



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



**World Health
Organization**

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Eighty seventh meeting**

**Food Additives
Rome, 4 to 13 June 2019
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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 87th 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.

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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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

1 December 2018

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 to the following e-mail address: jecfa@who.int or by sending it on a USB stick to:

Attention: Kim Petersen
Department of Food Safety and Zoonoses
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.

This information needs to be submitted electronically to the following e-mail address jecfa@fao.org or by sending it on a USB stick to:

Attention: Dr Markus Lipp
Food Safety and Quality Unit - Room C- 278
Agriculture and Consumer Protection Department (AG)
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00153 Rome
Italy
Facsimile: +39 06 5705 4593
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/food-safety-quality/scientific-advice/jecfa/guidelines0/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/food-safety-quality/scientific-advice/calls-data-experts/en/>

<http://www.who.int/foodsafety/call-data-expert/en/>

Annex 1**Joint FAO/WHO Expert Committee on Food Additives (JECFA)
87th meeting, Rome, 4 to 13 June 2018****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/> and <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/food-safety-quality/scientific-advice/jecfa/en/> and <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 7.

1. Food additives for which requests have been received for evaluation or re-evaluation by the 50th session of the Codex Committee on Food Additives (REP 18/FA - Appendix X)⁽¹⁾ and pending re-evaluations

1.1 Toxicological evaluation, exposure assessment and establishment of specifications

Food Additive	Reference (previous evaluations) and background	Information required
Black carrot extract	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications
Brilliant Black PN (INS 151)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 25 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽²⁾ FAO JECFA Monograph 1, (2006) ⁽³⁾	All data necessary for assessment of safety, dietary intake and specifications on in Flavoured fluid milk drinks (Food Category 01.1.4)
Carotenoids (INS 160x): <ul style="list-style-type: none"> • β-carotene • beta-carotene from <i>blakeslea trispora</i> • β-apo-8'-carotenal • β-apo-8'-carotenoic acid methyl and ethyl esters 	84 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁸⁾ FAO JECFA Monograph 20, (2017) ⁽⁹⁾ 57 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁷⁾	All data necessary for assessment of safety, dietary intake and specifications in order to evaluate the group ADI of β -carotene, beta-carotene from <i>blakeslea trispora</i> and the group ADI for β -apo-8'-carotenal and β -apo-

Food Additive	Reference (previous evaluations) and background	Information required
	18 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁶⁾	8'-carotenoic acid methyl and ethyl esters, in light of evidence that shows very low absorption of β -carotene in rodents and rabbits in contrast to humans.
Gellan gum (INS 418)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 79 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁴⁾ FAO JECFA Monograph 16, (2014) ⁽⁵⁾	All data necessary for (i) assessment of safety, dietary intake and specifications to assess the safety for use in infant formula, formula for special medical purposes for infants, and follow-up formula; (ii) for re-evaluation of the limit for ethanol in the specifications
Potassium polyaspartate	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications
Rosemary extract	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 82 nd report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁶⁾ FAO JECFA Monograph 19, (2016) ⁽⁷⁾	All data necessary for assessment of safety, dietary intake and specifications including pending data on: i) studies to elucidate the potential developmental and reproductive toxicity; ii) validation information on the method of determination of residual solvents; iii) data on typical use-levels in food

1.2. Establishment of framework for safety assessment of steviol glycosides produced by different technologies

Steviol glycosides form a complex and large group of compounds used as low-caloric sweeteners. Steviol glycosides can be obtained through various technologies such as extraction from leaves of *Stevia rebaudiana*, by enzymatic processes, by bioconversion or by fermentation. The steviol glycosides produced by the various technologies have many similarities with regard to safety, dietary intake and chemical properties, yet at the same time can differ in some chemical, functional and sensory aspects.

In order to facilitate the evaluation of steviol glycosides in the future, the joint FAO/WHO JECFA secretariats are evaluating the feasibility of establishing criteria for a procedure or framework that may allow grouping of certain steviol glycosides. The goal of this effort is to simplify and streamline the safety assessment and leveraging chemical and physiological/toxicological similarities of steviol glycosides to the extent possible and where justified. The joint FAO/WHO JECFA secretariat is inviting interested parties to share their views and proposals regarding the possibility of establishing groups or families of steviol glycosides that can be considered chemically and/or physiologically equivalent and thereby may be considered summarily rather than individually in a safety assessment and/or for the development of specifications. Interested parties are encouraged to outline the rationale of a possible approach in detail. Such submission shall include suitable explanations and considerations that reflect the chemical and toxicological features, different production

processes as well as consumption patterns of steviol glycosides and data necessary to establish the safety and identity of steviol glycosides under such a proposed approach.

1.3. Food additives for revision of specifications and analytical methods

Food Additive	Reference (previous evaluations) and background	Information required
β -Carotene-rich extract from <i>Dunaliella salina</i>	84 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁸⁾ FAO JECFA Monograph 20, (2017) ⁽⁹⁾	All data necessary for the maximum limit on arsenic
Metatartaric acid (INS 353)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 84 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁸⁾ FAO JECFA Monograph 20, (2017) ⁽⁹⁾	All data necessary for 1) characterization of the products (optical rotation, content of free tartaric acid, degree of esterification and molecular weight distribution) and the corresponding analytical methods; 2) infrared spectrum (in a suitable medium); and 3) analytical results including the above parameters from a minimum of five batches of products currently available in commerce, along with quality control data
Yeast extracts containing mannoproteins	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 84 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁸⁾ FAO JECFA Monograph 20, (2017) ⁽⁹⁾	The Committee requires chemical characterization of the product in commerce along with data to be able to complete specifications related to the use of yeast extracts containing mannoproteins in wine manufacture. The following information is required: - Composition of yeast extracts containing mannoproteins as well as the processes used in their manufacture; - Analytical data from five batches of each commercial product, including information related to impurities; and - Data on concentrations of yeast mannoproteins in wine in which yeast extracts containing mannoproteins have been used.
Steviol Glycosides (Rebaudioside M manufactured from two strains of yeast from the <i>Saccharomyces</i> family)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾	An amendment to the JECFA specification is justified based on the commercial availability of rebaudioside M, manufactured using a novel fermentation process.

Food Additive	Reference (previous evaluations) and background	Information required
		Rebaudioside M was included within the 2016 JECFA evaluation and incorporated within the 2016 JECFA specification.
Steviol Glycosides (Rebaudioside A and M, respectively, from Multiple Gene Donors Expressed in <i>Yarrowia lipolytica</i>) (INS 960)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾	All data necessary for possible inclusion of data on rebaudioside M and to rename the specifications as appropriate (e.g., Steviol glycosides produced by <i>Yarrowia lipolytica</i>)
Steviol glycosides (Steviol Glycosides, Rebaudioside A, Rebaudioside D, Rebaudioside M; Enzyme Modified Steviol Glycosides, Enzyme Modified Stevia Leaf Extract)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾	An amendment to the current JECFA specifications is justified based upon the commercial availability of a number of steviol glycoside preparations that contain for example a high proportion of singular steviol glycosides such as rebaudiosides A, D or M from fermentation or bioconversion and glycosides containing additional glucose units that are produced through enzyme modification

1.4. Establishment of specifications for certain flavouring agents

Vanillin (JECFA No: 889)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 57 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁰⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of melting point
Ethyl vanillin (JECFA No: 893)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 57 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁰⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of melting point
Methyl Propionate (JECFA No: 141)	49 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁸⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of specific gravity

2,6,6-Trimethyl-1&2-cyclohexen-1-carboxaldehyde (JECFA No: 979)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 59 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹²⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of C.A.S. number.
Sodium 2-(4-methoxyphenoxy)propanoate (JECFA No: 1029)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 59 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹²⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of C.A.S. number.
2,2,3-Trimethylcyclopent-3-en-1-yl acetaldehyde (JECFA No: 967)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 59 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹²⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of assay value.
Ethyl oleate (JECFA No: 345)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 51 st report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹³⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of assay value and secondary components.
2,2,6-Trimethyl-6-vinyltetrahydropyran (JECFA No: 1236)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 61 st report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁴⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of assay value.
alpha-Methyl-beta-hydroxypropyl alpha-methyl-beta-mercaptopropyl sulfide (JECFA No: 547)	Report of the 50 th session of CCFA, REP 18/FA - Appendix X ⁽¹⁾ 53 rd report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹⁵⁾ JECFA flavor specifications database ⁽¹¹⁾	All data necessary for revision of assay value.

References

1. Report of the 50th Session of the Codex Committee on Food Additives, Xiamen, China, 26-30 March 2018 (REP18/FA)
http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-50%252FReport%252FREP18_FAe.pdf
2. Report of the 25th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/41524/WHO_TRS_669.pdf?sequence=1

3. FAO Monograph 1, 2006:
http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-058.pdf
4. Report of the 79th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/150883/9789241209908_eng.pdf?sequence=1#page=68
5. FAO Monograph 16 (2014)
<http://www.fao.org/3/a-i4144e.pdf>
6. Report of the 82th meeting of JECFA
<http://apps.who.int/iris/bitstream/handle/10665/250277/9789241210003-eng.pdf?sequence=1#page=57%22%3E>
7. FAO Monograph 19 (2016):
<http://www.fao.org/documents/card/en/c/a6fe72dc-82fb-437c-81cc-bc4d739043a5/>
8. Report of the 84th meeting of JECFA
<http://apps.who.int/iris/bitstream/handle/10665/259483/9789241210164-eng.pdf?sequence=1#page=55%22%3E>
9. FAO Monograph 20 (2017)
<http://www.fao.org/documents/card/en/c/4b06cdda-3e70-4c80-b7e5-56034601836b/>
10. Report of the 57th meeting of JECFA
http://whqlibdoc.who.int/trs/WHO_TRS_909.pdf
11. JECFA flavour specification database
<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>
12. Report of the 59th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/42601/WHO_TRS_913.pdf?sequence=1
13. Report of the 51st meeting of JECFA
http://whqlibdoc.who.int/trs/WHO_TRS_891.pdf?ua=1
14. Report of the 61st meeting of JECFA
http://whqlibdoc.who.int/trs/WHO_TRS_922.pdf?ua=1
15. Report of the 53rd meeting of JECFA
http://whqlibdoc.who.int/trs/WHO_TRS_896.pdf?ua=1
16. Report of the 18th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/41117/WHO_TRS_557.pdf?sequence=1
17. Report of the 57th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/42578/WHO_TRS_909.pdf?sequence=1
18. Report of the 49th meeting of JECFA
http://apps.who.int/iris/bitstream/handle/10665/42142/WHO_TRS_884.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 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>