



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



**World Health
Organization**

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

Food additives
Geneva, 16 to 24 June 2009

**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-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 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 dossiers and information in electronic format. Such data should be presented preferably using standard word processing or document formats, and should be submitted on CD-ROMs. To facilitate review, an effort should be made to provide a "Table of contents" on each CD-ROM using fully descriptive file names.

Date for submission

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

15 December 2008.

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:

International Programme on Chemical Safety
Attention: Dr Angelika Tritscher
World Health Organization
Avenue Appia
1211 Geneva 27
Switzerland
Facsimile: (+41 (0)22)791 4848
Telephone: (+41 (0)22)791 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 (which should include a paper copy), 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 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. levels and patterns of contamination in food commodities of the listed contaminants;
5. analytical techniques used by manufacturers or authorities for identifying and quantifying the listed substances;
6. sampling protocols for the listed contaminants;

7. effects of processing on levels of the listed contaminants in food as consumed, and
8. methods available for the prevention and control of the listed contaminants

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.

Nutrition and Consumer Protection Division
Attention: Dr. Annika Wennberg
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00100 Rome
Italy
Facsimile: (+39) 06 5705 4593
Telephone: (+39) 06 5705 3283
E-mail: annika.wennberg@fao.org

The technological information for each food additive is summarized by the Committee in a Chemical and Technical Assessment (CTA). Guidelines for the preparation of CTAs are available from the FAO JECFA website at ftp://ftp.fao.org/es/esn/jecfa/2003-02-24_CTA.pdf. Applicants are encouraged to consider those when preparing their submission.

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. levels and patterns of contamination in food commodities of the listed contaminants; and
5. effects of processing on levels of the listed contaminants in food as consumed

should be sent to the attention of Dr. Wennberg at FAO (address above) 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 food additives and contaminants were published by WHO in 1987 (*Principles for the Safety Assessment of Food Additives and Contaminants in Food – Environmental Health Criteria No. 70*, available at <http://www.who.int/pcs/jecfa/ehc70.html>).

Specific procedural guidelines for food additives are as well available from FAO and WHO (see http://www.fao.org/ag/agn/jecfa/guidelines1_en.stm and <http://www.who.int/ipcs/food/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/ag/agn/jecfa/whatisnew_en.stm

<http://www.who.int/ipcs/food/jecfa/data/en/index.html>

Annex 1

Joint FAO/WHO Expert Committee on Food Additives (JECFA) Seventy-first meeting, Geneva, 16-24 June 2009

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 contaminants, intake, and flavouring agents are available at <http://www.who.int/ipcs/food/jecfa/guidelines/en/> and http://www.fao.org/ag/agn/agns/jecfa_guidelines_en.asp. 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 7.

1. Food additives for which requests have been received for evaluation or re-evaluation by the Codex Committee on Food Additives (CCFA) or sponsors

Toxicological evaluation, exposure assessment, specifications

Food additive	References	Information required
Branching enzyme from <i>Rhodothermus obamensis</i> and expressed in <i>Bacillus subtilis</i>	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Cassia gum	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications
Ferrous ammonium phosphate	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for assessment of safety for use in food fortification, dietary intake and specifications.
Glycerol ester of gum rosin	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Glycerol ester of tall oil rosin	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
Lycopene oleoresin extract from tomato	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for assessment of safety, dietary intake and specifications.
OSA (octenyl succinic acid)-modified acacia gum (gum Arabic)	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for safety assessment, dietary intake and specifications.

Sodium hydrogen sulfate	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾ Sixty-eighth report of JECFA ⁽²⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 4 ⁽³⁾	All data necessary for assessment of safety, dietary intake and revision of specifications.
Sucrose oligoesters Type I and II	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾	All data necessary for safety assessment, dietary intake and specifications.
Cyclamic acid and its salts ^a	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾ Twenty-sixth report of JECFA ⁽⁴⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 1 ⁽⁵⁾	All data necessary for dietary exposure assessment, including different maximum levels of use of 250 mg/kg, 500 mg/kg, 750 mg/kg and 1000 mg/kg in food category 14.1.4 "water-based flavoured drinks, including "sport", "energy", or "electrolyte" drinks and particulated drinks and actual use levels.
DATEM (Diacetyltartaric and fatty acid esters of glycerol)	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾ Sixty-first report of JECFA ⁽⁶⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 1 ⁽⁵⁾	All data necessary for revision of specifications.
Nisin preparation	Appendix XIV of the Report of the fortieth Session of CCFA ⁽¹⁾ Twelfth report of JECFA ⁽⁷⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 4 ⁽³⁾	All data necessary for revision of specifications, in particular for the definition and composition.

a: JECFA has established an ADI for cyclamic acid and its calcium and sodium salts and JECFA specifications exist for calcium cyclamate and sodium cyclamate. Safety evaluation or preparation of specifications for other cyclamates is not included in this request.

2. Food additives recommended for re-evaluation and/or review at previous meetings of the Joint FAO/WHO Expert Committee on Food Additives

Food additive	Reference	Information required
Mineral Oil (low- and medium-viscosity), class II and class III	Summary report of Sixty-ninth JECFA ⁽⁸⁾ , Fifty-ninth report of JECFA ⁽⁹⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 1 ⁽⁵⁾	The temporary ADI was extended at the 69 th meeting to the end of 2009. Information is required on the relevance to humans of the response of Fischer 344 and Sprague-Dawley rats to these materials. In order for the data to be applicable to as wide a range of mineral oils as possible, the Committee suggested that commercial mineral oils of the lowest viscosity be used in such studies. Additional studies might be required, depending on the outcome of these studies. All data necessary for revision of specifications, in case the material in commerce is not in compliance with the existing specifications.

Starch sodium octenylsuccinate (in specifications for Modified starches)	Twenty-sixth report of JECFA ⁽⁴⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 1 ⁽⁵⁾	All data necessary for revision of specifications, in particular the analytical method for residual octenyl succinic acid.
Nitrous oxide	Twenty-ninth report of JECFA ⁽¹⁰⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 1 ⁽⁵⁾	All data necessary for revision of specifications, in particular the method of assay.
Tannic acid	Thirty-fifth report of JECFA ⁽¹¹⁾ , Combined Compendium of Food Additive Specifications FAO JECFA Monographs 1 ⁽⁵⁾	All data necessary for revision of specifications, in particular the method of assay.

References

1. Report of the fortieth session of the Codex Committee on Food Additives (CCFA), The Beijing, China, 21-25 April 2008 (ALINORM 08/31/12).
2. 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.
3. Combined Compendium of Food Additive Specifications. FAO JECFA Monographs 4, 2007.
4. Evaluation of certain food additives and contaminants (Twenty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 683, 1982.
5. Combined Compendium of Food Additive Specifications. FAO JECFA Monographs 1, 2005.
6. 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.
7. Specification for the identity and purity of food additives and their toxicological evaluation: Some antibiotics. (Twelfth report of the Joint FAO/WHO Expert Committee on Food Additives). FAO Nutrition Meetings Report Series, No. 45, 1969. WHO Technical Report Series, No. 430, 1969.
8. Evaluation of certain food additives (Sixty-ninth meeting the Joint FAO/WHO Expert Committee on Food Additives). Summary report, accessible at:
http://www.fao.org/ag/agn/agns/files/jecfa69_final.pdf and
<http://www.who.int/ipcs/food/jecfa/summaries/summary69.pdf> .
9. Evaluation of certain food additives (Fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 913, 2002.
10. Evaluation of certain food additives and contaminants (Twenty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 733, 1986.
11. Evaluation of certain food additives and contaminants (Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 789, 1990.

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 inter-governmental 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 2008, a total of sixty-nine meetings of JECFA have been held. The reports are published in the WHO Technical Report Series. The toxicological evaluations, that summarize the data that serve as the basis for the safety assessments, are published in the WHO Food Additives Series. 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 document that summarizes all JECFA evaluations from the first through recent meetings, is available free of charge on the Internet in a searchable format at <http://www.who.int/ipcs/food/jecfa/en/index.html> , or http://www.fao.org/ag/agn/jecfa/archive_en.stm .