



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



**World Health  
Organization**

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES  
Eighty fourth meeting**

**Food Additives**  
**Rome, 6 to 15 June 2017**  
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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 84<sup>th</sup> 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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.

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 is requested before

**1 December 2016**

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.

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 Markus Lipp  
Food Safety and Quality Unit - Room C- 278  
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](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.

### ***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 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)  
84<sup>th</sup> meeting, Rome, 6 to 15 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](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 9.**

**1. Food additives for which requests have been received for evaluation or re-evaluation by the 48<sup>th</sup> session of the Codex Committee on Food Additives (REP 16/FA - Appendix XIV)<sup>(1)</sup> and pending re-evaluations**

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

<b>Food Additive</b>	<b>Reference (previous evaluations) and background</b>	<b>Information required</b>
Brilliant Blue FCF (INS 133)	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup> 30 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(3)</sup> 13 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(12)</sup> Fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives JECFA Monograph 1, 2006 <sup>(14)</sup>	All data necessary for re-evaluation of safety, dietary intake and specifications
Carotenes from <i>Dunaliella salina</i> (INS 160a(iv))	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup> Forty-first report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(2)</sup> Toxicological monograph <sup>(3)</sup>	All data necessary for re-evaluation of safety, dietary intake and specifications

Food Additive	Reference (previous evaluations) and background	Information required
	FAO/WHO Expert Committee on Food Additives JECFA Monograph 1, 2006 <sup>(4)</sup>	
Fast green FCF (INS 143)	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup> 30 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(3)</sup> 13 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(12)</sup> Fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(13)</sup> Compendium of Food Additive Specifications Joint FAO/WHO Expert Committee on Food Additives 69 <sup>th</sup> meeting 2008 <sup>(15)</sup>	All data necessary for re-evaluation of safety, dietary intake and specifications
Gum ghatti (INS 419)	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup> Twenty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(3)</sup> Fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives JECFA Monograph 1, 2006 <sup>(5)</sup>	All data necessary for re-evaluation of safety, dietary intake and specifications
Jagua ( <i>Genipa americana</i> ) extract	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications
Metatartaric acid (INS 353)	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications for evaluation from its uses as an emulsifier, stabilizer and Thickener.
Tamarind seed polysaccharide	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications
Tannins (oenological tannins) <sup>(9)</sup>	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup> For tannic acid see: Fourteenth report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(3)</sup> Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(7)</sup>	All data necessary for assessment of safety, dietary intake and specifications for evaluation from its uses as an emulsifier, stabilizer and Thickener.
Yeast mannoproteins (INS 455)	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications for evaluation from its uses as a stabilizer

**1.2 Food additives for revision of specifications and analytical methods**

<b>Food Additive</b>	<b>Reference (previous evaluations) and background</b>	<b>Information required</b>
Citric acid esters of mono- and diglycerides of fatty acids (CITREM) (INS 472c)	JECFA 79 <a href="#">(17)</a>	New test method for the determination of total citric acid to replace the current gas chromatographic method using a packed column with a suitable method using a capillary/wide-bore column or other.
Colour methods (Use of chloroform as solvent in the test methods associated with specifications monographs for synthetic colours)	JECFA 82 <a href="#">(16)</a>	Analytical methods with suitable solvent(s) to replace chloroform
Microcrystalline cellulose (INS 460 (i))	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	Data with regard to the solubility of microcrystalline cellulose
Phosphorous determination method	Compendium of food additive specifications, seventy-sixth meeting <sup>(8)</sup>	All data for new method for the determination of cyclic phosphates which does not employ perchloric acid.
Polyvinyl alcohol	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	All data regarding solubility in ethanol.

Food Additive	Reference (previous evaluations) and background	Information required
Silicon dioxide, amorphous	Compendium of food additive specifications, eightieth meeting <sup>(10)</sup>	<p>Data regarding:</p> <ul style="list-style-type: none"> <li>• raw materials used and methods of manufacture for different forms of silicon dioxide (pyrogenic silica, precipitated silica, hydrated silica, silica aerogel and colloidal silica);</li> <li>• identification methods allowing the differentiation between the above forms of silicon dioxide;</li> <li>• functional uses of different forms, and information on the types of products in which it is used and the use levels in these products;</li> <li>• data on solubility using the procedure documented in Volume 4 (Analytical methods) of the Compendium of Food Additive Specifications;</li> <li>• data on the impurities soluble in 0.5 M hydrochloric acid for all forms of silicon dioxide used as food additives, from a minimum of five batches. If a different extraction and determination method is used, data should be provided along with details of the method and quality control (QC) data;</li> <li>• suitability of the analytical method for the determination of aluminium, silicon and sodium using the proposed "Method of assay" along with data from a minimum of five batches. If a different method is used, data should be provided along with details of the method and QC data;</li> <li>• in addition to the above information, data on pH, loss on drying and loss on ignition for hydrated silica, silica aerogel and colloidal silica.</li> </ul>

Food Additive	Reference (previous evaluations) and background	Information required
Sodium aluminium silicate	Compendium of food additive specifications, eightieth meeting <sup>(10)</sup>	Data regarding: <ul style="list-style-type: none"> <li>• functional uses other than anticaking agent, if any, and information on the types of products in which it is used and the use levels in these products;</li> <li>• data on solubility using the procedure documented in Volume 4 (Analytical methods) of the Compendium of Food Additive Specifications;</li> <li>• data on the impurities soluble in 0.5 M hydrochloric acid, from a minimum of five batches. If a different extraction and determination method is used, data should be provided along with details of the method and QC data;</li> <li>• suitability of the analytical method for the determination of aluminium, silicon and sodium using the proposed “Method of assay”, along with data, from a minimum of five batches, using the proposed method. If a different method is used, data should be provided along with details of the method and QC data.</li> </ul>
Steviolglycosides	JECFA82 <sup>(16)</sup>	The specifications were made tentative pending submission of following information: <ul style="list-style-type: none"> <li>• method of assay to replace the existing method and including as many steviol glycosides as possible (at least those listed in Appendix 1 of the specifications) in steviol glycoside mixtures, along with supporting validation information and chromatograms;</li> <li>• analysis results from a minimum of five batches for commercial samples, including supporting chromatograms.</li> </ul>
Sucrose esters of fatty acids (INS 473)	Report of the 48 <sup>th</sup> session of CCFA, REP 16/FA - Appendix XIV <sup>(1)</sup>	All data regarding solubility of compound



## References

1. Report of the 48<sup>th</sup> Session of the Codex Committee on Food Additives, Xi'an, China, 14-18 March 2016 (REP16/FA).
2. Evaluation of certain food additives (Forty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 837, 1993
3. Toxicological monograph FAS 32-JECFA 41/87 available online only here:  
<http://www.inchem.org/pages/jecfa.html>  
Evaluation of certain food additives (Twenty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 733, 1986
4. FAO Monograph 1, 2006; specifications for Carotenes (algae) are available here:  
[http://www.fao.org/fileadmin/user\\_upload/jecfa\\_additives/docs/monograph4/additive-114-m4.pdf](http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph4/additive-114-m4.pdf)
5. FAO Monograph 1, 2006; specifications for Gum Ghatti are available here:  
[http://www.fao.org/fileadmin/user\\_upload/jecfa\\_additives/docs/Monograph1/Additive-220.pdf](http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-220.pdf)
6. FAO Nutrition Meetings Report Series No. 48A WHO/FOOD ADD/70.39; Toxicological evaluation of some extraction solvents and certain other substances
7. Evaluation of certain food additives (Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 789, 1990
8. Compendium of food additive specifications, seventy-sixth meeting; FAO JECFA Monographs 13, 2012
9. The requestor specified that the safety evaluation should include all oenological tannins excluding those covered under tannic acid (INS181); CX/FA 15/47/16 Add.1
10. Compendium of food additive specifications, eightieth meeting; FAO JECFA Monographs 17, 2015
11. Evaluation of certain food additives and contaminants (30th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, 751, 1987
12. Toxicological Evaluation of Some Food Colours, Emulsifiers, Stabilizers, Anti-Caking Agents And Certain Other Substances; FAO Nutrition Meetings Report Series No. 46A WHO/FOOD ADD/70.36
13. 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
14. FAO Monograph 1, 2006; specifications for Brilliant Blue FCF are available here:  
[http://www.fao.org/fileadmin/user\\_upload/jecfa\\_additives/docs/Monograph1/additive-059-m1.pdf](http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/additive-059-m1.pdf)
15. FAO Monograph 5, 2008 (containing erratum for FAO Monograph 1), combined version of specifications for Fast Green FCF are available here:  
[http://www.fao.org/fileadmin/user\\_upload/jecfa\\_additives/docs/monograph5/additive-187-m5.pdf](http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph5/additive-187-m5.pdf)
16. Summary and conclusions of the 82<sup>nd</sup> JECFA meeting  
[http://www.who.int/foodsafety/publications/JECFA\\_82\\_Summary\\_Report.pdf?ua=1](http://www.who.int/foodsafety/publications/JECFA_82_Summary_Report.pdf?ua=1)
17. Summary and conclusions of the 79<sup>th</sup> JECFA meeting  
<http://www.fao.org/3/a-at861e.pdf>

## 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-2016, a total of eighty two 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>