



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



**World Health
Organization**

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

Food Additives
Geneva, 7 to 16 June 2016
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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 eighty second 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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.

FAO and WHO have only limited data storage capacity. The submitted data can either be returned to submitters at their expense or destroyed after the evaluations have been completed. Please indicate the preferred procedure for data disposal at the time of submission. Key material can be stored up to five years and will then be destroyed. For substances that are being re-evaluated, the FAO and WHO Secretariats of JECFA encourage the sponsor to contact them before submission of data to determine whether documents and data reviewed at previous meetings of the Committee should be re-submitted.

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.

Date for submission

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

1 December 2015

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

Three copies of the data are required, one for submission to the address below, one for submission directly to the WHO Expert who will be reviewing the data (if requested a paper copy should also be provided), and one for the Member assigned to peer review the working paper. Please contact the WHO Joint Secretary prior to submission of the data for information on where to send the copies.

Attention: Dr Angelika Tritscher
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 3569
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; and

Three copies of the data are required, one for submission to the address below, and two for submission directly to the FAO experts who will be reviewing the data. Please contact the

FAO Joint Secretariat prior to submission of the data for information on where to send the copies.

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

Intake 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

should be sent to FAO at the address above (jecfa@fao.org) and to WHO under the address above (jecfa@who.int). Additional copies should be sent to the experts assigned for the exposure assessment; please contact the FAO or WHO Secretariat for information on where to send the copies.

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 procedural guidelines 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)
Eighty second meeting, Geneva, 7 to 16 June 2016****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. FAO and WHO procedural guidelines and guidelines for the preparation of chemical and technical assessments (CTA), toxicological working papers and guidelines for the preparation of working papers on food additives, intake, and flavouring agents are available at <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/> and http://www.who.int/foodsafety/areas_work/chemical-risks/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.

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 47th session of the Codex Committee on Food Additives (REP 15/FA - Appendix XIII)⁽¹⁾ and pending re-evaluations

1.1 Toxicological evaluation, exposure assessment and establishment of specifications

Food Additive	Reference (previous evaluations) and background	Information required
<i>Acacia polyacantha</i> var. <i>Campylacantha</i> , kakamut gum, arabino-galactan protein complex	Report of the 47 th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications
Allura Red AC (INS 129)	Report of the 47 th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾ 25 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽²⁾ FAO JECFA Monographs 1, (2006) ⁽³⁾	All data necessary for assessment of safety, dietary intake and specifications
Carob bean gum (INS 410)	Report of the 47 th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾ 25 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽²⁾	All data necessary for assessment of safety and dietary intake for use in infant formula and formulae for special medical purposes intended for infants. In particular data regarding lead levels are requested.
Octenyl succinic acid modified gum Arabic (INS 423)	79 th Report of JECFA ⁽⁴⁾ FAO JECFA Monograph 16, p45 (2014) ⁽⁶⁾	All information to define suitable specifications are requested, in particular, details of the manufacturing and purification process, batch data

Food Additive	Reference (previous evaluations) and background	Information required
		of the product in commerce, analytical methods for the determination of esterified (bound) and residual (free) OSA and an HPLC-method for the determination of residual octenyl succinic acid. Additional safety data may be needed to complete the evaluation of OSA-modified gum arabic.
Pectin	Report of the 47 th session of CCFA, REP 15/FA ⁽¹⁾ Report of the 79 th JECFA meeting ⁽⁴⁾ FAO JECFA Monographs 7, p. 75 (2009) ⁽⁵⁾	Additional data to support the safety evaluation of pectin in infant formula, including an explanation for the decreased feed intake and body weight gain in neonatal pigs. Data on levels of lead when the additive is intended for use in infant formula.
Quinoline Yellow	Report of the 74 th JECFA meeting ⁽⁷⁾ FAO JECFA Monograph 11, p. 111– 2011 ⁽⁸⁾	Submission of unpublished long-term toxicity studies in mice and rats. Additional information on the product in commerce, in particular on identify and purity of unmethylated form of Quinoline Yellow as detailed in the tentative specifications (FAO JECFA Monograph 11 - 2011) ⁽⁸⁾ .
Rosemary extract (INS 392)	Report of the 47 th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Steviol glycosides (INS 960)	Report of the 47 th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾ 69 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽⁹⁾ FAO JECFA Monographs 10, p. 17 (2010) ⁽¹⁰⁾	All data necessary to revise the assessment of safety, dietary intake and specifications
Tartrazine (INS 102)	Report of the 47 th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾ 8 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹¹⁾ FAO JECFA Monographs 1, (2006) ⁽³⁾	All data necessary for assessment of safety, dietary intake and specifications.

Food Additive	Reference (previous evaluations) and background	Information required
Xanthan gum (INS 415)	Report of the 47th session of CCFA, REP 15/FA - Appendix XIII ⁽¹⁾ 30 th report of the Joint FAO/WHO Expert Committee on Food Additives ⁽¹²⁾ FAO JECFA Monographs 1, (2006) ⁽³⁾	All data necessary for assessment of safety and dietary intake for use in infant formula and formulae for special medical purposes intended for infants. In particular data for a suitably protective lead level are requested.

1.2 Food additives for revision of specifications and analytical methods

Food Additive	Reference (previous evaluations) and background	Information required
Cassia gum (INS 427)	Report of 47 th session of CCFA, REP 15/FA ⁽¹⁾ FAO JECFA Monographs 10, p. 7 (2010) ⁽¹⁰⁾	Data on suitable analytical method for the determination of anthraquinones within the full specifications of cassia gum (INS 427) (adopted by CAC34 in 2011) is required as current method is deficient.
Citric and fatty acid esters of glycerol (INS 472c)	Report of the 47 th session of CCFA, REP 15/FA ⁽¹⁾ FAO JECFA Monograph 16, p15 (2014) ⁽⁶⁾	Data on levels of lead when the additive is intended for use in infant formula to include specific limit in the specifications.
Lutein esters from <i>Tagetes erecta</i>	79 th Report of JECFA ⁽⁴⁾ FAO JECFA Monograph 16, p23 (2014) ⁽⁶⁾	All information to define suitable specifications are requested, in particular, details on the manufacturing and purification process, batch data from commercial production and methods for analysis for determination of carotenoid composition as well as the non-carotenoid lipidic fraction. Establishment of full specifications is required to remove the temporary designation of the ADI 'not specified'.
Modified starches (INS 1400-1405, 1410, 1412-1414, 1420, 1422, 1440, 1442, 1450, 1451)	79 th Report of JECFA ⁽⁴⁾ CCFA 47 th Session Matters of interest arising from JECFA; CX/FA 15/47/3 Add.1 ⁽⁷⁾ JECFA - Draft Specification Monographs for sixteen Modified Starches ⁽¹⁴⁾	All information to define suitable specifications are requested, for details see endnote ⁽¹⁴⁾
Octanoic acid	FAO JECFA Monographs 1, (2006) ⁽³⁾	Missing data on IR spectrum identity test: conditions of performing the test and reference spectrum
Sodium dihydrogen phosphate (INS 339(i))	FAO JECFA Monographs 1, (2006) ⁽³⁾	Change of conditions for loss on drying to be consistent with testing requirements for other phosphate monographs

Food Additive	Reference (previous evaluations) and background	Information required
Starch sodium octenyl succinate (INS 1450)	Report of the 47 th session of CCFA, REP 15/FA ⁽¹⁾ FAO JECFA Monograph 16, p45 (2014) ⁽⁶⁾	Data on levels of lead when the additive is intended for use in infant formula to include specific limit in the specifications.
Total Colouring Matters Content (Tentative) (Volume 4)	74 th Report of JECFA ⁽⁷⁾ FAO JECFA Monograph 11, p. 133 – 2011 ⁽⁸⁾	Data on the wavelength of maximum absorbance, absorptivity and/or specific absorbance are requested for the following colours: Allura Red AC, Amaranth, Azorubine, Brilliant Black PN, Brilliant Blue FCF, Brown HT, Erythrosine, Fast Green FCF, Fast Red E, Green S, Indigotine, Patent Blue V, Ponceau 4R, Quinoline Yellow, Red 2G, Sunset Yellow FCF and Tartrazine. The data to be provided should also indicate the solvents used as well as any standardization for pH in order to allow for the establishment of consensus values for the wavelength of maximum absorbance, absorptivity and/or specific absorbance.

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

JECFA No	FEMA No	CAS	Principle Name
CINNAMYL ALCOHOL AND RELATED SUBSTANCES – previous group evaluations JECFA 55 – TRS 901⁽¹⁵⁾			
Structural Class I			
2211	4597	620-80-4	Ethyl alpha-acetylcinnamate
2212	4599	1205-17-0	3-(3,4-Methylenedioxyphenyl)-2-methylpropanal
2213	4598	15399-05-0	Ethyl 2-hydroxy-3-phenylpropionate
Structural Class III			
2214	4596	895950	Cinnamaldehyde propyleneglycol acetal
2215	4595	67634-23-5	2-Phenylpropanal propyleneglycol acetal
ALIPHATIC SECONDARY ALCOHOLS, KETONES AND RELATED ESTERS – previous group evaluations JECFA 59, 69 and 73– TRS 913⁽¹⁶⁾, 952⁽⁹⁾ and 960⁽¹⁷⁾			
Structural Class II			
2216	4706	35194-30-0	9-Decen-2-one
2217	4691	1009814-14-5	Yuzunone
2218	4732	83861-74-9	1,5-Octadien-3-ol
2219	4746	68973-20-6	3,5-Undecadien-2-one
2220	4775	67801-20-1	3-Methyl-5-(2,2,3-trimethylcyclopent-3-en-1-yl)pent-4-en-2-ol
2221	4794	1193-81-3	(±)-Cyclohexylethanol
ALICYCLIC, ALICYCLIC-FUSED AND AROMATIC-FUSED RING LACTONES – previous group evaluations JECFA 61– TRS 922⁽¹⁸⁾			
Structural Class I			

2222	4438	591-11-7	beta-Angelicalactone
Structural Class III			
2223	4140	57743-63-2	2-(2-Hydroxy-4-methyl-3-cyclohexenyl)propionic acid gamma-lactone
2224	4270	5617-64-1	2-(2-Hydroxyphenyl)cyclopropanecarboxylic acid delta-lactone
ALIPHATIC AND AROMATIC AMINES AND AMIDES – previous group evaluations JECFA 65, 68, 73 and 76 – TRS 934⁽¹⁹⁾, 947⁽²⁰⁾, 960⁽¹⁷⁾ and 974⁽²¹⁾			
Structural Class III			
2225	4741	851670-40-1	N1-(2,3-Dimethoxybenzyl)-N2-(2-(pyridin-2-yl)ethyl) oxalamide
2226	4751	851669-60-8	(R)-N-(1-Methoxy-4-methylpentan-2-yl)-3,4-dimethylbenzamide
2227	4773	125187-30-6	(E)-N-[2-(1,3-benzodioxol-5-yl)ethyl]-3-(3,4-dimethoxyphenyl)prop-2-enamide
2228	4788	1309389-73-8	(E)-3-Benzo[1,3]dioxol-5-yl-N,N-diphenyl-2-propenamide
2229	4808	1582789-90-9	N-Ethyl-5-methyl-2-(methylethenyl)cyclohexanecarboxamide
TETRAHYDROFURAN AND FURANONE DERIVATIVES – previous group evaluations JECFA 63 – TRS 928⁽²²⁾			
Structural Class II			
2230	4101	1440-67-0	2,5-Dimethyl-3(2H)-furanone
2231	4104	65330-49-6	2,5-Dimethyl-4-ethoxy-3(2H)-furanone
Structural Class III			
2232	4176	3511-32-8	5-Methyl-3(2H)-furanone
2233	4546	39156-54-2	Ethyl 2,5-dimethyl-3-oxo-4(2H)-furyl carbonate
2234	4070	36871-78-0	4-Acetyl-2,5-dimethyl-3(2H)-furanone

1.4. Revision of specification for certain flavourings

The following revisions of specifications have been requested at the 46th CCFA meeting⁽²³⁾

SPECIFICATIONS CHANGES			
1114	3196	488-10-8	3-Methyl-2-(2-pentenyl)-2-cyclopenten-1-one
1122	3542	3796-70-1	6,10-Dimethyl-5,9-undecadien-2-one
1203	2054	7563-33-9	3-Ammonium isovalerate
1238	3774	36431-72-8	Theaspirane
2031	4666	23089-26-1	alpha-Bisabolol
2123	4709	38837-70-6	Glutamyl-valyl-glycine

References

1. Report of the 47th Session of the Codex Committee on Food Additives, Xi'an, China, 23-27 March 2015 (REP15/FA).
2. Evaluation of certain food additives (25th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 669, 1981
3. Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives, 65th meeting 2005
4. Evaluation of certain food additives and contaminants (79th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, 990, 2014
5. Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives, 71st meeting 2001
6. Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives, 79th meeting 2014
7. Evaluation of certain food additives (74th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 966, 2011

8. Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives, 74th meeting 2011
9. Evaluation of certain food additives (69th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 952, 2009
10. Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives, 73rd meeting 2010
11. Evaluation of certain food additives (80th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No 309, 1964
12. Evaluation of certain food additives and contaminants (30th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 751, 1987
13. Codex Committee on Food Additives 47th Session - Matters of interest arising from JECFA; CX/FA 15/47/3 Add.1 (ftp://ftp.fao.org/codex/meetings/CCFA/ccfa47/fa47_03e Add. 1.pdf)
14. JECFA FAO Joint Secretariat, Rome, 20 February 2015: Draft Specification Monographs for sixteen Modified Starches (http://www.fao.org/fileadmin/user_upload/agns/pdf/jecfa/2015_02_22_Modified_Starches.pdf)
15. Evaluation of certain food additives and contaminants (55th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 901, 2001.
16. Evaluation of certain food additives and contaminants (59th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 913, 2002.
17. Evaluation of certain food additives and contaminants (73rd report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 960, 2011.
18. Evaluation of certain food additives and contaminants (61st report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 922, 2004.
19. Evaluation of certain food additives and contaminants (65th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 934, 2006.
20. Evaluation of certain food additives and contaminants (68th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 947, 2007.
21. Evaluation of certain food additives and contaminants (76th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 974, 2012.
22. Evaluation of certain food additives and contaminants (63rd report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 928, 2005.
23. Codex Committee on Food Additives 46th Session – Appendix XV

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.

Through mid-2015, a total of eighty meetings of JECFA have been held. The reports 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/>.

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>