



JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES Ninetieth meeting

Food Contaminants

Geneva, 27 October to 5 November 2020 Published on 21 October 2019

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 ninetieth-first 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 Codex Committee on Contaminants in Foods (CCCF), previous Expert Committees, and direct requests from governments, or other interested organizations.

Also attached to this call for data is the list of Acceptable Previous Cargoes (Annex 2) requested by the Codex Committee on Fats and Oils (CCFO) to be evaluated by FAO and WHO. CCFO have requested FAO/WHO whether the listed substances were suitable as previous cargoes and to provide an assessment against the four criteria as mentioned in the Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk (CAC/RCP 36-1987).

Submission of data

Governments, interested organizations and individuals are invited to submit data for the toxicological evaluation and for estimating the exposure to the contaminants that are listed in annex 1. Governments, interested organizations and individuals are also invited to submit previous evaluations or information about ease of cleaning and toxicological profile to the substances listed in list of previous cargoes in annex 2.

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data, epidemiological evidence of human exposures and associated health endpoints, or examination of the occurrence of chemicals in the food system. 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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 JECFA 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.

Submissions of recent regulatory reviews or comprehensive literature reviews with supporting publications are particularly encouraged.

Date for submission

The submission of data on the contaminants listed in Annex 1 and Annex 2 is requested before

15th April 2020

This deadline applies to all data.

Toxicological data for contaminants (Annex 1)

Data relevant to the toxicological evaluations of the contaminants on the agenda including the results of:

- 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 (including interactions among related contaminants, in particular as mentioned in annex 1), immune responses, or macromolecular binding

Data for previous cargoes (Annex 2)

Data or relevant evaluations related to the toxicological assessment of the previous cargoes listed in Annex 2.

- 1. Information about ease of cleaning (impact with respect to possible carry-over of residues into edible oils and fats);
- 2. toxicological profile; possible allergenicity; reactivity with edible oils and fats resulting in reaction products that would result in adverse human health effects for the substances and their expected impurities;

should be sent 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

Facsimile: +41 (0) 22 791 4807 Telephone: +41 (0)22 791 1439

E-mail: jecfa@who.int

Additional copies of the data might be needed and the JECFA Secretariat will inform the data provider on where to send additional copies in due course.

Occurrence data for contaminants (Annex 1)

Data relevant to the occurrence, and quantification of contaminants listed in annex 1 including:

- 1. levels and patterns of occurrence (and in some cases co-occurrence, see annex 1) of the listed contaminants in raw commodities and finished food products
- 2. levels of the listed contaminants in animal feed
- 3. information on carry-over of contaminants from feed to animals for human consumption
- 4. effects of processing on levels of contaminants in food as consumed and in feed
- 5. analytical techniques used by investigators or authorities for identifying and quantifying the listed contaminants in foodstuffs and/or human and animal tissues;
- 6. sampling protocols for the listed contaminants
- 7. methods available for the prevention and control of the listed contaminants

Data for previous cargoes (Annex 2)

Data or relevant evaluations related to the assessment of the previous cargoes listed in Annex 2.

- 1. Information about ease of cleaning (impact with respect to possible carry-over of residues into edible oils and fats);
- 2. Dilution factor in relation to the potential amount of residues of the previous cargo (including any impurity that the previous cargo might have contained) and the volume of fats/oils transported.
- 3. Solubility of contaminating residues
- 4. Refining/ processing of the fats and oils
- 5. Availability of analytical methods for the detection of trace amount of residues or for verifying the absence of contamination.
- 6. Reactivity
- 7. Allergenicity

should be sent to:

Attention: Dr Markus Lipp

Food Safety and Quality Unit - Room B-619

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

Additional copies of the data might be needed and the JECFA Secretariat will inform the data provider on where to send additional copies in due course.

Please note

Data on occurrence of the listed contaminants in food should be submitted to the GEMS/Food on-line database (https://extranet.who.int/gemsfood/).

For more information please refer to the GEMS/Food Electronic Reporting Manual available at the WHO Website –

http://www.who.int/foodsafety/chem/instructions GEMSFood january 2012.pdf

Intake assessment data

All data relevant to:

- 1. levels and patterns of human exposure from all relevant sources of the listed contaminants;
- 2. food consumption patterns; also considering different (age-)population groups
- 3. biomarkers of exposure

should be sent to FAO at the address above (iecfa@fao.org) and to WHO under the address above (iecfa@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) Ninetieth meeting, Geneva, 26 October to 6 November 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. 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/jecfa/en/).

Previous JECFA reports and monographs should be consulted to obtain background information on the previous evaluations

References

Contaminant	Question(s) to be answered, reference, and background	Information required
Ergot alkaloids ¹	Full evaluation (toxicological assessment and exposure assessment)	All information related to toxicology, occurrence and intake assessment (as detailed in pages 2-3 of this call).
	Report of the 13 th session of CCCF, REP 19/CF – Appendix X ¹	
	Update of risk assessment, including exposure assessment (T2, HT2, DAS)	All information related to toxicology, occurrence and intake assessment (as detailed in pages 2-3 of this call).
Trichothecenes (T2 and HT2)	Report of the 13 th session of CCCF, REP 19/CF – Appendix X ¹	
	56 th report of the Joint FAO/WHO Expert Committee on Food Additives ²	

- Report of the 13th Session of the Codex Committee on Contaminants in Food, Yogyakarta, Indonesia, 29 April - 3 May 2019 (REP 19/CF – Appendix X) <a href="https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-13%252FREPORT%252FFinal%252520Report%252FREP19_CFe.pdf
- 2. Evaluation of certain mycotoxins in food (56th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 906, 2002 https://apps.who.int/iris/bitstream/handle/10665/42448/WHO_TRS_906.pdf?sequence=1

Annex 2

Joint FAO/WHO Expert Committee on Food Additives (JECFA) Ninetieth-first meeting, Geneva, 26 October to 6 November 2020

Review of the list of acceptable previous cargoes

The Codex Alimentarius Commission (CAC) has adopted the recommended international code of practice for the storage and transport of edible fats and oils in bulk (CAC/RCP 36- 1987)^a. This Code applies to the handling, storage and transport of all crude or processed edible oils and fats in bulk.

The Codex Committee on Fats and Oils (CCFO) have requested FAO/WHO whether the listed substances were suitable as previous cargoes and to provide an assessment against the four criteria as mentioned in the *Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk* (CAC/RCP 36-1987).

No.	Substance	CAS No.	Chemical Group			
	A) Current Substances in the List of Acceptable Previous Cargoes ¹					
1	Acetic anhydride (ethanoic anhydride)	108-24-7	Solvents,			
			reactants			
2	1,4-Butanediol (1,4-butylene glycol)	110-63-4	Alcohol			
3	Butyl acetate, sec-	105-46-4	Solvents, reactants			
4	Butyl acetate, tert-	540-88-5	Solvents, reactants			
5	Cyclohexane (hexamethylene; hexanaphthene; hexahydrobenzene)	110-82-7	Solvents, reactants			
6	Iso decyl alcohol (isodecanol)	25339-17-7	Alcohols			
7	Myristyl alcohol (1-tetradecanol; tetradecanol)	112-72-1	Alcohols			
8	Iso nonyl alcohol (isononanol)	27458-94-2	Alcohols			
9	Tridecyl alcohol (I-tridecanol)	27458-92-0	Alcohols			
10	Methyl tertiary butyl ether (MBTE)	1634-04-4	Butyl ethers			
11	Montan wax	8002-53-7	Oils / Waxes			
12	iso-Octyl alcohol (isooctanol)	26952-21-6	Alcohols			
13	Pentane	109-66-0	Solvents, reactants			
14	1,3 -Propylene glycol	504-63-2	Alcohols			
15	Propylene tetramer (tetrapropylene; dodecene)	6842-15-5	Oils / Waxes			
16	Soybean oil epoxidized	8013-07-8	Oils / Waxes			
17	Mineral oil, medium and low viscosity, class II		Oils / Waxes			
18	Mineral oil, medium and low viscosity, class III		Oils / Waxes			
19	Calcium ammonium nitrate solution*	6484-52-2	Solutions			
20	Calcium nitrate (CN-9) solution*	35054-52-5	Solutions			
21	Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats*		Oils / Waxes			

^ahttp://www.fao.org/fao-who-codexalimentarius/sh-

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B36-1987%252FCXP_036e.pdf

22	Calcium lignosulphonate liquid (lignin liquor; sulphite lye)	8061-52-7			
B) New Substance Proposed to be Added to the List of Acceptable Previous Cargoes					
23	Ethyl tertiary butyl ether (ETBE)	637-92-3	Butyl ethers		

^{*} Recommended for evaluation due to its reaction products

- Report of the 24th Session of the Codex Committee on Fats and Oils, Melaka, Malaysia, 9 -13 13
 February 2015 (REP 15/FO Appendix V) https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-709-24%252FREP15 FOe.pdf
- FAO/WHO. 2007. Development of criteria for acceptable previous cargoes for fats and oils. Report
 of a Joint FAO/WHO Technical Meeting, Bilthoven, the Netherlands. 7-9 November 2006.
 http://www.fao.org/3/a-a1090e.pdf

Annex 3

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