

# CODEX ALIMENTARIUS COMMISSION **E**



Food and Agriculture  
Organization of  
the United Nations



World Health  
Organization

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**CL 2014/13-FA**  
**April 2014**

**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 2015

**COMMENTS: To:**

Secretariat	<b>Copies to:</b>
Codex Committee on Food Additives	Secretariat
China National Center for Food Safety Risk Assessment (CFSA),	Codex Alimentarius Commission
Building 2, No. 37 Guangqu Road,	Joint FAO/WHO Food Standards Programme
Chaoyang District, Beijing 100022, China,	Viale delle Terme di Caracalla
E-mail: <a href="mailto:secretariat@ccfa.cc">secretariat@ccfa.cc</a>	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 on which information on the substances to be evaluated by JECFA is provided;

**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 47<sup>th</sup> 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 ON WHICH INFORMATION ON THE SUBSTANCE TO BE EVALUATED BY JECFA IS PROVIDED**

*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.*

<b>Name of Substance(s):</b>	
<b>Question(s) to be answered by JECFA</b> <i>(kindly 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***

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

**Annex 3**

(Appendix XV of REP14/FA)

**PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA**

<b>Substance(s) (High Priority*)</b>	<b>Question(s) to be answered</b>	<b>Data availability (when, what)</b>	<b>Proposed by</b>
<i>Acacia polyacantha</i> var. <i>Campylacantha</i> , kakamut gum, arabino-galactan protein complex	Safety assessment and establishment of specifications	December 2014	Sudan
Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2014	European Union
Aspartame (INS 951) *	Revision of specifications ((1) Change of test of 5-benzyl-3,6-dioxo-2-piperazine acetic acid; (2) Change of test of other optical isomers)	December 2014	Japan
Benzoates	Dietary exposure assessment	December 2014	46 <sup>th</sup> CCFA. Australia, the European Union, and ICBA to provide data
Beta-glucanase, cellulase and xylanase from <i>Talaromyces emersonii</i> *	Safety assessment and establishment of specifications	December 2014	European Union
Beta-glucanase and xylanase from <i>Disporotrichum dimorphosporum</i> *	Safety assessment and establishment of specifications	December 2014	European Union
Dipotassium tartrate (INS 336 (ii))	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	Australia, European Union, OIV
Flavouring substances (continued from the priority list recommended by the 43 <sup>rd</sup> CCFA)	Safety assessment and establishment of specifications	December 2014	United States of America
Flavourings (JECFA no: 973, 1114, 1122, 1203, 1238, 2031 and 2123)	Revision of specifications and safety assessment as appropriate	December 2014	United States of America
Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2014	European Union
Lipase from <i>Fusarium heterosporum</i> expressed in <i>Hansenula polymorpha</i> *	Safety assessment and establishment of specifications	December 2014	European Union
Magnesium stearate (INS 470(iii)) *	Safety assessment and establishment of specifications	December 2014	European Union

<b>Substance(s) (High Priority*)</b>	<b>Question(s) to be answered</b>	<b>Data availability (when, what)</b>	<b>Proposed by</b>
Maltotetrahydrolase from <i>Pseudomonas saccharophila</i> expressed in <i>Bacillus licheniformis</i> *	Safety assessment and establishment of specifications	December 2014	European Union
Metatartaric acid	Safety assessment and establishment of specifications	To be confirmed	Australia
Monk fruit extract/Lo han guo (LHG); <i>Siraitia grosvenorii</i> Swingle *	Safety assessment and establishment of specifications	December 2014	United States of America
Monopotassium tartrate (INS 336 (i))	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	Australia, European Union, OIV
Monosodium tartrate (INS 335(i))	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	European Union
Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2014	European Union
Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer *	Safety assessment and establishment of specifications	December 2014	European Union
Potassium acetates (INS 261)	Establishment of specifications and clarification whether the group ADI also includes potassium diacetate (INS 261(ii)).	To be determined	46 <sup>th</sup> CCFA
Potassium adipates (INS 357)	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	European Union
Potassium Ascorbate (INS 303)	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	India
Potassium bisulfite (INS 228)	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	Australia
Potassium malate (INS 351(ii))	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	European Union
Propane (INS 944)	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	European Union
Rosemary extract (INS 392)	Safety assessment and establishment of specifications	December 2014	European Union
Stevia extract, steviol glycosides (INS 960), purity 85% and 90%	Safety assessment and establishment of specifications	June 2015	Paraguay
Steviol glycosides	Safety assessment and revision of specifications ((1) To include rebaudioside M and rebaudioside E; (2) delete the requirement for stevioside and/or rebaudioside A as the primary steviol glycosides in stevia preparations)	December 2014	Malaysia and the United States of America

<b>Substance(s) (High Priority*)</b>	<b>Question(s) to be answered</b>	<b>Data availability (when, what)</b>	<b>Proposed by</b>
Sodium adipates (INS 356)	Safety assessment and establishment of specifications	To be confirmed by 47 <sup>th</sup> CCFA	European Union
Tannins (Tannic acid)	Safety assessment and establishment of specifications	To be confirmed	Australia
Yeast mannoproteins	Safety assessment and establishment of specifications	To be confirmed	Australia
Xylanase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2014	European Union