



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



**World Health
Organization**

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

Food Additives
Geneva, 2 to 11 June 2020
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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 89th 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.

A list of enzymes scheduled for evaluation or re-evaluation in a 2020 meeting of the 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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

15 December 2019

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 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.

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/>

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

Annex 1**Joint FAO/WHO Expert Committee on Food Additives (JECFA)
89th meeting, Geneva, 2 to 11 June 2020****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 10

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
Fulvic acid	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
Jagua Blue (Genipin-Glycine)	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ 84 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽²⁾	All data necessary for assessment of safety, dietary intake and specifications. To support the above JECFA 84 recommends additional biochemical and toxicological studies (e.g. absorption, distribution, metabolism and excretion studies, long-term toxicity, carcinogenicity, reproductive and developmental toxicity studies), including on the use of higher doses of the "blue polymer", including the dimers.

Food Additive	Reference (previous evaluations) and background	Information required
		<p>To support the above, additional information is also required on:</p> <ul style="list-style-type: none"> • Characterization of the low molecular weight components of the “blue polymer”; • A validated method for the determination of the dimers; and • Data on concentrations of dimers from five batches of the commercial product.
Natamycin (INS 235)	<p>Report of the 51th session of CCFA, REP 19/FA - Appendix X⁽¹⁾</p> <p>57th report of the Joint FAO/WHO Expert Committee on Food Additives⁽³⁾</p> <p>20th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁴⁾</p>	All data necessary for assessment of safety, dietary intake and specifications
Nisin (INS 234)	<p>Report of the 51th session of CCFA, REP 19/FA - Appendix X⁽¹⁾</p> <p>77th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁵⁾</p> <p>12th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁶⁾</p>	All data necessary for assessment of safety, dietary intake and specifications
Riboflavin from <i>Ashbya gossypii</i>	<p>Report of the 51th session of CCFA, REP 19/FA - Appendix X⁽¹⁾</p>	All data necessary for assessment of safety, dietary intake and specifications
Sucrose esters of fatty acids (INS 473)	<p>Report of the 51th session of CCFA, REP 19/FA - Appendix X⁽¹⁾</p> <p>84th report of the Joint FAO/WHO Expert Committee on Food Additives⁽²⁾</p> <p>49th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁷⁾</p> <p>44th report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁸⁾</p>	All data necessary for assessment dietary intake
Sucrose oligoesters, type I and type II (INS 473a)	<p>Report of the 51th session of CCFA, REP 19/FA - Appendix X⁽¹⁾</p> <p>71st report of the Joint FAO/WHO Expert Committee on Food Additives⁽⁹⁾</p>	All data necessary for assessment of dietary intake

1.2. Food additives for revision of specifications and analytical methods

Food Additive	Reference (previous evaluations) and background	Information required
Magnesium stearate (INS 470(iii))	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ FAO JECFA specification database ¹²	All data necessary for a revision of method of assay to determine magnesium
Polyvinyl alcohol (INS 1203)	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ FAO JECFA specification database ¹²	All data necessary to support a change of the solubility of polyvinyl alcohol (PVOH) in ethanol from "sparingly soluble in ethanol" to "practically insoluble or insoluble in ethanol". In 2011, a solubility testing for PVOH was carried out by Nippon and the test results were interpreted as PVOH being "practically insoluble or insoluble in ethanol"
Sorbitan monostearate (INS 491)	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ FAO JECFA specification database ¹²	All data necessary to replace the specification for congealing range.
Sorbitan tristearate (INS 492)	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ FAO JECFA specification database ¹²	All data necessary to replace the specification for congealing range.
Sorbitan monopalmitate (INS 495)	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ FAO JECFA specification database ¹²	All data necessary to replace the specification for congealing range.

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

JECFA No	FEMA No	CAS	Principle Name
PHENOL AND PHENOL DERIVATIVES JECFA 76, 73 and 55 – TRS 974 ⁽¹⁰⁾ , TRS 960 ⁽¹¹⁾ and TRS 901 ⁽¹³⁾			
	4228	462631-45-4	(-)-Homoeriodictyol, sodium salt
	4797	480-41-1	(±)-Naringenin
	4799	1449417-52-0	(2R)-3',5-Dihydroxy-4'-methoxyflavanone
	4830	38183-03-8	7,8-Dihydroxyflavone
	4833	87733-81-1	(2S)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan
	4834	1796034-68-2	(R)-5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one
	4872	35400-60-3	3-(3-Hydroxy-4-methoxy-phenyl)-1-(2,4,6-trihydroxyphenyl)propan-1-one
ALICYCLIC KETONES, SECONDARY ALCOHOLS AND RELATED ESTERS JECFA 73 and 59 - TRS 960 ⁽¹¹⁾ and 913 ⁽¹⁴⁾			

	4724	21862-63-5	trans-4-tert-Butylcyclohexanol
	4780	38284-26-3	Caryophylla-3(4),8-dien-5-ol
AMINO ACIDS AND RELATED SUBSTANCES– previous group evaluations JECFA 76 and 63 – TRS 974⁽¹⁰⁾ and 928⁽¹²⁾			
	4223	107-43-7	Betaine
	4738	16869-42-4	Glutamyl-2-aminobutyric acid
	4739	38837-71-7	Glutamyl-norvalyl-glycine
	4740	71133-09-0	Glutamyl-norvaline
	4752	1188-37-0	N-Acetyl glutamate
	4781	18598-63-5	L-Cysteine methyl ester hydrochloride

1.4. Establishment of specifications for certain flavouring agents

JECFA No	Substance	Source	Request
2002	3,4-Dimethyl-5-pentylidene-2(5H)-furanone	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to revise the secondary Components
1575	beta-Caryophyllene oxide	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update isomeric composition
1604	2-Acetylpyrroline	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update assay value, CAS number and secondary components
2077	(2E,6E/Z,8E)-N-(2-Methylpropyl)-2,6,8-decatrienamide	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update isomeric mixture
1125	4-Hexen-3-one	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update assay value and isomeric composition
380.1	d-Carvone	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update refractive index
1491	2-Pentylfuran	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update specific gravity range and assay value

1497	3-(2-Furyl)acrolein	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update melting point range
1502	2-Phenyl-3-(2-furyl)prop-2-enal	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to updated assay value and physical and odor descriptions
1504	2-Acetyl-5-methylfuran	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update Physical appearance description; specific gravity
1506	3-Acetyl-2,5-dimethylfuran	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update Specific gravity range
1511	4-(2-Furyl)-3-buten-2-one	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update Physical appearance and melting point range
1513	Ethyl 3-(2-furyl)propanoate	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update Physical form, refractive index and specific gravity
1517	Phenethyl 2-furoate	Report of the 51 th session of CCFA, REP 19/FA - Appendix X ⁽¹⁾ JECFA flavor specifications database ⁽¹⁵⁾	All data necessary to update Refractive index and specific gravity ranges; physical appearance

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_FAE.pdf
2. Report of the 84th meeting of JECFA
<https://apps.who.int/iris/bitstream/handle/10665/259483/9789241210164-eng.pdf?sequence=1>
3. Report 57th report of the Joint FAO/WHO Expert Committee on Food Additives⁽³⁾
https://apps.who.int/iris/bitstream/handle/10665/42578/WHO_TRS_909.pdf?sequence=1
4. Report of the 20th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/41217/WHO_TRS_599.pdf?sequence=1
5. Report of the 77th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/98388/9789241209830_eng.pdf?sequence=1

6. Report of the 12th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/40752/WHO_TRS_430.pdf?sequence=1
7. Report of the 49th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/42142/WHO_TRS_884.pdf?sequence=1
8. Report of the 44th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/37246/WHO_TRS_859.pdf?sequence=1
9. Report of the 71st meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/44266/WHO_TRS_956_eng.pdf?sequence=1
10. Report of the 76th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/77752/WHO_TRS_974_eng.pdf?sequence=1
11. 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
12. FAO JECFA Specification Database:
<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>
13. Report of the 55th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/42388/WHO_TRS_901.pdf?sequence=1
14. Report of the 59th meeting of JECFA
https://apps.who.int/iris/bitstream/handle/10665/42601/WHO_TRS_913.pdf?sequence=1
15. 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 (<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>