CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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CL 2013/12-FA
April 2013

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 2014**

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: secretariat@ccfa.cc

Copies to:
Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy
E-mail: codex@fao.org

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 by the 45th CCFA to the 36th Session of the Commission for approval.

2. Information and comments, submitted in response to this Circular Letter, will be considered at the 46th 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.

Name of Substance(s):	
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	

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 XI of REP13/FA)

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

	Question(s) to be answered	***Data availability (when, what)***	***Proposed by***
Acacia polyacantha var. *Campylacantha*, kakamut gum, arabino-galactan protein complex	Safety assessment and establishment of specifications	December 2014	Sudan
Beta-glucanase and xylanase from *Disporotrichum dimorphosporum*	Safety assessment and establishment of specifications	December 2013	European Union
Beta-glucanase, cellulase and xylanase from *Talaromyces emersonii*	Safety assessment and establishment of specifications	December 2013	European Union
Carrageenan (INS 407)*	Safety assessment for use in infant formula and review of specifications	December 2013	Philippines
Citric acid (INS 330) *	Revision of specifications (revision of oxalate test method)	Immediately	European Union
Citric acid esters of mono- and diglycerides of fatty acids (CITREM) (INS 472c)*	Safety assessment for use in infant formula and formulae for special medical purposes intended for infants and review of specifications	December 2013	European Union
Flavourings (114) (39 new + 75 from the priority list recommended by the 43rd CCFA)	Safety assessment and establishment of specifications	December 2013	United States of America
Gardenia yellow (Crocin)*	Safety assessment and establishment of specifications	December 2013	China
Gellan gum (INS 418)	Revision of specifications (permit the use of ethanol in the manufacturing process as an alternative to isopropyl alcohol)	December 2013	European Union
Lipase from *Fusarium heterosporum* expressed in *Hansenula polymorpha*	Safety assessment and establishment of specifications	December 2013	European Union
Magnesium stearate INS 470(iii)	Safety assessment and establishment of specifications	November 2013	European Union
Maltotetraohydrolase from *Pseudomonas saccharophila* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2013	European Union
Monk fruit extract/Lo han guo (LHG); *Siraitia grosvenorii* Swingle	Safety assessment and establishment of specifications	December 2014	United States of America

	Question(s) to be answered	***Data availability (when, what)***	***Proposed by***
OSA-modified starch (starch sodium octenyl succinate) (INS 1450) *	Safety assessment for use in infant formula and formulae for special medical purposes intended for infants	December 2013	United States of America
Pectin (INS 440)*	Safety assessment for use in infant formula and formulae for special medical purposes intended for infants	December 2013	United States of America and Iran
3-Phytase from *Aspergillus niger* expressed in *Aspergillus niger**	Revision of specifications	Immediately	CCFA 45th Session
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60) (INS 435)	Revision of specifications (change of saponification value and hydroxyl value)	December 2013	Japan
Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer	Safety assessment and establishment of specifications	December 2013	European Union
Quillaia extract, type 2 (INS 999(ii))*	Revision of specifications (revision of upper limit in the loss on drying specification from 80% to 90%)	Immediately	Chile
Tagetes extract (INS 161b(ii))*	Safety assessment and revision of specifications	December 2013	European Union

*High priority