla-3(4),8-dien-5-ol (2264).
13. Tentative specifications for seven additives were developed:  $\alpha$ -Amylase from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis* (JECFA95-1),  $\alpha$ -Amylase from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis* (JECFA95-2),  $\alpha$ -Amylase from *Rhizomucor pusillus* expressed in *Aspergillus niger* (JECFA95-3), Amyloglucosidase from *Rasamsonia emersonii* expressed in *Aspergillus niger* (JECFA95-4), Asparaginase from *Pyrococcus furiosus* expressed in *Bacillus subtilis* (JECFA95-5),  $\beta$ -Amylase from *Bacillus flexus* expressed in *Bacillus licheniformis* (JECFA95-6), Xylanase from *Bacillus licheniformis* expressed in *Bacillus licheniformis* (JECFA95-9).
14. The evaluation was not completed for Phospholipase A2 (PLA2) from porcine pancreas expressed in *Aspergillus niger* (JECFA95-8) due to late submission of highly relevant toxicological data, other missing information and time constraints.
15. The full specifications to be discussed and considered by CCFA53 for adoption are listed in Annex 2.
16. The specification monographs will be available (in English only) on the JECFA Online Edition of: "Combined Compendium of Food Additive Specifications" <https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/> as FAO JECFA Monographs 30, FAO, Rome, 2023. The publication will be further available to download as pdf-document at the FAO JECFA website at: <https://www.fao.org/food-safety/resources/publications/en/>.

## RECOMMENDATIONS

17. CCFA53 is requested to review the specifications designated as "Full" for the food additives listed in Annexes 1 and 2 with a view to recommending their adoption by CAC46 as Codex Specifications, taking into account comments received.

**PROPOSED DRAFT SPECIFICATIONS RESULTING FROM THE 92nd JECFA MEETING****FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS FULL (FAO JECFA Monographs 27, Rome, 2022<sup>2</sup>):**

Benzoic acid, its salts and derivatives (N)

Collagenase from *Streptomyces violaceoruber* expressed in *S. violaceoruber* (N)

$\beta$ -Glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber* (N)

Phospholipase A2 from *Streptomyces violaceoruber* expressed in *S. violaceoruber* (R)

Riboflavin from *Ashbya gossypii* (INS 101(iv)) (N)

Ribonuclease P from *Penicillium citrinum* (N)

**Food additives considered for specifications only**

Modified starches (R)

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<sup>2</sup> (M) existing specifications maintained; (N) new specifications; (R) revised specifications; (T) tentative specifications.

**PROPOSED DRAFT SPECIFICATIONS RESULTING FROM THE 95th JECFA MEETING****FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS FULL (FAO JECFA Monographs 30, Rome, 2022<sup>2</sup>):**

Lipase from *Thermomyces lanuginosus* and *Fusarium oxysporum* expressed in *Aspergillus oryzae* (JECFA95-7) (N)

Spirulina extract (INS 134) (R)

**NEW SPECIFICATIONS FOR FLAVOURING AGENTS (FAO JECFA Monographs 30, Rome, 2022<sup>2</sup>):*****Alicyclic ketones, secondary alcohols and related esters***

<b>Flavouring agent<sup>3</sup></b>	<b>No.</b>	<b>Specifications</b>	<b>Conclusion based on current estimated dietary exposure</b>
Trans-4- <i>tert</i> -butylcyclohexanol	2263	N	No safety concern
Caryophylla-3(4),8-dien-5-ol	2264	N	No safety concern

<sup>3</sup> Both flavouring agents are in structural class I.