



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-fifth Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 99TH JECFA MEETINGS

(Prepared by JECFA Secretariat)

Codex Members and Observers wish to submit comments at Step 3 on the proposed draft Specifications for the Identity and Purity of Food Additives arising from the 99th JECFA Meeting (Annex) should do so as instructed in CL 2025/01-FA available on the Codex webpage/Circular Letters 2025:
<http://www.codexalimentarius.org/circular-letters/en/>.

BACKGROUND

A. Proposed draft specifications for identity and purity of food additives arising from the 99th JECFA meeting

1. At the 99th meeting held in Geneva, from 11 to 20 June 2024, Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the safety of four (4) food additives, four (4) processing aids and revised the specifications for ten (10) flavouring agents.
2. Full specifications were prepared for three (3) processing aids: i) endo-1,4- β -xylanase from *Bacillus subtilis* expressed in *Bacillus subtilis* (JECFA99-2), ii) endo-1,4- β -xylanase from *Rasamsonia emersonii* expressed in *Aspergillus niger* (JECFA99-3) and iii) glucosidase from *Aspergillus niger* expressed in *Trichoderma reesei* exhibiting α -glucosidase and transglucosidase activity (JECFA99-4a, JECFA99-4b).
3. Revised specifications were prepared for three (3) food additives: i) natamycin (INS 235), ii) nisin A and iii) polyglycerol esters of fatty acids (INS 475).
4. Revised specifications were prepared for ten (10) flavouring agents.
5. Nisin is a group of antimicrobial polypeptides with natural variants such as nisin A, nisin Q, and nisin Z. Previous JECFA evaluations focused on nisin A, the only commercially available variant until about 2005, and data submitted supported its specifications. For the current evaluation, no new data were provided, so the focus remained on nisin A.
6. The specifications to be discussed and considered by CCFA55 for adoption are listed in the Annex.
7. 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-safety/resources/publications/en/> as FAO JECFA Monographs 34, 2025. The publication is further available to download as pdf-document at the FAO JECFA website at: <https://doi.org/10.4060/cd3748en>.
8. The Committee discussed the importance of receiving data in support of the establishment of specifications for processing aids. The Committee reiterated the conclusions from the 95th of JECFA meeting¹ that, when considering enzymes as processing aids, the submissions from the sponsor should always conform to the requirements set out in the appendix of section 9.1.4.2 of the second edition of Principles related to specific groups of substances, chapter 9 of [Environmental Health Criteria 240](#).
9. The Committee recommends that sponsors use the checklist (Annex 3 of TRS1056²) and supply the requested information. Sponsors are reminded of the requirement to provide a statement detailing the enzyme activity as per the checklist. To clarify, this statement should take the following format: "One unit of XX enzyme activity is defined as the amount of enzyme required to convert one (1) mmole of substrate to product per minute under the conditions of the test". The method that is submitted should be sufficiently detailed to be easy

¹ <https://openknowledge.fao.org/items/9a44799e-9f08-42ca-93c0-d9cb8b516398>

² <https://iris.who.int/bitstream/handle/10665/378972/9789240100152-eng.pdf?sequence=1>

to apply in any laboratory; it should not require unique or expensive equipment (such as an autoanalyser), a calibrant with unique assigned activity or other restricted substances.

RECOMMENDATIONS

10. CCFA55 is requested to review the specifications designated as “Full” for the food additives listed in the Annex with a view to recommending their adoption by CAC48 as Codex Specifications for the identity and purity of food additives, taking into account comments received in response to CL 2025/01-FA.

B. Other specifications for identity and purity of food additives resulting from the 99th JECFA meeting (for information only)

11. Specifications were drafted at the 99th meeting for adenosine-5c-monophosphate deaminase from *Aspergillus sp.* (JECFA99-1) and butterfly pea flower extract, however the Committee could not finalize them due to lack of critical information.

ANNEX**PROPOSED DRAFT SPECIFICATIONS RESULTING FROM THE 99TH JECFA MEETING****FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS FULL (FAO JECFA Monographs 34³, 2025):**

Natamycin (INS 235) (R)

Nisin A (R)

Polyglycerol esters of fatty acids (INS 475) (R)

NEW SPECIFICATIONS DESIGNATED AS FULL FOR PROCESSING AIDS (FAO JECFA Monographs 34³, 2025):Endo-1,4- β -xylanase from *Bacillus subtilis* expressed in *Bacillus subtilis* (JECFA99-2) (N)Endo-1,4- β -xylanase from *Rasamsonia emersonii* expressed in *Aspergillus niger* (JECFA99-3) (N)Glucosidase from *Aspergillus niger* expressed in *Trichoderma reesei* exhibiting α -glucosidase and transglucosidase activity (JECFA99-4a, JECFA99-4b) (N)**FLAVOURING AGENTS CONSIDERED FOR SPECIFICATIONS ONLY**

Flavouring agent	No.	Specifications
S-methyl thioacetate	482	R
S-methyl 3-methylbutanethioate	487	R
4,5-dihydro-3(2H) thiophenone	498	R
2-methyltetrahydrothiophen-3-one	499	R
1-Butanethiol	511	R
o-Toluenethiol	528	R
bis(Methylthio)methane	533	R
3-Mercaptohexyl acetate	554	R
3-Mercaptohexyl butyrate	555	R
3-Mercapto-2-pentanone	560	R

N: New specifications

R: Revised specifications

³ <https://doi.org/10.4060/cd3748en>