



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



**World Health  
Organization**

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES  
Eightieth meeting**

**Food Additives and Contaminants**

**Rome, 16 to 25 June 2015**

Published 25 July 2014

**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 eightieth 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 and contaminants 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 2014**

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

Three copies of the data are required, one for submission to the address below, one for submission directly to the WHO Expert 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.

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](mailto:jecfa@who.int)

***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; and
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 Secretariat prior to submission of the data for information on where to send the copies.

Attention: Dr Vittorio Fattori  
Food Safety and Quality Unit - Room C- 276  
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 6951  
E-mail: [jecfa@fao.org](mailto:jecfa@fao.org)

### ***Intake 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;
3. 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

should be sent to FAO at the address above ([jecfa@fao.org](mailto:jecfa@fao.org)) and to WHO under the address above ([jecfa@who.int](mailto: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.

For the contaminants the corresponding intake assessment data are defined in a separate call for data published in May 2014 (for web links see footnote on page 4).

### ***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)  
Eightieth meeting, Geneva, 16 to 25 June 2015****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/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/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.

**Previous reports and monographs should be consulted to obtain background information on the previous evaluations. Detailed bibliographical references are available on page 6.**

**1. Contaminants for which requests have been received for evaluation or re-evaluation by the 8<sup>th</sup> session of the Codex Committee on Contaminants in Foods (REP14/CF – Appendix XIII)<sup>(1)</sup>**

Please note that a call for data for non-dioxin-like PCBs and pyrrolizidine alkaloids has been published in May 2014<sup>a</sup>. These contaminants will be evaluated by the 80<sup>th</sup> meeting of JECFA. Interested parties are invited to consult this call for data for a more detailed description of the data required.

***Toxicological evaluation and exposure assessment***

<b>Contaminant</b>	<b>Reference (previous evaluations) and background</b>	<b>Information required</b>
Non-dioxin-like PCBs	Report of the eighth session of CCCF, REP 14/CF - Appendix XIII <sup>(1)</sup>	See separate call for data of May 2014 <sup>a</sup>
Pyrrolizidine alkaloids	Report of the eighth session of CCCF, REP 14/CF - Appendix XIII <sup>(1)</sup>	See separate call for data of May 2014 <sup>a</sup>

<sup>a</sup> <http://www.who.int/foodsafety/jecfa-call-data.pdf?ua=1>  
[http://www.fao.org/fileadmin/user\\_upload/agns/pdf/Call\\_for\\_data\\_experts/JECFA\\_call\\_for\\_data\\_on\\_NDL-PCB\\_and\\_PAs.pdf](http://www.fao.org/fileadmin/user_upload/agns/pdf/Call_for_data_experts/JECFA_call_for_data_on_NDL-PCB_and_PAs.pdf)

**2. Food additives for which requests have been received for evaluation or re-evaluation by the 46th session of the Codex Committee on Food Additives (REP 14/FA - Appendix XV)<sup>(2)</sup> and pending re-evaluations**

**2.1 Toxicological evaluation, exposure assessment and establishment of specifications**

Food Additive	Reference (previous evaluations) and background	Information required
<b>Benzoates</b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup> Fifty-first Report of JECFA <sup>(3)</sup>	All data necessary for assessment of dietary intake
<b>Beta-glucanase, Cellulase and xylanase form <i>Talaromyces emersonii</i></b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup>	All data necessary for assessment of safety, dietary intake and specifications
<b>Beta-glucanase and xylanase from <i>Disporotrichum dimorphosporum</i></b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup>	All data necessary for assessment of safety, dietary intake and specifications
<b>Lipase from <i>Fusarium heterosporum</i> expressed in <i>Hansenula polymorpha</i></b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup>	All data necessary for assessment of safety, dietary intake and specifications.
<b>Magnesium stearate (INS 470(iii))</b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup> , Twenty-ninth Report of JECFA <sup>(4)</sup>	All data necessary for assessment of safety, dietary intake and specifications
<b>Maltotetraohydrolase from <i>Pseudomonas saccharophila</i> expressed in <i>Bacillus licheniformis</i></b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup>	All data necessary for assessment of safety, dietary intake and specifications
<b>Monk fruit extract/Lo han guo(LHG) <i>Siraitia grosvenorii</i> Swingle</b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup>	All data necessary for assessment of safety, dietary intake and specifications
<b>Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer</b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup>	All data necessary for assessment of safety, dietary intake and specifications

**2.2 Food additives for revision of specifications**

Food Additive	Reference (previous evaluations) and background	Information required
<b>Advantame</b>	Seventy-seventh Report of JECFA <sup>(6)</sup> FAO JECFA Monographs 14 (pp. 3, 94) <sup>(7)</sup>	All information requested by the 77 <sup>th</sup> JECFA for revision of tentative specifications
<b>Annatto extracts (solvent-extracted bixin and solvent-extracted norbixin)</b>	Seventy-seventh Report of JECFA <sup>(6)</sup> FAO JECFA Monographs 14 (p.83) <sup>(7)</sup>	All information necessary for revision of the draft method <i>Determination of residual solvents in annatto extracts (solvent-extracted bixin and norbixin)</i> as proposed by the 77 <sup>th</sup> JECFA

Food Additive	Reference (previous evaluations) and background	Information required
<b>Aspartame (INS 951)</b>	Report of the forty-sixth session of CCFA, REP 14/FA - Appendix XV <sup>(2)</sup> , Twenty-fifth Report of JECFA <sup>(5)</sup> FAO JECFA Monographs 1 <sup>(8)</sup>	All information necessary for revision of specifications, in particular change of test of 5-benzyl-3,6-dioxo-2-piperazine acetic acid and change of test of other optical isomers
<b>Food additives containing aluminium and/or silicon:</b> <ul style="list-style-type: none"> <li>• <b>Aluminium silicate (INS 559)</b></li> <li>• <b>Calcium aluminium silicate (INS 556)</b></li> <li>• <b>Calcium silicate (INS 552)</b></li> <li>• <b>Silicon dioxide, amorphous (INS 551)</b></li> <li>• <b>Sodium aluminosilicate (INS 554)</b></li> </ul>	Seventy-seventh Report of JECFA <sup>(6)</sup> FAO JECFA Monographs 14 (pp.11, 15, 19, 73, 77) <sup>(7)</sup>	All information necessary for revision of specifications, in particular information requested in FAO JECFA Monographs 14. <u>Note:</u> at the 77 <sup>th</sup> meeting the Committee stated that “ <i>the tentative specifications will be withdrawn unless the requested information becomes available by the end of 2014</i> ”.
<b>Glycerol ester of gum rosin</b>	Seventy-seventh Report of JECFA <sup>(6)</sup> FAO JECFA Monographs 14 (p. 27) <sup>(7)</sup>	Updated information requested by the 77 <sup>th</sup> JECFA for revision of tentative specifications

## References

1. Report of the Eighth Session of the Codex Committee on Contaminants in Foods, The Hague, The Netherlands, 31 March-4 April 2014 (REP14/CF).
2. Report of the Forty-Sixth Session of the Codex Committee on Food Additives, Beijing, China, 17-21 March 2014 (REP14/FA).
3. Evaluation of certain food additives (Fifty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 891, 2000
4. 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
5. Evaluation of certain food additives (Twenty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 669, 1981.
6. Evaluation of certain food additives and contaminants (Seventy-seventh report of the Joint FAO/WHO Expert Committee on Food Additives) WHO Technical Report Series, No. 983, 2013
7. Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives, 77<sup>th</sup> meeting 2014.
8. Compendium of food additive specifications – JECFA specifications and monographs from 1<sup>st</sup> to 65<sup>th</sup> meeting. Vol. 1: Food additives A-D 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 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-2014, a total of seventy-nine meetings of JECFA have been held. The reports 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-additives/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/>.

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>