



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



**World Health
Organization**

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

Food Additives

Rome, 7 to 16 June 2022

or

Remote, 6 to 17 June 2022

Published 6 September 2021

**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 95th 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. If conditions allow, the meeting will be held as a physical meeting in Rome, otherwise JECFA will convene remotely.

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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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.

Data already submitted for compounds scheduled for the 92nd JECFA meeting but postponed to the 95th JECFA meeting does not need to be resubmitted.

Date for submission

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

31 December 2021

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 the following e-mail address: jecfa@who.int, 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
Facsimile: +41 (0) 22 791 4807
Telephone: +41 (0)22 791 1439
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.

As FAO is still teleworking at the time of publication of this call for data, this 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)
95th meeting**

Rome, 7 to 16 June 2022

or

Remote, 6 to 17 June 2022

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/toxicological-monographs](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/publications/toxicological-monographs)

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.

http://www.who.int/foodsafety/chem/jecfa/en/intake_guidelines.pdf?ua=1

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

1. Food additives for which requests have been received for evaluation or re-evaluation by the 51th session of the Codex Committee on Food Additives (REP 19 /FA - Appendix X)⁽¹⁾ and pending re-evaluations

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

Food Additive	Reference (previous evaluations) and background	Information required
Acid prolyl endopeptidase from <i>Aspergillus niger</i> expressing a gene from <i>Aspergillus niger</i>	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications
Alpha-amylase from <i>Bacillus licheniformis</i> expressing a modified alpha-amylase gene from <i>Geobacillus stearothermophilus</i>		
Alpha-amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>		
Alpha-amylase from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>		
Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i>		
Asparaginase from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>		
Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i>		
Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i>		
Xylanase from <i>Bacillus licheniformis</i> expressed in <i>B. licheniformis</i>		

1.2. Food additives for revision of specifications and analytical methods

Food Additive	Reference (previous evaluations) and background	Information required
Spirulina	see Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾	<ul style="list-style-type: none"> - Full compositional characterization of commercial products in both liquid and powder forms. - Full compositional characterization of the aqueous extract before formulation/standardization. - Validated analytical methods for identification of the substance with a suitable specificity (including validation data and representative batch data). - Validated analytical methods for the determination of the purity of the substance with a suitable specificity (including validation data and representative batch data).

1.3. Toxicological evaluation, exposure assessment and establishment of specifications for certain flavourings

JECFA No	FEMA No	CAS	Principle Name
ALICYCLIC KETONES, SECONDARY ALCOHOLS AND RELATED ESTERS JECFA 73 and 59 - TRS 960⁽²⁾ and 913⁽³⁾			
	4724	21862-63-5	trans-4-tert-Butylcyclohexanol
	4780	38284-26-3	Caryophylla-3(4),8-dien-5-ol

References

1. Report of the 51th Session of the Codex Committee on Food Additives, Jinan, China, 25-29 March 2019 (REP19/FA)
http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-51%252FReport%252FREP19_FAe.pdf
2. Report of the 73rd meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/44515/WHO_TRS_960_eng.pdf;jsessionid=1B03128AB53719D88378E444CB38F683?sequence=1
3. Report of the 59th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/42601/WHO_TRS_913.pdf?sequence=1
FAO JEFA Flavour Specifications Database:
<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>

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)