



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



**World Health
Organization**

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

Food Additives
Rome, 8 to 17 June 2021
Or
Remote, 7 to 18 June 2021

Published 3 September 2020

**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 92nd 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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.

Date for submission

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

31 December 2020

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:

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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;
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 the following e-mail address 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;
4. food consumption patterns; also considering different (age-) population groups

This information should be sent to FAO at the address above (jecfa@fao.org) and to WHO under the address above (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 (Methods and *Principles for the Safety Assessment of Food Additives and Contaminants in Food* – Environmental Health Criteria No. 240, available at <http://www.who.int/foodsafety/publications/chemical-food/en/>

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 <http://www.who.int/foodsafety/chem/jecfa/guidelines/en/index.html>).

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/en/>

<https://www.who.int/activities/assessing-chemical-risks-in-food>

Annex 1

**Joint FAO/WHO Expert Committee on Food Additives (JECFA)
92nd meeting, Rome, 8 to 17 June 2021
Or
Remote, 7 to 18 June 2021**

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/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/>
- <http://www.who.int/foodsafety/publications/jecfa/en/>.

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/food-safety/scientific-advice/jecfa/en/>
- <http://www.who.int/foodsafety/chem/jecfa/guidelines/en/>.

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

Previous reports and monographs should be consulted to obtain background information on the previous evaluations. Detailed bibliographical references are available on page 8

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 for food additives

Food Additive	Reference (previous evaluations) and background	Information required
Benzoic acid and its salts (INS 210-212)	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ Eightieth Report of the JECFA ⁽³⁾ Forty-sixth Report of JECFA ⁽⁴⁾	All data necessary for assessment of safety and dietary intake
Riboflavin from <i>Ashbya gossypii</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

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
Alpha-amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</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>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>		
Beta-glucanase from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>		
Collagenase from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>		
Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i>		
Phosphodiesterase from <i>Penicillium citrinum</i>		
Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i>		
Phospholipase A2 from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>		
Xylanase from <i>Bacillus licheniformis</i> expressed in <i>B. licheniformis</i>		
Xylanase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>		

1.3. Food additives for revision of specifications and analytical methods

Food Additive	Reference (previous evaluations) and background	Information required
Modified Starches	see JECFA86 ⁽²⁾ report	See below
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).

Data required for modified starches

The Committee requests suitable microbiological acceptance criteria and supporting data for all modified starches.

The committee requests the following information (the number of the Annex listed in table below refers to the specifications monograph 21 published by JECFA86⁽²⁾):

ANNEX	Modification	Starches to which it applies	Information required
1	Minor fragmentation	INS 1400: Dextrin roasted starch; INS 1401: Acid treated starch; INS 1402: Alkaline treated starch; INS 1405: Enzyme-treated starch All modified starches that are additionally fragmented.	A suitable method for dispersion and a method for reducing sugars and data on at least 5 representative batches using the method(s) from each of the fragmentation processes.
2	Bleaching	INS 1403: Bleached starch All modified starches if additionally bleached.	Suitable method(s) for the determination of residual reagents and data on at least 5 representative batches using the method(s).
3	Esterification and/or crosslinking with phosphorus containing compounds	INS 1410: Monostarch phosphate; INS 1412: Distarch phosphate; INS 1413: Phosphated distarch phosphate; INS 1414: Acetylated distarch phosphate; INS 1442: Hydroxypropyl distarch phosphate	A suitable method for identification of crosslinking and data on at least 5 representative batches of crosslinked and non-crosslinked starches.
4	Acetylation	INS 1420: Starch acetate; INS 1414: Acetylated distarch phosphate; INS 1422: Acetylated distarch adipate; INS 1451: Acetylated oxidized starch	Currently no additional information required.
5	Oxidation	INS 1404: Oxidized starch; INS 1451: Acetylated oxidized starch	A suitable method for determination of residual hypochlorite and data on at least 5 representative batches using the method.
6	Esterification with octenyl succinic anhydride	INS 1450: Starch sodium octenyl succinate	Currently no additional information required.
7	Etherification with propylene epoxide	INS 1440: Hydroxypropyl starch; INS 1442: Hydroxypropyl distarch phosphate	A suitable method for the determination of propylene chlorohydrin with detection limit lower than 0.1 mg/kg and data on at least 5 representative batches of Hydroxypropyl starch using the method
8	Crosslinking with adipic anhydride	INS 1422: Acetylated distarch adipate	A suitable method for identification of crosslinking and data on at least 5 representative batches of crosslinked and non-crosslinked starches. Levels of free adipic acid in at least 5 representative batches

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/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-51%252FReport%252FREP19_FAc.pdf
2. Report of the 86th meeting of JECFA
<https://apps.who.int/iris/bitstream/handle/10665/279832/9789241210232-eng.pdf?ua=1>
3. Report of the 80th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/204410/9789240695405_eng.pdf?sequence=1#page=27
4. Report of the 46th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/41962/WHO_TRS_868.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 (<http://www.who.int/foodsafety/publications/jecfa-reports/en/>). The toxicological evaluations that summarize the data that serve as the basis for the safety assessments, are published in the WHO Food Additives Series (<http://www.who.int/foodsafety/publications/monographs/en/>). 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/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. 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/food-safety-quality/scientific-advice/jecfa/technical-assessments/en/>.

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 <http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx>