



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

Food Additives

Rome, 30 October to 10 November 2023

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LIST OF SUBSTANCES SCHEDULED FOR EVALUATION AND REQUEST FOR DATA

Attached is **an addendum** to the list of substances (Annex 1) scheduled for evaluation or reevaluation at the 97th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This addendum contains a list of flavours for evaluation at the 97th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in addition to the food additives mentioned in the call for data published on 2 November 2022.

https://www.fao.org/3/cc2758en/cc2758en.pdf

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 background and purpose of JECFA is described in Annex 2. The meeting will be held as a physical meeting in Rome, Italy.

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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 the compounds listed in Annex 1 is requested before

7 April 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 the following e-mail address: jecfa@who.int, if an electronic submission is not possible, please contact us for alternative delivery methods:

Attention: Kim Petersen

Department of Nutrition and Food Safety World Health Organization Avenue Appia 1211 Geneva 27 Switzerland Facsimile: +41 (0) 22 791 4807

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:

- 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 delivery methods:

Dr Markus Lipp Food Systems and Food Safety Division Food and Agriculture Organization of the United Nations (FAO) 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).

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 on both the FAO and WHO websites: http://www.fao.org/food-safety/scientific-advice/calls-for-data-and-expert-expert-rosters/en/
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) 97th meeting

Rome, 30 October to 10 November 2023

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 on 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

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

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/publications/m/item/guidelines-for-the-preparation-of-working-papers-on-intake-of-food-additives

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 52nd session of the Codex Committee on Food Additives (REP 21 /FA Appendix XI)⁽¹⁾ and pending re-evaluations
- 1.1. Toxicological evaluation, exposure assessment and establishment of specifications for certain flavourings

FEMA No	CAS	Principle Name	
LINEAR AND BRANCHED-CHAIN ALIPHATIC, UNSATURATED, UNCONJUGATED ALCOHOLS, ALDEHYDES, ACIDS, AND RELATED ESTERS			
4735	13552-95-9	(4Z,7Z)-Trideca-4,7-dienal	
4825	2277-20-5	E-6-Nonenal	
4841	16676-96-3	cis-5-Dodecenyl acetate	
4885	68820-34-8	trans-5-Dodecenal	
4886	126745-61-7	cis-6-Dodecenal	
4887	56219-03-5	cis-9-Dodecenal	
4891	2088117-65-9	(E)-3-Methyl-4-dodecenoic acid	
4898	41547-29-9	trans-5-Octenal	
4904	115018-39-8	trans-Tetradec-4-enal	

4905	2119671-25-7	2,6-Dimethylheptenyl formate	
4917	22032-47-9	(Z)-9-Dodecenoic acid	
4918	68820-38-2	Tridec-5-enal	
4926	65398-36-9	(Z)-8-Pentadecenal	
4927	934534-30-2	4,7-Decadienal	
4945	174155-46-5	cis-9-Decenal	
SATURATED ALIPHATIC ACYCLIC LINEAR PRIMARY ALCOHOLS, ALDEHYDES, AND ACIDS			
4010	123-63-7	Paraldehyde	
4334	1002-84-2	Pentadecanoic acid	
4335	10486-19-8	Tridecanal	
4336	638-53-9	Tridecanoic acid	
4432	25334-93-4	(+/-) Acetaldehyde ethyl isopropyl acetal	
4527	5669-09-0	Acetaldehyde di-isobutylacetal	
4528	6986-51-2	Acetaldehyde ethyl isobutyl acetal	
4688	105-82-8	1,1-Dipropoxyethane	
ALIPHATIC PRIMARY ALCOHOLS, ALDEHYDES, CARBOXYLIC ACIDS, ACETALS, AND ESTERS CONTAINING ADDITIONAL OXYGENATED FUNCTIONAL GROUPS			
4719	110-15-6	Succinic acid	
4745	62439-41-2	(±)-6-Methoxy-2,6-dimethylheptanal	
4765	1367348-37-5	Ethyl 5-formyloxydecanoate	
4804	61789-44-4	Mixture of Ricinoleic acid, Linoleic acid, and Oleic acid	
4903	26516-27-8	Ethyl 3-methyl-2-oxopentanoate	
4943	111-20-6	Decandioic acid	
4944	6402-36-4	trans-2-Dodecendioic acid	

References

1. Report of the 52nd Session of the Codex Committee on Food Additives, Virtual, 8-13 November 2021 (REP21/FA)

https://www.fao.org/fao-who-codexalimentarius/sh-

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%25 2FMeetings%252FCX-711-

52%252FFinal%252520report%252FREP21_FAe_revised%2Bon%2B14%2BOctober.pdf

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 Members, and requests for assessment may come directly from them. JECFA is <u>not</u> 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 <u>not</u> 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). 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).

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 online 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/foodsafety-quality/scientific-advice/jecfa/jecfa-flav/en/. The Chemical Technical Assessments available http://www.fao.org/foodare at "JECFA safety/resources/publications/en/ (Select chemical technical and 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