



Food and Agriculture
Organization of the
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World Health
Organization

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 the list of substances (Annex 1) scheduled for evaluation or re-evaluation at the 97th 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 Rome, Italy.

Please note that a list of additional food additives scheduled for evaluation or re-evaluation in the 97th Joint FAO/WHO Expert Committee on Food Additives (JECFA) will be published at a later time and in a separate call for data.

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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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

28 February 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. Quality of data: Requirement to provide a rationale where studies have not been to GLP or followed OECD guidelines;
2. Genotoxicity data: The contribution titanium dioxide and its nanoform has on the interpretation of *in vitro* and *in vivo* genotoxicity;
3. Structural changes following ingestion: The contribution of changes to the form of titanium dioxide once ingested with or without food;
4. Metabolism and pharmacokinetic studies: Changes to the form of titanium dioxide once absorbed;
5. *In vivo* toxicity studies: Any additional data on short-term toxicity, long-term toxicity / carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals which may influence the outcome on the safety of titanium dioxide/titanium dioxide-nano particles;
6. Modes of Action (MoA): Consideration of Modes of Action and the influence on the toxicity of titanium dioxide;
7. Modes of Action: Requirement for data supporting proposed Modes of Action around markers evaluating such MoA as indirect reactive oxygen species (ROS), inflammation, apoptosis etc.;
8. Special studies: A review of studies which may add to the assessment of the safety of titanium dioxide in foods such as immune responses, macromolecular binding designed to investigate specific effects;
9. Human intervention studies: A review of the need for these studies to assess the adverse effects reported in animal studies;
10. Epidemiological studies: A review of epidemiological studies considering the use and effects of titanium dioxide in foods.

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. A full compositional characterization of commercial products used in foods;
2. A clear definition of the types of Titanium Dioxide analysed;
3. A specification for the identity and purity of the Titanium Dioxide used (specifications applied during development and toxicological studies; proposed specifications for material in commerce);
4. Validated analytical methods for the determination of the purity of the substance with a suitable specificity (including validation data and representative batch data);
5. Technological and nutritional considerations relating to the manufacture and use of titanium dioxide in foods;
6. Technological and nutritional considerations relating to the potential changes when ingested;
7. The levels of the Titanium Dioxide and or Titanium Dioxide-Nanoparticles used in food or expected to be used in food based on technological function and the range of foods in which it is used; and
8. Analytical techniques (including limitations and validation data) used by manufacturers or authorities for identifying and quantifying titanium dioxide in food, including the particle size distribution.
9. Supplemental data to already published studies (if available).

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)
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 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.

<https://www.who.int/publications/m/item/guidelines-for-the-preparation-of-working-papers-on-intake-of-food-additives-for-the-joint-fao-who-expert-committee-on-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 of substances used as food additives

Food Additive	Reference (previous evaluations) and background	Information required
Titanium dioxide (INS 171)	Report of the 52 nd session of CCFA, REP 21/FA - Appendix XI ⁽¹⁾ 13 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽²⁾	All data necessary for assessment of safety, dietary intake and specifications,

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/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-52%252FFinal%252520report%252FREP21_FAe_revised%2Bon%2B14%2BOctober.pdf
2. Report of the 13th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/40773/WHO_TRS_445.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)