



JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES Eighty-sixth meeting

Food Additives

Geneva, 12 to 21 June 2018 Published 1 September 2017

Addendum to the JECFA Call for data published on 22nd June 2017

THE LIST OF SUBSTANCES SCHEDULED FOR EVALUATION AND REQUEST FOR DATA

Attached is an addendum to the list of substances in Annex 1 (pt. 1.3 -Toxicological evaluation, exposure assessment and establishment of specifications for certain flavouring agents and pt. 1.4 Revision of specification for certain flavourings) scheduled for evaluation or re-evaluation at the 86th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This addendum contains a list of flavouring agents for evaluation or re-evaluation at the 86th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in addition to the food additives already mentioned in the call for data published on 22 June 2017.

http://www.who.int/foodsafety/JECFA_86_Call_for_data_22_June_2017.pdf?ua=1

The 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 1.3 and 1.4** is requested before

1 January 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: 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:

- 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

Viale 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;
- 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 (*Principles and methods for the risk assessment of chemicals 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) 86th meeting, Geneva, 12 to 21 June 2018

Addendum to the JECFA Call for data published on 22nd June 2017

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 6.

1. Food additives for which requests have been received for evaluation or reevaluation by the 49th session of the Codex Committee on Food Additives (REP 17/FA - Appendix XIV)⁽¹⁾ and pending re-evaluations

Note: For information about food additives to be evaluated at the 86th meeting of JECFA please consult the call for data published on 22 June 2017.

http://www.who.int/foodsafety/JECFA 86 Call for data 22 June 2017.pdf?ua=1

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

The flavouring agents will be evaluated according to procedures outlined here: http://apps.who.int/iris/bitstream/10665/250277/1/9789241210003-eng.pdf?ua=1

JECFA No	FEMA No	CAS	Principle Name		
MISCELLANEOUS NITROGEN-CONTAINING SUBSTANCES – previous group evaluations JECFA 65, 69, 76 and 79 – TRS 934 ⁽²⁾ , 952 ⁽³⁾ , 974 ⁽⁴⁾ and 990 ⁽⁵⁾					
			Structural Class III		
	4798	902136-79-2	2-(((3-(2,3-Dimethoxyphenyl)-1 <i>H</i> -1,2,4-triazol-5-yl)thio)methyl)pyridine		
	4802	1469426-64-9 1479020-92-2 (sodium salt)	(S)-1-(3-(((4-Amino-2,2-dioxido-1H-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbutan-1-one		
	4809	1374760-95-8	2-(4-Methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide		
	SATURATED ALIPHATIC ACYCLIC BRANCHED-CHAIN PRIMARY ALCOHOLS, ALDEHYDES, AND ACIDS – previous group evaluations JECFA 49 – TRS 884 ⁽⁶⁾				

			Characterizal Class I
	4795	127793-88-8	Structural Class I 8-Methyldecanal
	4803	3085-26-5	8-Methylnonanal
INEAD			PHATIC, UNSATURATED, UNCONJUGATED
ALCOH		DEHYDES, ACIDS, AN	ND RELATED ESTERS – previous group evaluations Structural Class I
	4787	63196-63-4	trans-6-Octenal
	4789	4234-93-9	2,6-Dimethyl-5-heptenol
CARV		D STRUCTURALLY R	ELATED SUBSTANCES – previous group evaluations ECFA 51 – TRS 891 ⁽⁷⁾ Structural Class II
	4525	929116-08-5	Pinocarvyl isobutyrate
	4515	929222-96-8	Carvyl palmitate
	4523		, ,
		51200-86-3	6-Hydroxycarvone
	2249	2244-16-8/6485-40-	Carvone
			Structural Class I
	4509	2230-90-2	Menthyl formate
	4510	86014-82-6	Menthyl propionate
	4524	68366-64-3	I-Menthyl butyrate
	4729	3623-52-7	dl-Isomenthol
	4604	406179-71-3	Dimenthyl glutarate
427	2665	89-78-1	Menthol
	•	•	Structural Class II
	4718	28804-53-7	(±)2-[(2-p-Menthoxy)ethoxy]ethanol
MALTO			ES – previous group evaluations JECFA 65 – TRS 934 ⁽²⁾
			Structural Class III
	4534	852997-28-5	Ethyl maltol isobutyrate
1480	2656	118-71-8	Maltol
			DEHYDES, ACIDS AND RELATED ESTERS (RE-
			uations JECFA 59 and 73 – TRS 913 ⁽⁸⁾ and 960 ⁽⁹⁾
			Structural Class I
	4783	1049017-63-1/	Mixture of 1-Vinyl-3-cyclohexenecarbaldehyde and 4-
		1049017-68-6	Vinyl-1-cyclohexenecarbaldehyde
973	3557	2111-75-3	p-Mentha-1,8-dien-7-al (Perillaldehyde)
974	2664	536-59-4	p-Mentha-1,8-dien-7-ol
975	3561	15111-96-3	p-Mentha-1,8-dien-7-yl acetate
982	3765	1079-01-2	Myrtenyl acetate
981	3439	515-00-4	Myrtenol
980	3395	564-94-3	Formyl-6,6-dimethylbicyclo[3.1.1]hept-2-ene
		1	Structural Class II
	4776	198404-98-7	(1-Methyl-2-(1,2,2-trimethylbicyclo[3.1.0]hex-3-
			ylmethyl)cyclopropyl)methanol
			Structural Class III
	4790	10138-32-6	(±)-Bicyclo[2.2.1]hept-5-ene-2-carboxylic acid, ethyl ester
CARBO	XYLIC A	CIDS AND RELATED	YDROCARBONS, ALCOHOLS, ALDEHYDES, KETONES, ESTERS, SULFIDES, DISULFIDES AND ETHERS.(RE- Lations JECFA 65, 69 and 76 – TRS 934 ⁽²⁾ , 952 ⁽³⁾ and
∵ 1			Structural Class II
1491	3317	3777-69-3	2-Pentylfuran
1492	3401	3777-71-7	2-Heptylfuran
1493	4090	83469-85-6	2-Decylfuran
1494	4174	15186-51-3	3-Methyl-2-(3-methylbut-2-enyl)-furan
1497	2494	623-30-3	3-(2-Furyl)acrolein

1499	4175	5555-90-8	3-(5-Methyl-2-furyl)prop-2-enal		
1503	3163	1192-62-7	2-Furyl methyl ketone		
1504	3609	1193-79-9	2-Acetyl-5-methylfuran		
1505	4071	22940-86-9	2-Acetyl-3,5-dimethylfuran		
1507	4083	4208-57-5	2-Butyrylfuran		
1508	2496	6975-60-6	(2-Furyl)-2-propanone		
1509	4192	3194-17-0	2-Pentanoylfuran		
1510	4120	699-17-2	1-(2-Furyl)butan-3-one		
1511	2495	623-15-4	4-(2-Furyl)-3-buten-2-one		
1513	2435	10031-90-0	Ethyl 3-(2-furyl)propanoate		
1514	2198	105-01-1	Isobutyl 3-(2-furan)propionate		
1515	2071	7779-67-1	Isoamyl 3-(2-furan)propionate		
1516	2070	7779-66-0	Isoamyl 4-(2-furan)butyrate		
1517	2865	7149-32-8	Phenethyl 2-furoate		
1520	3159	13679-46-4	Furfuryl methyl ether		
1521	4114	6270-56-0	Ethyl furfuryl ether		
1522	3337	4437-22-3	Difurfuryl ether		
1523	4034	55764-22-2	2,5-Dimethyl-3-furanthiol acetate		
1524	4119	109537-55-5	Furfuryl 2-methyl-3-furyl disulfide		
1525	4056	61295-44-1	3-[(2-Methyl-3-furyl)thio]-2-butanone		
1526	4043	376595-42-5	O-Ethyl S-(2-furylmethyl)thiocarbonate		
	Structural Class III				
1495	3535	3782-00-1	2,3-Dimethylbenzofuran		
1496	4095	64280-32-6	2,4-Difurfurylfuran		
1498	2704	874-66-8	2-Methyl-3(2-furyl)acrolein		
1500	3307	31704-80-0	3-(5-Methyl-2-furyl)-butanal		
1501	2492	770-27-4	2-Furfurylidene-butyraldehyde		
1502	3586		2-Phenyl-3-(2-furyl)prop-2-enal		
1506	3391	10599-70-9	3-Acetyl-2,5-dimethylfuran		
1512	3418	14360-50-0	Pentyl 2-furyl ketone		
1518	2945	623-22-3	Propyl 2-furanacrylate		
1519	3970	114099-96-6	2,5-Dimethyl-3-oxo-(2H)-fur-4-yl butyrate		
2103	4541	53282-12-5	(E)-Ethyl 3-(2-furyl)acrylate		
2104	4540	1197-40-6	di-2-Furylmethane		
2105	4543	4265-25-2	2-Methylbenzofuran		

1.4. Revision of specification for certain flavourings

The following revisions of specifications have been requested at the 49th CCFA meeting(1)

SPECIFICATION CHANGES					
2123	4709	38837-70-60	Glutamyl-valyl-glycine		
433	3748	59259-38-0	I-Menthyl lactate		

References

- Report of the 49th Session of the Codex Committee on Food Additives, Macao, China, 20-24 March 2017 (REP17/FA)
 http://www.fao.org/fao-who-codexalimentarius/sh-
 - proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252 FMeetings%252FCX-711-49%252FReport%252FREP17_FAe.pdf
- 2. 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.
- 3. Evaluation of certain food additives (69th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 952, 2009.

4. 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.

- 5. Evaluation of certain food additives and contaminants (79th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 990, 2014.
- 6. Evaluation of certain food additives and contaminants (49th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 884, 1999.
- 7. Evaluation of certain food additives and contaminants (51st 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 (59th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 913, 2002.
- 9. 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.

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 <u>not</u> 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 <u>not</u> 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-flav/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 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