

Food and Agriculture Organization of the United Nations



#### JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES Eighty-sixth meeting

#### Food Additives Geneva, 12 to 21 June 2018 Published 22 June 2017

#### 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 86<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.

A list of flavouring agents scheduled for evaluation or re-evaluation at the 86<sup>th</sup> meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) will be published at a later time and in a separate call for data.

#### 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 The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data.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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 2017

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

This information needs to be submitted electronically to the following e-mail address: jecfa@who.int or by sending it on a USB stick to:

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

#### Technological data

Data relevant to the manufacturing, quality, use, occurrence, identification and quantification of the substances on the agenda including:

- 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.

This information needs to be submitted electronically to the following e-mail address jecfa@fao.org or by sending it on a USB stick to:

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

#### Dietary exposure 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

This information should be sent to FAO at the address above (jecfa@fao.org) 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 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 <a href="http://www.who.int/foodsafety/publications/chemical-food/en/">http://www.who.int/foodsafety/publications/chemical-food/en/</a>

Specific guidance on the evaluation of and data needs for food additives are also available from FAO and WHO (see <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/</a> and <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/</a> and <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/</a> and <a href="http://www.who.int/foodsafety/chem/jecfa/guidelines/en/index.html">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/</a> and <a href="http://www.who.int/foodsafety/chem/jecfa/guidelines/en/index.html">http://www.who.int/foodsafety/chem/jecfa/guidelines/en/index.html</a>).

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/

#### Joint FAO/WHO Expert Committee on Food Additives (JECFA) 86<sup>th</sup> meeting, Geneva, 12 to 21 June 2018

#### 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: <u>http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/</u> and <u>http://www.who.int/foodsafety/publications/jecfa/en/</u>.

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 available agents are 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 national assessments submitting their of intake. http://www.who.int/foodsafetv/chem/iecfa/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 7.

1. Food additives for which requests have been received for evaluation or reevaluation by the 49th session of the Codex Committee on Food Additives (REP 17/FA - Appendix XIV)<sup>(1)</sup> and pending re-evaluations

1.1 Toxicological evaluation, exposure assessment and establishment of
specifications

Food Additive	Reference (previous evaluations) and background	Information required
Basic methacrylate copolymer (INS 1205)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications on use as a glazing/coating agent on food supplements (Food Category 13.6)
Neutral methacrylate copolymer (INS 1206)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications on use as a glazing/coating agent on food supplements (Food Category 13.6)
Anionic methacrylate copolymer (INS 1207)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications on use as a glazing/coating agent on food supplements (Food Category 13.6)
Lutein from <i>Tagetes erecta</i> (INS 161b(i))	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup>	All data necessary for re- evaluation of safety, dietary intake and specifications to

Food Additive	Reference (previous evaluations) and background	Information required
	82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monograph 19, (2016) <sup>(5)</sup>	establishing a group ADI "not specified" for lutein esters that would include lutein from Tagetes erecta, synthetic zeaxanthin and related xanthophylls.
Spirulina extract	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup>	All data necessary for assessment of safety, dietary intake and specifications
Erythrosine (INS 127)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 37 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(4)</sup> FAO JECFA Monograph 1, (2006) <sup>(8)</sup>	All data necessary for re- evaluation of safety, dietary intake and specifications
Indigotine (INS 132)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 18 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(4)</sup> FAO JECFA Monograph 10, (2010) <sup>(9)</sup>	All data necessary for re- evaluation of safety, dietary intake and specifications

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

Food Additive	Reference (previous evaluations) and background	Information required
Citric and Fatty Acid Esters of Glycerol (INS 472 c)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monograph 19, (2016) <sup>(5)</sup>	Data suitable for the replacement of the packed column gas chromatography test method for the determination of total citric acid
Glycerol ester of wood rosin (GEWR) (INS445(iii))	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 77 <sup>th</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(7)</sup> FAO JECFA Monograph 14, (2013) <sup>(2)</sup>	All data for a revision of specifications to allow for additional species of pine as source materials
Cassia gum	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	Validated methods of analysis on anthraquinones

Food Additive	Reference (previous evaluations) and background	Information required
Dextrin roasted starch (INS 1400)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, (2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable method for the Dispersion or Reducing Sugars Distinguishing Test</li> </ol>
Acid treated starch (INS 1401)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable method for the Dispersion or Reducing Sugars Distinguishing Test</li> </ol>
Alkaline treated starch (INS 1402)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable method for the Dispersion or Reducing Sugars Distinguishing Test</li> </ol>
Bleached starch (INS1403)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) typical levels of residual reagents or by-products</li> </ol>
Enzyme-treated starch (INS 1405)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable method for the Dispersion or Reducing Sugars Distinguishing Test</li> </ol>
Monostarch phosphate (INS 1410)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable test for the identification of the phosphate groups</li> </ol>
Distarch phosphate (INS 1412)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable test for the identification of the phosphate groups and of crosslinking</li> </ol>

Food Additive	Reference (previous evaluations) and background	Information required
Phosphated distarch phosphate (INS 1413)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>data on the method of manufactured</li> <li>suitable test for the identification of the phosphate groups and of crosslinking</li> </ol>
Acetylated distarch phosphate (INS 1414)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable test for the identification of the phosphate groups and of crosslinking</li> </ol>
Acetylated distarch adipate (INS 1422)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable test for the identification of the adipate groups; Levels of adipic acid</li> </ol>
Hydroxypropyl starch (INS 1440)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable method for the determination of propylene chlorohydrin</li> </ol>
Hydroxypropyl distarch phosphate (INS 1442)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable method for the determination of propylene chlorohydrin; Suitable test for the identification of the phosphate groups</li> </ol>
Starch sodium octenyl succinate (INS 1450)	Report of the 49 <sup>th</sup> session of CCFA, REP 17/FA - Appendix XI <sup>(1)</sup> 82 <sup>nd</sup> report of the Joint FAO/WHO Expert Committee on Food Additives <sup>(6)</sup> FAO JECFA Monographs 19, 2016) <sup>(5)</sup>	<ol> <li>1) data on the method of manufactured</li> <li>2) suitable test for the identification of octenylsuccinate groups</li> </ol>

# **1.3.** Toxicological evaluation, exposure assessment and establishment of specifications for certain flavouring agents

A separate list of flavouring agents to be evaluated at the 86<sup>th</sup> meeting will be published in a separate call for data. The flavouring agents will be evaluated according to procedures outlined here:

#### http://apps.who.int/iris/bitstream/10665/250277/1/9789241210003-eng.pdf?ua=1

#### 1.4. Revision of specification for certain flavourings

A separate list of flavouring agents for revision of specification at the 86<sup>th</sup> meeting will be published in a separate call for data.

#### References

- Report of the 49<sup>th</sup> Session of the Codex Committee on Food Additives, Macao, China, 20-24 March 2017 (REP17/FA) <u>http://www.fao.org/fao-who-codexalimentarius/sh-</u> proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252 FMeetings%252FCX-711-49%252FReport%252FREP17\_FAe.pdf
- 2. FAO Monograph 14, 2013; specifications for Glycerol ester of wood rosin are available here: http://www.fao.org/fileadmin/user\_upload/jecfa\_additives/docs/monograph14/additive-213-m14.pdf
- 3. Report of the 37<sup>th</sup> meeting of JECFA <u>http://apps.who.int/iris/bitstream/10665/40288/1/WHO\_TRS\_806.pdf</u>
- 4. Report of the 18<sup>th</sup> meeting of JECFA http://apps.who.int/iris/bitstream/10665/41117/1/WHO\_TRS\_557.pdf
- 5. FAO Monograph 19, 2016; <u>http://www.fao.org/fileadmin/user\_upload/jecfa\_additives/docs/monograph10/additive-442-m10.pdf</u>
  6. Report of the 82<sup>nd</sup> meeting of JECFA
- http://apps.who.int/iris/bitstream/10665/250277/1/9789241210003-eng.pdf?ua=1
   Report of the Z<sup>th</sup> meeting of JECEA
- 7. Report of the 77<sup>th</sup> meeting of JECFA <u>http://apps.who.int/iris/bitstream/10665/98388/1/9789241209830\_eng.pdf</u>
- 8. FAO Monograph 1, 2006; specifications for Erythrosine are available here: http://www.fao.org/fileadmin/user\_upload/jecfa\_additives/docs/Monograph1/Additive-174.pdf
- 9. FAO Monograph 10, 2010; specifications for Indigotine are available here: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/detail/en/c/112/

#### 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 <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 (<u>http://www.who.int/foodsafety/publications/jecfa-reports/en/</u>). 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 <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/</a>. The updated database on specifications for flavouring agents is available at <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/</a>. The Chemical Technical Assessments are available at <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/</a>. The Chemical Technical Assessments are available at <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/</a>.

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 <a href="http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx">http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx</a>