CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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- 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 compounds proposed for evaluation by JECFA
- DEADLINE: 15 January 2013

COMMENTS: To:

|): | | Copies to: |
|----|--|--------------------------------|
| | Secretariat | Secretariat |
| | Codex Committee on Food Additives | Codex Alimentarius Commission |
| | China National Center for Food Safety Risk | Joint FAO/WHO Food Standards |
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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 compounds already included in the priority list of compounds 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 compounds in the priority list;

Annex 2 - Form on which information on the compound to be evaluated by JECFA is provided;

Annex 3 - Priority list of compounds proposed for evaluation by JECFA, forwarded by the 43rd CCFA to the 34th Session of the Commission for approval.

2. Information and comments, submitted in response to this Circular Letter, will be considered at the 45th Session of the Codex Committee on Food Additives, tentatively scheduled to be held in Beijing, China, from 18 to 22 March 2013.

Annex 1

CRITERIA FOR THE INCLUSION OF COMPOUNDS IN THE PRIORITY LIST

(Codex Procedural Manual – Risk Analysis Principles applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods)

The Codex Committee on Food Additives (CCFA) shall consider the following when preparing its priority list of compounds 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 COMPOUND 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 Compound(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 compound; 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 compound is used as a food additive or as an ingredient, including use level(s):
- 8. Is the compound currently used in food that is legally traded in more than one country? (please identify the countries); or, has the compound 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 compounds (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 compound

Intake assessment data

- (i) Levels of the listed compound 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 compound may be used.

Other information as necessary

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

Annex 3 (Appendix XIV of REP12/FA)

PRIORITY LIST OF COMPOUNDS PROPOSED FOR EVALUATION BY JECFA

| Compound | Question(s) to be answered | Data availability (when, what) | Proposed by |
|--|---|---|--------------------------------------|
| Xanthan gum (INS 415) | 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 |
| 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 2012 | United States of America |
| Monk fruit extract/Lo han guo (LHG); <i>Siraitia grosvenorii</i> Swingle | Safety assessment and establishment of specifications | December 2013 | United States of America |
| Acacia polyacantha var. Campylacantha, kakamut gum, arabino- galactan protein complex | (1) Establishment of specifications; and(2) Safety assessment (pending further data) | (1) December 2012(2) December 2013 | Sudan |
| 72 Flavourings | Safety assessment and establishment of specifications | Immediately | United States of America |
| Advantame | Safety assessment and establishment of specifications | Immediately | Australia |
| Glucoamylase from <i>Trichoderma reesei</i> expressed in <i>Trichoderma reesei</i> | Safety assessment and establishment of specifications | November 2012 | European Union |
| Annatto extracts, bixin-based (INS 160b(i)) and annatto extracts, norbixin-based (INS 160b(ii)) | Revision of specifications (change of purity test and revision of specific limits for residual solvents) | December 2012 | Japan |
| Nisin (INS 234) | Re-evaluation (subject to confirmation) | December 2012 | 44 th CCFA Japan |