

# CODEX ALIMENTARIUS COMMISSION **E**



Food and Agriculture  
Organization of  
the United Nations



World Health  
Organization

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**CX 4/30.2**

**CL 2010/10-FA**  
**April 2010**

**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 2011**

**COMMENTS: To:**

Secretariat  
Codex Committee on Food Additives  
National Institute of Nutrition and Food  
Safety, China CDC  
7 Panjiayuan Nanli, Chaoyang District,  
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**Copies to:**

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## **BACKGROUND**

1. The 42<sup>nd</sup> Session of the Codex Committee on Food Additives (CCFA) agreed to forward the Priority list of compounds proposed for evaluation by JECFA to the 33<sup>rd</sup> Session of the Commission for approval (ALINORM 10/33/12, para. 147 and Appendix XI).

## **REQUEST FOR INFORMATION AND COMMENTS**

2. 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 42<sup>nd</sup> CCFA to the 33<sup>rd</sup> Session of the Commission for approval.

3. Information and comments, submitted in response to this Circular Letter, will be considered at the 43<sup>rd</sup> Session of the Codex Committee on Food Additives, to be held in China on 14-18 March 2011.

**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.*

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 XI of ALINORM 10/33/12)

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

	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
<b>Aluminium containing food additives<sup>1</sup></b>  Aluminium ammonium sulphate; Aluminium lactate; Aluminium sulphate; Aluminium phosphates	Safety assessment (bioavailability, developmental toxicity and multi-generation toxicity)	End of 2010  (Bioavailability 2-generation reproductive toxicity study)  IFAC; IAI  information to be provided to JECFA Secretariat by May 2010	Japan
Potassium aluminium silicate (INS 555)	Safety assessment as a carrier for TiO <sub>2</sub> and Fe <sub>2</sub> O <sub>3</sub> ; establishment of specifications	Available 2010  (CIAA)	Germany
Pullulan <sup>1</sup>	Safety assessment (for use as a dietary fibre)	Available 2009	Switzerland
Pullulanase <sup>1</sup>	Safety assessment and establishment of specifications	Available 2009	Denmark
Flavouring agents <sup>1</sup>	Safety assessment and specifications (134 compounds remaining from 315 listed in 2009 )	End of 2009	United States of America
<i>Benzoe tonkinensis</i> (Gum benzoin, Siam)	Safety assessment and establishment of specifications	April 2010	France, EU
Magnesium silicate (synthetic) (INS 553(i))	Revision of specifications	Available 2010	United States of America
Polydimethylsiloxane (PDMS) (INS 900a)	Re-evaluation of safety, addressing specific question raised by JECFA	November 2010	(CEFIC)

	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
Quinoline Yellow (INS 104); Sunset Yellow FCF (INS 110); Ponceau 4R (INS 124) <sup>1</sup>	Review of safety assessment	Available 2010 (pending release of data submitted to EFSA by sponsors)	European Union
Hydroxypropyl methylcellulose (INS 464)	Revision of specifications	November 2010	(CEFIC)
Octenyl succinic acid (OSA) modified gum Arabic	Re-evaluation of safety, addressing specific question raised by JECFA	October 2010	United States of America

<sup>1</sup>High priority