

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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CL 2016/13-FA
May 2016

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 the priority list of substances proposed for
evaluation by JECFA

DEADLINE: 15 January 2017

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
Programme
Viale delle Terme di Caracalla
00153 Rome, Italy
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REQUEST FOR INFORMATION AND COMMENTS

1. Members and observers, 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. Information and 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 49th Session of the Codex Committee on Food Additives.

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 XIV of REP16/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
Acid prolyl endopeptidase from <i>Aspergillus niger</i> expressing a gene from <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
D-Allulose 3-epimerase from <i>Arthrobacter globiformis</i> expressed in <i>Escherichia coli</i>	Safety assessment and establishment of specifications	December 2016	United States of America
Alpha-amylase from <i>Bacillus licheniformis</i> expressing a modified alpha-amylase gene from <i>Geobacillus stearothermophilus</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Alpha-amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Alpha-amylase from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
Amyloglucosidase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Asparaginase from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>	Safety assessment and establishment of specifications	December 2016	European Union
Beta-amylase from <i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i>	Safety assessment and establishment of specifications	December 2016	European Union
Beta-glucanase from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>	Safety assessment and establishment of specifications	December 2016	Japan
*Carotenes from <i>Dunaliella salina</i>	Safety assessment and revision of specifications	December 2016	European Union
Flavouring substances (8 new + 20 from previous Priority Lists + 55 for which JECFA requested additional info = 83 total)	Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable	December 2016	United States of America
Gellan gum (INS 418) (Pending confirmation of technological justification from CCNFSDU)	Safety assessment for use in infant formula, formula for special medical purposes for infants, and follow-up formula	December 2016	United States of America
*Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Gum ghatti	Safety assessment and revision of specifications	December 2016	United States of America
*Jagua (<i>Genipa americana</i>) extract	Safety assessment and establishment of specifications	December 2016	Colombia
INS 1205 Basic methacrylate copolymer	Safety assessment and establishment of specifications	December 2016	European Union
INS 1206 Neutral methacrylate copolymer	Safety assessment and establishment of specifications	December 2016	European Union

Substance(s) (High Priority (*))	Question(s) to be answered	Data availability (when, what)	Proposed by
INS 1207 Anionic Methacrylate copolymer	Safety assessment and establishment of specifications	December 2016	European Union
Lactase from <i>Bifidobacterium bifidum</i> expressed in <i>Bacillus licheniformis</i>	Safety assessment and establishment of specifications	December 2016	European Union
Lipase from <i>Aspergillus oryzae</i> expressing a modified gene from <i>Thermomyces lanuginosus</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Metatartaric acid (INS 353)	Safety assessment and establishment of specifications	December 2016	Australia
*Microcrystalline cellulose (INS 460 (i))	Revision of specifications	December 2016	Japan
Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of <i>Pseudomonas fluorescens</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
Phospholipase A2 from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>	Safety assessment and establishment of specifications	December 2016	Japan
Polyvinyl alcohol (INS 1203)	Revision of specifications	December 2016	European Union
Sodium sorbate (INS 221)	Safety assessment and establishment of specifications	To be confirmed by CCFA 49	CCFA 48
Spirulina extract	Safety assessment and establishment of specifications	December 2016	United States of America
Sucrose esters of fatty acids (INS 473)	Revision of specifications	December 2016	Japan
*Tamarind seed polysaccharide	Safety assessment and establishment of specifications	December 2016	Japan
*Tannins	Safety assessment and establishment of specifications	December 2016	Australia
Transglucosidase/alpha-glucosidase from <i>Trichoderma reesei</i> expressing an Alpha-glucosidase gene from <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Xylanase from <i>Bacillus licheniformis</i> expressed in <i>Bacillus licheniformis</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Xylanase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	Safety assessment and establishment of specifications	December 2016	European Union
*Yeast mannoproteins (INS 455)	Safety assessment and establishment of specifications	December 2016	Australia
Substances for re-evaluation			
Brilliant Blue FCF (INS 133)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM; EU)
Erythrosine (INS 127)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM; EU)
Fast green FCF (INS 143)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM)
Indigotine (INS 132)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM; EU)