



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



**World Health
Organization**

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Seventy-ninth meeting

Food additives and Flavourings

Geneva, 17 to 26 June 2014

Published 16 September 2013

**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 seventy-ninth 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 2013.

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 studies:

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

should be sent to:

Department of Food Safety and Zoonoses
Attention: Dr Angelika Tritscher
World Health Organization
Avenue Appia
1211 Geneva 27
Switzerland
Facsimile: +41 (0) 22791 4807
Telephone: +41 (0)22791 3569
E-mail: jecfa@who.int

Three copies of the data are required, one for submission to the address above, one for submission directly to the WHO Temporary Adviser who will be reviewing the data (if request 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.

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;
5. effects of processing on levels of the listed contaminants in food as consumed; 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 Secretary prior to submission of the data for information on where to send the copies.

Attention: Mr. Steve Crossley
Room C2-78, Food Safety Unit
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-Call@fao.org

Intake assessment data

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;

should be sent to the attention of Mr. Steve Crossley at FAO address above (JECFA-Call@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 recently 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/chem/principles/en/index1.html> .

Specific procedural guidelines for food additives are as well 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/chem/jecfa/data/en/index.html>

Annex 1

**Joint FAO/WHO Expert Committee on Food Additives (JECFA)
Seventy-ninth meeting, Geneva, 17 to 26 June 2014**

List of substances scheduled for evaluation or re-evaluation

General information: Links to 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/en/> and <http://www.who.int/foodsafety/chem/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. The guidance on provision of data related to use levels of flavourings can be found in the sixty-ninth report of JECFA⁽¹⁾.

Previous reports and monographs should be consulted to obtain background information on the previous evaluations. Detailed bibliographical references are available on page 11.

1. Food additives and flavourings for which requests have been received for evaluation or re-evaluation by the 45th session of the Codex Committee on Food Additives (REP 13/FA - Appendix XI) and pending re-evaluations

1.1 Toxicological evaluation, exposure assessment and establishment of specifications

Food Additive	Reference (previous evaluations) and background	Information required
Carrageenan (INS 407) (for use in infant formula)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All data necessary for assessment of safety, dietary intake for use in infant formula and review of specifications.
Citric acid esters of mono- and diglycerides of fatty acids (CITREM) (INS 472c) (for use in infant formula and formulas for special medical purposes intended for infants)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All data necessary for assessment of safety, dietary intake for use in infant formula and formulas for special medical purposes intended for infants and review of specifications.
Gardenia yellow (Crocin)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All data necessary for assessment of safety, dietary intake and specifications.
OSA-modified starch (starch sodium octenyl succinate) (INS 1450) (for use in infant formula and formulas for special medical purposes intended for infants)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All data necessary for assessment of safety, dietary intake for use in infant formula and formulas for special medical purposes intended for infants
Octenyl succinic acid (OSA) modified gum arabic	Seventy-seventh report of JECFA ⁽³⁾	All data necessary for assessment of safety in particular data on the stability of OSA modified gum arabic in food such as information on its chemical state in food and aqueous solutions, which could help to explain the contradictory results of

		the hydrolysis study submitted to the 77 th meeting. All information necessary for revision of specifications, in particular purity test of the degree of substitution, an analytical method to measure the degree of substitution and results of the analysis of at least five commercially available batches.
Paprika extract	Sixty-ninth report of JECFA ⁽⁴⁾ , FAS 60 ⁽⁵⁾ , FAO JECFA Monographs 5 ⁽⁶⁾	Information as to whether the material used in the toxicological tests submitted was representative of the products in commerce, as specified by JECFA.
Pectin (INS 440) (for use in infant formula and formulas for special medical purposes intended for infants)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All data necessary for assessment of safety, dietary intake for use in infant formula and formulas for special medical purposes intended for infants
Tagetes extract (INS 161b(ii))	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All data necessary for assessment of safety, dietary intake and specifications

1.2 Food additives for revision of specifications

Food Additive	Reference (previous evaluations) and background	Information required
Benzoe Tonkinesis	Seventy-seventh report of JECFA ⁽³⁾	All information necessary for revision of specifications, in particular complete data on composition of the ethanol extract and on microbiological contaminants. Analytical method to distinguish between Benzoe tonkinensis and Benzoe sumatranus.
Citric acid	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All information necessary for revision of specifications (Oxalate test method)
Gellan gum (INS 418)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All information necessary for revision of specifications, in particular for permitting the use of ethanol in the manufacturing process as an alternative to isopropyl alcohol
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60) (INS 435)	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All information necessary for revision of specifications, in particular change of saponification value and hydroxy value
Quillaia extract, type 2 (INS 999(ii))	Report of the forty-fifth session of CCFA, REP 13/FA - Appendix XI ⁽²⁾	All information necessary for revision of specifications, in particular revision of upper limit in the loss on drying specification from 80% to 90%

2.1. Flavourings – New compounds as additions to previously evaluated groups of related flavouring substances

JECFA No.	FEMA No.	C.A.S. No.	Flavouring substance
IONONES AND STRUCTURALLY RELATED SUBSTANCES - previous group evaluations JECFA 51 - TRS 891⁽⁷⁾			
			Structural Class I
	4151	79-89-0	<i>beta</i> -Isomethylionone
	4299	141-10-6	Pseudoionone
			Structural Class II
	4088	24720-09-0	<i>trans-alpha</i> -Damascone
ALIPHATIC AND AROMATIC ETHERS - previous group evaluations JECFA 61 and 76 - TRS 922⁽⁸⁾ and 974⁽⁹⁾, respectively			
			Structural Class III
	4731	871465-49-5	Cassyrane
	4759	16510-27-3	1-Cyclopropanemethyl-4-methoxybenzene
2137	4536	1424-83-5	Nerolidol oxide
ALIPHATIC AND ALICYCLIC HYDROCARBONS - previous group evaluation JECFA 63 - TRS 928⁽¹⁰⁾			
			Structural Class I
	4293	111-66-0	1-Octene
	4292	56700-78-8	2,4-Nonadiene
	4264	475-03-6	<i>alpha</i> -Ionene
	4650	691-38-3	4-Methyl-cis-2-pentene
	4651	124-11-8	1-Nonene
	4652	116963-97-4	1,3,5,7-Undecatetraene
	4311	30640-46-1; 1888-90-0	Mixture of methyl cyclohexadiene and methylene cyclohexene
MONOCYCLIC AND BICYCLIC SECONDARY ALCOHOLS, KETONES, AND RELATED ESTERS - previous group evaluations JECFA 63 and 69 - TRS 928⁽¹⁰⁾ and 952⁽¹¹⁾, respectively			
			Structural Class I
	4521	97866-86-9	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-ol
			Structural Class II
	4513	21368-68-3	<i>d</i> -Camphor
	4519	7787-20-4	<i>l</i> -Fenchone
	4522	97844-16-1	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-one
PHENYL-SUBSTITUTED ALIPHATIC ALCOHOLS AND RELATED ALDEHYDES AND ESTERS - previous group evaluation JECFA 63 - TRS 928⁽¹⁰⁾			
			Structural Class II
	4758	20921-04-4	Ethyl 3-(2-hydroxyphenyl)propanoate
2069	4194	26643-92-5	(±)-2-Phenyl-4-methyl-2-hexenal
MISCELLANEOUS NITROGEN-CONTAINING SUBSTANCES - previous group evaluation JECFA 65 and 76 - TRS 934⁽¹²⁾ and 974⁽⁹⁾, respectively			
			Structural Class III

	4766	1160112-20-8	3-[3-(2-Isopropyl-5-methylcyclohexyl)-ureido]-butyric acid ethyl ester
	4774	1359963-68-0	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid
SULFUR-CONTAINING HETEROCYCLIC COMPOUNDS - previous group evaluation JECFA 59, 68 and 76- TRS 913⁽¹⁵⁾, 947⁽¹⁶⁾ and 974⁽⁹⁾			
			Structural Class II
	4748	54717-17-8	Triethylthialdine
1051	3527	2530-10-1	3-Acetyl-2,5-dimethylthiophene
			Structural Class III
	4767	67936-13-4	2-Isopropyl-4-methyl-3-thiazoline
PHENOL AND PHENOL DERIVATIVES - previous group evaluation JECFA 55, 73 and 76 - TRS 901⁽¹³⁾, 960⁽¹⁴⁾ and 974⁽⁹⁾, respectively			
			Structural Class II
	4491	17912-87-7	Myricitrin
			Structural Class III
	4495	18916-17-1	Naringin dihydrochalcone
	4764	50297-39-7	1-(2,4-Dihydroxyphenyl)-3-(3-hydroxy-4-methoxyphenyl)propan-1-one
	4762	580-72-3	(-)-Matairesinol

References

1. Evaluation of certain food additives (Sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 952, 2009.
2. Report of the Forty-fifth Session of the Codex Committee on Food Additives, Beijing, China, 18-22 March 2013 (ALINORM REP13/FA).
3. Evaluation of certain food additives and contaminants (Seventy-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, (under preparation), 2013.
4. Evaluation of certain food additives (Sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 952, 2009
5. Safety evaluation of certain food additives. WHO Food Additive Series No. 60, 2009.
6. Combined Compendium of Food Additive Specifications. FAO JECFA Monographs 5, 2008.
7. Evaluation of certain food additives and contaminants (Fifty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 891, 2000.
8. Evaluation of certain food additives and contaminants (Sixty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 922, 2004.
9. Evaluation of certain food additives and contaminants (Seventy-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 974, 2012.
10. Evaluation of certain food additives and contaminants (Sixty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 928, 2005.
11. Evaluation of certain food additives and contaminants (Sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 952, 2009.
12. Evaluation of certain food additives and contaminants (Sixty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 934, 2006.
13. Evaluation of certain food additives and contaminants (Fifty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 901, 2001.
14. Evaluation of certain food additives and contaminants (Seventy-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 960, 2011.
15. Evaluation of certain food additives and contaminants (Fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 913, 2002.
16. Evaluation of certain food additives and contaminants (Sixty-eighth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 947, 2007.

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 2011, a total of seventy-four meetings of JECFA have been held. The reports are published in the WHO Technical Report Series (<http://www.who.int/entity/foodsafety/chem/jecfa/publications/reports/en/index.html>). 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/entity/foodsafety/chem/jecfa/publications/monographs/en/index.html>). 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/ag/agn/jecfa-additives/search.html?lang=en>. The newly updated data base on specifications for flavouring agents is available at <http://www.fao.org/ag/agn/jecfa-flav/search.html>.

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/ipsc/database/evaluations/search.aspx>, or <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/summary-reports/en/>.