



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



**World Health
Organization**

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

Food Additives and Contaminants

Rome, 4 to 13 June 2013

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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 seventy-sixth 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), the Codex Committee on Contaminants in Foods (CCCF), 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 should be submitted on CD-ROMs. To facilitate review, a "Table of contents" on each CD-ROM should be provided using fully descriptive file names.

Date for submission

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

17 December 2012.

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 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.

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.

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 Sarah Cahill
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00153 Rome
Italy
Tel: + 39 06 5705 3614
Fax: + 39 06 5705 4593
E-mail: jecfa@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 FAO for the attention of Dr Sarah Cahill (jecfa@fao.org) and to WHO for the attention of Dr Angelika Tritscher (jecfa@who.int); the full addresses of both are provided above.. 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 as *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 also 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/food/food-safety-quality/scientific-advice/calls-data-experts/en/>
<http://www.who.int/ipcs/food/jecfa/data/en/index.html>

Annex 1

**Joint FAO/WHO Expert Committee on Food Additives (JECFA)
Seventy-seventh meeting, Rome, 4 to 13 June 2013**

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 published in the FAO monographs series 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.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 provided after the tables.

1. Contaminants and Naturally Occurring Toxicants for which requests have been received for evaluation or re - evaluation by the 6th session of the Codex Committee on Contaminants in Foods (REP12/CF – Appendix XI)⁽¹⁾

Toxicological evaluation and exposure assessment

Contaminant	Reference (previous evaluations) and background	Information required
Cadmium	Report of the sixth session of CCCF, REP12/CF Appendix XI ⁽¹⁾ . Seventy-third report of JECFA ⁽²⁾ . FAS 64 ⁽³⁾ . Sixty-fourth report of JECFA ⁽⁴⁾ , FAS 55 ⁽⁵⁾ , Sixty-first report of JECFA ⁽⁶⁾ , FAS 52 ⁽⁷⁾ , Fifty-fifth report of JECFA ⁽⁸⁾ , FAS 46 ⁽⁹⁾ , Forty-first report of JECFA ⁽¹⁰⁾ , Thirty-third report of JECFA ⁽¹¹⁾ , FAS 24 ⁽¹²⁾ , Sixteenth report of JECFA ⁽¹³⁾	All information related to exposure assessment from cocoa and cocoa-products

2. Food additives for which requests have been received for evaluation or re-evaluation by the 44th session of the Codex Committee on Food Additives (REP 12/FA - Appendix XIV) and pending re-evaluations⁽¹⁴⁾

2.1 Toxicological evaluation, exposure assessment and establishment of specifications

Food Additive	Reference (previous evaluations) and background	Information required
Advantame	Report of the forty-fourth session of CCFA, REP12/FA Appendix XIV ⁽¹⁴⁾ .	All data and information relevant to the safety assessment and establishment of specifications
Glucoamylase from <i>Trichoderma reesei</i> expressed in <i>Trichoderma reesei</i>	Report of the forty-fourth session of CCFA, REP12/FA Appendix XIV ⁽¹⁴⁾ .	All data and information relevant to the safety assessment and establishment of specifications

Glycerol ester of gum rosin (GEGR)	Seventy-fourth report of JECFA ²² .	<ul style="list-style-type: none"> - Compositional data on GEGR to characterize material in commerce: <ol style="list-style-type: none"> 1) the refined gum rosin currently used as the source rosin for the production of GEGR, 2) the glycerol ester of gum rosin, 3) the total glycerol esters of resin acids and 4) the neutrals. - Validated methods for the determination of the substances considered in the specifications - Full reports of the 90-day toxicity studies on GEGR
Glycerol ester of tall oil rosin (GETOR)	Seventy-fourth report of JECFA ²² .	<ul style="list-style-type: none"> - Compositional data are required to characterize the GETOR in commerce <ol style="list-style-type: none"> 1) the refined tall oil rosin used as the source rosin, 2) the glycerol ester of tall oil rosin, 3) the total glycerol esters of resin acids 4) the neutrals. - Validated methods for the determination of the substances considered in the specifications
Glycerol ester of wood rosin (GEWR)	Seventy-fourth report of JECFA ²² .	<ul style="list-style-type: none"> - Compositional data on GEWR to characterize material in commerce: <ol style="list-style-type: none"> 1) the refined wood rosin used as the source rosin for the production of GEWR, 2) the glycerol ester of wood rosin 3) the total glycerol esters of resin acids 4) the neutrals. - Validated methods for the determination of the substances considered in the specifications
Nisin	Report of the forty-fourth session of the CCFA, REP12/FA, para 75-78, Appendix XIV ⁽¹⁴⁾ . Seventy-first report of JECFA ⁽¹⁷⁾ Sixty-eighth report of JECFA ⁽¹⁸⁾ Twelfth report of JECFA ⁽¹⁹⁾ FAO JECFA Monographs 7 ⁽²⁴⁾	All data and information relevant to a full re-evaluation of the Acceptable Daily Intake and the specifications for nisin
Octenyl succinic acid (OSA) modified gum arabic	Seventy-fourth report of JECFA ⁽²²⁾	Data resolving the concern about the stability of OSA modified gum arabic in food as well as data on the extent to which OSA modified gum arabic is hydrolysed in the gastrointestinal tract

2.2 Food additives for revision of specifications only

Food additive	Reference (previous evaluations) and background	Information required
Annatto extracts, bixin-based (INS 160b(i)) and annatto extracts, norbixin-based (INS 160b(ii))	Report of the forty-fourth session of CCFA, REP12/FA Appendix XIV ⁽¹⁴⁾ . Sixty-seventh report of JECFA ⁽¹⁵⁾ . FAS58 ⁽¹⁶⁾	All data and information relevant revision of purity tests and revision of specific limits for residual solvents
Benzoe tonkinensis	Seventy-fourth report of JECFA ⁽²²⁾ FAO Monographs 11 ⁽²⁵⁾	<ul style="list-style-type: none"> - Additional information on the complete composition of the ethanolic extract, - data on microbiological contaminants - data on inorganic contaminants (lead, arsenic, antimony, chromium, mercury and cadmium) - all relevant data and information on any analytical method to distinguish between Benzoe tonkinensis and Benzoe sumatranus.
Paprika extract	Seventy-sixth summary report of JECFA (http://www.who.int/entity/foodsafety/chem/jecfa/summaries/Summary76.pdf). FAO JECFA Monograph 5 ⁽²⁶⁾ , Sixty-ninth report of JECFA ⁽²¹⁾ .	All data and information relevant to the revision of tentative specifications for paprika extract (INS 160c) and specifically analytical data on composition, levels of capsaicinoids and levels of arsenic.
Analytical methods for the determination of phosphorus as phosphorus pentoxide and diphosphate additives other than magnesium dihydrogene diphosphate	Seventy-sixth report of JECFA (in preparation). The titrimetric and gravimetric methods in JECFA Monographs 1 ⁽²⁸⁾ , are not reliable for the determination of phosphorus as phosphorus pentoxide. Consequently a method based on ICP was introduced in the specifications for magnesium dihydrogen diphosphate.	Information on the applicability of the new ICP based method for the determination of phosphorous or on a different method reliable for the determination of phosphorous diphosphate additives.
Food additives containing aluminium and/silicon. Determination of aluminium oxide and silicon oxide as food additives	Seventy-sixth report of JECFA (in preparation). Some of the test methods use potentially corrosive or hazardous reagents that are not always permitted in current laboratory practices because of safety concerns. The specifications for some additives are old or tentative and require additional information to revise the specifications.	Data for the revision of the specifications for calcium aluminium silicate (INS 556), aluminium silicate (INS 559), calcium silicate (INS 552), silicon dioxide (INS 551)
Modified starches . Test methods for degree of substitution in modified starches	Seventy-sixth report of JECFA (in preparation),FAO JECFA Monograph 11 ⁽²⁵⁾ Seventy-fourth report of JECFA ⁽²²⁾ , Report of the forty-fourth session of CCFA, REP12/FA, paragraph 154 and Appendix XIV ⁽¹⁴⁾ . The Committee revised the specific	Data for the revision of the specifications for monostarch phosphate (INS 1410), distarch phosphate (INS 1412), phosphate distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414), starch acetate (INS 1420), acetylated distarch adipate (INS 1422), hydroxypropyl starch (INS 1440),

	test for degree of substitution of starch sodium octenylsuccinate (INS No. 1450). It is necessary to align the description of the esterification test to be consistent with the end product specifications.	hydroxypropyl distarch phosphate (INS 1442) and acetylated oxidized starch (INS 1451).
Mineral oil Low and medium viscosity mineral oils-Class I	Seventy-sixth report of JECFA (in preparation) New specifications for mineral oil (medium and low viscosity) class I with the title mineral oil (medium viscosity). The 76 th JECFA only extracted the specifications from the previously published specifications for mineral oil (medium and low viscosity) and did not review the provisions and methods.	Data for the revision of provisions and methods in the specifications for mineral oil (medium viscosity).
Potassium aluminium silicate	Seventy-fourth report of JECFA ²² FAO JECFA Monograph 11 ⁽²⁵⁾ ,	Preparation and purification methods, particle size distribution, methods of identification for silicate and aluminium, data on the levels of the inorganic impurities, the suitability of an inductively coupled plasma atomic emission spectroscopy (ICP-AES) method for the determination of inorganic impurities, and the suitability of a proposed method based on alkali fusion followed by ICP-AES for the assay for potassium aluminium silicate based on the determination of aluminium.
Potassium aluminium silicate-based pearlescent pigments	Seventy-fourth report of JECFA ²² FAO JECFA Monograph 11 ⁽²⁵⁾ ,	Their manufacture, stability in food, particle size distribution, pH range, methods for the identification of iron, titanium and aluminium, data on the levels of the inorganic impurities, the suitability of an ICP-AES method for the determination of inorganic impurities, a filtration method appropriate for the small particle sizes associated with the pigments, and the suitability of a proposed method based on alkali fusion followed by ICP-AES for the assay for titanium, iron and aluminium.

References

1. Report of the Sixth Session of the Codex Committee on Contaminants, Maastricht, The Netherlands, 26- 30 March 2012 (ALINORM REP12/CF).
2. 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
3. Safety evaluation of certain food additives and contaminants. WHO Food Additives Series No. 64, 2011.
4. Evaluation of certain food contaminants (Sixty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 930, 2006.

5. Safety evaluation of certain contaminants, WHO Food Additive Series No. 55 and FAO Food and Nutrition Paper 82, 2006.
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. Safety evaluation of certain food additives and contaminants, WHO Food Additive Series No. 52, 2004.
8. 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.
9. Safety evaluation of certain food additives and contaminants, WHO Food Additive Series No. 46, 2001.
10. Evaluation of certain food additives and contaminants (Forty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 837, 1993.
11. Evaluation of certain food additives and contaminants (Thirty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 776, 1989.
12. Toxicological evaluation of certain food additives and contaminants, WHO Food Additive Series No. 24, 1989.
13. Evaluation of certain food additives and the contaminants mercury, lead and cadmium (Sixteenth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 505, 1972.
14. Report of the Forty-fourth Session of the Codex Committee on Food Additives, Hangzhou, China, 12-16 March 2012 (ALINORM REP12/FA).
15. Evaluation of certain food additives and contaminants (Sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 940, 2007.
16. Safety evaluation of certain food additives and contaminants. WHO Food Additives Series No. 58, 2007.
17. Evaluation of certain food additives (Seventy-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 956, 2010
18. 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.
19. Specifications 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 Series, No. 45, 1969; WHO Technical Report Series, No. 430, 1969.
20. Combined Compendium of Food Additive Specifications. FAO JECFA Monographs 4, 2007.
21. 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
22. Evaluation of certain food additives and contaminants (Seventy-fourth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 966, 2011
23. 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.
24. Compendium of food additive specifications, seventy-first meeting. FAO JECFA Monographs 7. 2009.
25. Compendium of food additive specifications, seventy-fourth meeting. FAO JECFA Monographs 11. 2011.
26. Compendium of food additive specifications, sixty-ninth meeting. FAO JECFA Monographs 5. 2008
27. Compendium of food additive specifications, seventy-third meeting. FAO JECFA Monographs 10. 2010.
28. Combined compendium of food additive specifications: Volume 4. FAO JECFA Monographs 1. 2006.

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 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 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/ag/agn/jecfa/archive_en.stm.