



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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CL 2015/11-FA
May 2015

TO: Codex Contact Points
Interested International Organisations

FROM: Secretariat, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission,
Viale delle Terme di Caracalla,
00153 Rome, Italy

SUBJECT: Request for information and comments on Priority list of substances proposed for
evaluation by JECFA

DEADLINE: 15 January 2016

COMMENTS: **To:** Secretariat
Codex Committee on Food Additives
China National Center for Food Safety Risk
Assessment (CFSA),
Building 2, No. 37 Guangqu Road,
Chaoyang District, Beijing 100022, China,
E-mail: ccfa@cfsa.net.cn

Copies to: Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards
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Viale delle Terme di Caracalla
00153 Rome, Italy
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REQUEST FOR INFORMATION AND COMMENTS

1. Members and interested International Organizations, as directed above, are invited to provide information on new requests and on substances already included in the priority list of substances proposed for evaluation by JECFA. Comments should be submitted on the basis of the following attached Annexes to this Circular Letter:

Annex 1 - Criteria for the inclusion of substances in the priority list;

Annex 2 - Form for the submission of substances to be evaluated by JECFA;

Annex 3 - Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up.

2. Information and comments, submitted in response to this Circular Letter, will be considered at the 48th Session of the Codex Committee on Food Additives.

Annex 1**CRITERIA FOR THE INCLUSION OF SUBSTANCES IN THE PRIORITY LIST**

(Codex Procedural Manual – *Risk Analysis Principles applied by the Codex Committee on Food Additives*)

The Codex Committee on Food Additives (CCFA) shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCFA's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e. magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations.

Annex 2**FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA**

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

| | |
|---|--|
| Name of Substance(s): | |
| Question(s) to be answered by JECFA <i>(Provide a brief justification of the request in case of re-evaluations)</i> | |

1. Proposal for inclusion submitted by:
2. Name of substance; trade name(s); chemical name(s):
3. Names and addresses of basic producers:
4. Has the manufacturer made a commitment to provide data?
5. Identification of the manufacturer that will be providing data (Please indicate contact person):
6. Justification for use:
7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):
8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))
9. List of data available (please check, if available)

Toxicological data

- (i) Metabolic and pharmacokinetic studies
- (ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
- (iii) Epidemiological and/or clinical studies and special considerations
- (iv) Other data

Technological data

- (i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)
- (ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

- (i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used
- (ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Other information (as necessary/identified)

10. Date on which data could be submitted to JECFA.

Annex 3

(Appendix XIII of REP15/FA)

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

| Substance(s) (High Priority (*)) | Question(s) to be answered | Data availability (when, what) | Proposed by |
|---|--|---------------------------------------|--------------------------|
| <i>Acacia polyacantha</i> var. <i>Campylacantha</i> , kakamut gum, arabino-galactan protein complex | Safety assessment and establishment of specifications | December 2015 | Sudan |
| Alpha-amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i> | Safety assessment and establishment of specifications | November 2015 | European Union |
| Alpha-amylase from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i> | Safety assessment and establishment of specifications | November 2015 | European Union |
| Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i> | Safety assessment and establishment of specifications | Immediately | European Union |
| Asparaginase from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i> | Safety assessment and establishment of specifications | November 2015 | European Union |
| Carbohydrate-derived fulvic acid | Safety assessment and establishment of specifications | Immediately | South Africa |
| Carob bean gum (INS 410) | Safety assessment for use in infant formula and formulae for special medical purposes intended for infants | December 2015 | Australia |
| Carotenes from <i>Dunaliella salina</i> | Safety assessment and revision of specifications | December 2015 | European Union |
| Flavouring substances (3 new + 21 from previous Priority Lists + 39 for which JECFA requested additional info = 63 total) | Safety assessment and establishment of specifications | December 2015 | United States of America |
| Flavouring substances (JECFA no: 973, 1114, 1122, 1203, 1238, 2031 and 2123) | Revision of specifications and safety assessment as appropriate | Immediately | United States of America |
| Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i> | Safety assessment and establishment of specifications | Immediately | European Union |
| Gum Arabic | Safety assessment and establishment of specifications | December 2015 | Sudan |
| Gum ghatti | Safety assessment and revision of specifications | December 2015 | United States of America |
| Jagua (<i>Genipa americana</i>) extract | Safety assessment and establishment of specifications | Immediately | Colombia |
| Metatartaric acid (INS 353) | Safety assessment and establishment of specifications | Immediately | Australia |

| Substance(s) (High Priority (*)) | Question(s) to be answered | Data availability (when, what) | Proposed by |
|--|--|---------------------------------------|------------------------------------|
| Microcrystalline cellulose (INS 460 (i)) | Revision of specifications | December 2015 | Japan |
| Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i> | Safety assessment and establishment of specifications | Immediately | European Union |
| Potassium bisulfite (INS 228) | Safety assessment and establishment of specifications | Immediately | Australia |
| Rosemary extract (INS 392) | Safety assessment and establishment of specifications | Immediately | European Union |
| Steviol glycosides | Safety assessment and revision of specifications | December 2015 | Malaysia |
| Tamarind seed polysaccharide | Safety assessment and establishment of specifications | December 2015 | Japan |
| Tannins | Safety assessment and establishment of specifications | Immediately | Australia |
| Yeast mannoproteins (INS 455) | Safety assessment and establishment of specifications | Immediately | Australia |
| Xanthan gum (INS 415) | Safety assessment for use in infant formula and formulae for special medical purposes intended for infants | December 2015 | United States of America |
| Xylanase from <i>Bacillus licheniformis</i> expressed in <i>Bacillus licheniformis</i> | Safety assessment and establishment of specifications | November 2015 | European Union |
| Xylanase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i> | Safety assessment and establishment of specifications | December 2015 | European Union |
| Substances for re-evaluation | | | |
| Allura red AC (INS 129) | Re-evaluation of safety and specifications | December 2015 | CCFA46 (data from Japan; IACM; EU) |
| Brilliant Blue FCF (INS 133) | Re-evaluation of safety and specifications | December 2015; December 2016 | CCFA46 (data from Japan; IACM; EU) |
| Erythrosine (INS 127) | Re-evaluation of safety and specifications | December 2015; December 2016 | CCFA46 (data from Japan; IACM; EU) |
| Fast green FCF (INS 143) | Re-evaluation of safety and specifications | December 2015; December 2016 | CCFA46 (data from Japan; IACM) |
| Indigotine (INS 132) | Re-evaluation of safety and specifications | December 2015; December 2016 | CCFA46 (data from Japan; IACM; EU) |
| Tartrazine (INS 102) | Re-evaluation of safety and specifications | December 2015 | CCFA46 (data from Japan; IACM; EU) |