



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Ninety-ninth meeting**

Food Additives

Geneva, 4 to 13 June 2024

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**LIST OF SUBSTANCES SCHEDULED FOR EVALUATION
AND REQUEST FOR DATA**

Attached is the list of substances (Annex 1) scheduled for evaluation or re-evaluation at the 99th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This list has been prepared by the Joint FAO/WHO Secretariat of the Committee and is based on recommendations of the Codex Committee on Food Additives (CCFA), previous Expert Committees, and direct requests from governments, other interested organizations, and producers of substances that have been evaluated previously. The meeting will be held as a physical meeting in Geneva, Switzerland.

Submission of data

Annex 1 lists the food additives to be considered at the meeting. Governments, interested organizations, producers of these chemicals, and individuals are invited to submit data for the toxicological evaluations, for the preparation of specifications for the identity and purity, and for estimating the intake of the compounds that are listed. The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. Summaries in the form of monographs are helpful, but they are not in themselves sufficient for evaluation.

Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA. Summaries of the studies will be published by FAO and WHO after the meetings in the form of specifications and toxicological monographs.

The Secretariats of JECFA at FAO and WHO encourage submission of data in electronic format. Such data should be presented preferably using standard word processing or document formats, and need to include a "Table of contents" using fully descriptive file names. For large volume submissions or for any questions related to data submissions please contact the Secretariat.

Date for submission

The submission of data on those compounds listed in Annex 1 is requested before

31 December 2023

This deadline applies to all data **including those for specifications for food additives**.

Toxicological data

Data relevant to the toxicological evaluations of the substances on the agenda including the results of:

1. metabolism and pharmacokinetic studies;
2. short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies;
3. epidemiological studies; and
4. special studies designed to investigate specific effects, such as the mechanism of toxicity, immune responses, or macromolecular binding.

This information needs to be submitted electronically (preferred) to WHO JECFA Secretariat. Please send an email to jecfa@who.int and request an individual SharePoint folder link for uploading data package. If an electronic submission is not possible, please contact us for alternative deliveries:

Attention: Kim Petersen

Department of Nutrition and Food Safety
World Health Organization
Avenue Appia
1211 Geneva 27
Switzerland
Telephone: +41 (0)79 728 7487
E-mail: jecfa@who.int

Technological data

Data relevant to the manufacturing, quality, use, occurrence, identification and quantification of the substances on the agenda including:

1. specifications for the identity and purity of the listed food additives (specifications applied during development and toxicological studies; proposed specifications for material in commerce);
2. technological and nutritional considerations relating to the manufacture and use of the listed food additives;
3. levels of the listed food additives used in food or expected to be used in food based on technological function and the range of foods in which they are used; and
4. analytical techniques used by manufacturers or authorities for identifying and quantifying the listed substances.

The information needs to be submitted electronically to jecfa@fao.org. If an electronic submission is not possible, please contact us for alternative deliveries:

Dr Markus Lipp
Food Systems and Food Safety Division
Telephone: +39 06 5705 3283
E-mail: jecfa@fao.org

Dietary exposure assessment data

For additives, all data relevant to:

1. technical levels of use of the additive in the foods in which it may be used;
2. annual poundage of the additive introduced into the food supply;
3. estimation of additive intakes based on food consumption data for foods in which the additive may be used; and
4. food consumption patterns; also considering different (age-) population groups.

This information should be sent to FAO at jecfa@fao.org and to WHO at jecfa@who.int.

Presentation of data

Please note that the above lists are not meant to be all-inclusive since it is recognized that other studies may, in some instances, assist in the evaluation.

Procedures for the evaluation of chemicals in food were updated and published by FAO and WHO (*Principles and methods for the risk assessment of chemicals in food* – Environmental Health Criteria No. 240), available at <https://www.who.int/publications/i/item/9789241572408>.

Specific guidance on the evaluation of and data needs for food additives are also available from FAO and WHO (see <http://www.fao.org/food-safety/scientific-advice/jecfa/jecfa-guidelines/en/> and [https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/procedural-guidance](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/procedural-guidance)).

All relevant data, both positive and negative, should be submitted. Data should be presented, summarized and referenced in a clear and concise manner.

This call for data is available at both the FAO and WHO web sites:

<http://www.fao.org/food-safety/scientific-advice/calls-for-data-and-experts-expert-rosters/en/>
[https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/calls-for-data](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/calls-for-data)

Annex 1**Joint FAO/WHO Expert Committee on Food Additives (JECFA)
99th meeting****Geneva, 4 to 13 June 2024****List of substances scheduled for evaluation or re-evaluation**

General information: Links to the available electronic versions of the reports published in the WHO Technical Report Series, monographs published in the WHO Food Additives Series, and specifications that are referenced below are available at the JECFA web pages of FAO and WHO:

- <http://www.fao.org/food-safety/resources/publications/en/>
[https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/publications](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/publications)

FAO and WHO procedural guidelines and guidelines for the preparation of chemical and technical assessments (CTA), toxicological working papers on food additives, intake assessment, and flavouring agents are available at:

- <http://www.fao.org/3/at896e/at896e.pdf> (CTA guidelines)
- [https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/procedural-guidance](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/procedural-guidance)

Appendix B of the guidelines for the preparation of working papers on the intake of food additives provides guidance to countries submitting their national assessments of intake.

[https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/procedural-guidance](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/procedural-guidance)

Previous reports and monographs should be consulted to obtain background information on the previous evaluations. Detailed bibliographical references are available on page 7

1. Food additives for which requests have been received for evaluation or re-evaluation by the 53rd session of the Codex Committee on Food Additives (REP 23 /FA - Appendix XI)⁽¹⁾ and pending re-evaluations

1.1. Toxicological evaluation, exposure assessment and establishment of specifications of substances used as food additives

Food Additive	Reference (previous evaluations) and background	Information required
Butterfly Pea Flower Extract	Report of the 53 rd session of CCFA, REP 23/FA - Appendix XI ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Natamycin (INS 235)	<p>Report of the 53rd session of CCFA, REP 23/FA - Appendix XI⁽¹⁾</p> <p>67th monograph of the Joint FAO/WHO Expert Committee on Food Additives⁽²⁾</p> <p>57th report of the Joint FAO/WHO Expert Committee on Food Additives⁽³⁾</p>	All data necessary for assessment of safety including data on natamycin's role (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora; dietary intake and specifications.
Nisin (INS 234)	<p>Report of the 53rd session of CCFA, REP 23/FA - Appendix XI⁽¹⁾</p> <p>77th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁴⁾</p> <p>12th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁵⁾</p>	All data necessary for assessment of safety including data on (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora; dietary intake and specifications.
Polyglycerol esters of fatty acids (INS 475)	<p>Report of the 53rd session of CCFA, REP 23/FA - Appendix XI⁽¹⁾</p> <p>35th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁶⁾</p>	All data necessary for assessment of safety, dietary intake and specifications.

1.2. Toxicological evaluation, exposure assessment and establishment of specifications of substances used as processing aids

Food Additive	Reference (previous evaluations) and background	Information required
Adenosine-5'- monophosphate deaminase from <i>Aspergillus oryzae</i>	Report of the 53 rd session of CCFA, REP 23/FA - Appendix XI ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Endo-1,4- β -xylanase from <i>Bacillus subtilis</i> produced by <i>B. subtilis</i> LMG S-28356	Report of the 53 rd session of CCFA, REP 23/FA - Appendix XI ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Transglucosidase/alphaglucosidase from <i>Trichoderma reesei</i> expressing an Alphaglucosidase gene from <i>Aspergillus niger</i>	Report of the 53 rd session of CCFA, REP 23/FA - Appendix XI ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Xylanase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	Report of the 53 rd session of CCFA, REP 23/FA - Appendix XI ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.

1.3. Flavouring agents for revision of specifications

JECFA No.	CAS No.	Principal Name	Most Recent Specification Evaluation	Status	Update
554	136954-20-6	3-Mercaptohexyl acetate	1999 (Session 53)	Full	The Purity Specification requires clarity. The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
555	136954-21-7	3-Mercaptohexyl butyrate	1999 (Session 53)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
511	109-79-5	1-Butanethiol	1999 (Session 53)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
560	67633-97-0	3-Mercapto-2-pentanone	2000 (Session 55)	Full	The Refractive Index does not reflect the material currently in commerce.
533	1618-26-4	bis(Methylthio) methane	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce
528	137-06-4	o-Toluenethiol	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.

482	1534-08-3	S-Methyl thioacetate	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce.
487	23747-45-7	S-Methyl 3-methylbutanethioate	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce.
498	1003-04-9	4,5-Dihydro-3(2H)thiophenone	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce.
499	13679-85-1	2-Methyltetrahydrothiophen-3-one	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.

References

1. Report of the 53rd Session of the Codex Committee on Food Additives, Hong Kong, 27-31, China, March 2023 (REP23/FA)
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/it/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-53%252FFinal%2Breport%252FREP23_FAe.pdf
2. Monograph of the 67th meeting of JECFA
<https://www.who.int/publications/i/item/9789241660587>
3. Report of the 57th meeting of JECFA
<https://www.who.int/publications/i/item/9241209097>
4. Report of the 77th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/98388/9789241209830_eng.pdf?sequence=1
5. Report of the 12th meeting of JECFA
<https://www.who.int/publications/i/item/9241204303>
6. Report of the 35th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/37651/WHO_TRS_789.pdf?sequence=1

Annex 2

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

BACKGROUND

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) was established in the mid-1950s by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to assess chemical additives in food on an international basis. The first meeting was held in 1956 in response to recommendations made at an FAO/WHO Conference on Food Additives that met in Geneva in 1955.

In the early 1960s the Codex Alimentarius Commission (CAC), which is an international intergovernmental body, was established. The primary aims of the CAC are to protect the health of the consumer and facilitate international trade in food. At the time that the CAC was formed it was decided that JECFA would provide expert advice to Codex on matters relating to food additives. A system was established whereby the Codex Committee on Food Additives, a general subject committee, identified food additives that should receive priority attention, which were then referred to JECFA for assessment before being considered for inclusion in Codex Food Standards.

This system is still in place, but it has been expanded to include food contaminants and residues of veterinary drugs in food to provide advice to the presently-existing Codex Committee on Food Additives (CCFA), Codex Committee on Contaminants in Food (CCCF) and Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). JECFA also provides scientific advice directly to FAO and WHO Member States, and requests for assessment may come directly from them. JECFA is not a component of the CAC.

Specialists invited to serve as Members of JECFA are independent scientists who serve in their individual capacities as experts, and not as representatives of their governments or employers. The goal is to establish safe levels of intake and to develop specifications for identity and purity (food additives) or maximum residue limits when veterinary drugs are used in accordance with good practice in the use of veterinary drugs.

The reports of previous JECFA meetings are published in the WHO Technical Report Series ([https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/publications/reports](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/publications/reports)). The toxicological evaluations that summarize the data that serve as the basis for the safety assessments, are published in the WHO Food Additives Series ([https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/publications/toxicological-monographs](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/publications/toxicological-monographs)).

The specifications and veterinary drug residue evaluations are published in the FAO JECFA Monographs. The Combined Compendium of Food Additive Specifications of all current JECFA specifications is available on-line (<http://www.fao.org/food-safety/resources/publications/en/>) (Select “JECFA monographs” in the “Categories” window and click “Search”). The updated database on

specifications for flavouring agents is available at <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>. The Chemical Technical Assessments are available at <http://www.fao.org/food-safety/resources/publications/en/> (Select “JECFA chemical and technical assessments” in the “Categories” window and click “Search”).

A *Summary of Evaluations* performed by the Joint FAO/WHO Expert Committee on Food Additives, a comprehensive searchable database that summarizes all JECFA evaluations from the first through recent meetings, is available at [https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/publications/summary-reports](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/publications/summary-reports)