

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 7

CRD6

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Fifty-first Session

#### REVISIONS TO THE CIRCULAR LETTER FOR REQUESTING INFORMATION AND COMMENTS ON THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

Prepared by the joint FAO/WHO JECFA Secretariat

1. The Codex Committee for Food Additives at its 50<sup>th</sup> Session (CCFA50)<sup>1</sup> noted that the JECFA and Codex Secretariats would work together, in consultation with Canada, to update the circular letter for requesting information and comments on the priority list of substances proposed for evaluation by JECFA for consideration by the in-session WG on the Priority at CCFA51.
2. CCFA50 agreed to include Annex 4 to the Circular Letter and further provided additional information to Annex 2 (*Form for the submission of substances to be evaluated by JECFA*). Following these revisions, the [Circular Letter](#) is composed of four annexes<sup>2</sup>, namely
  - 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; and
  - Annex 4 – Confirmation of previous requests and data availability.
3. Annexes 2 and 4 with additional revisions are proposed for consideration by the in-session WG on the Priority at CCFA51.

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<sup>1</sup> REP18/FA, para 161

<sup>2</sup> REP18/FA, appendix XII

## 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.*

<b>Name of Substance(s):</b>	
<b>Question(s) to be answered by JECFA</b> <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), IUPAC name, C.A.S number (as applicable):
3. Names and addresses of basic producers:
4. Identification of the manufacturer that will be providing data (Please indicate contact person):
5. Justification for use:
6. 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):
7. 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))
8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.
9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.
10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries
11. Please indicate the type of data that are available in the table below.

Ensure that the available data are directly relevant to the substance of interest in this request. In particular, for substances obtained from natural resources, characterization of the products in commerce and a relevant set of biochemical and toxicological data on such products are essential for JECFA to develop a specifications monograph and the related safety. Such data/information typically include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances; etc.

	<b>Data available? (Y/N)</b>
<b>Toxicological data</b>	
(i) Metabolic and pharmacokinetic studies (please specify)	
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	
(iv) Other data (please specify)	
<b>Technological data</b>	
(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	

<b><i>Dietary exposure assessment data</i></b>	
(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 exposures based on food consumption data for foods in which the substance may be used.	
<b><i>Other information:</i></b> (please specify)	

12. Specify earliest date when data can be made available to JECFA. (Data shall only be submitted in response to a JECFA call for data; **do NOT include any data intended for JECFA to this form.**)

## Annex 4

**CONFIRMATION OF PREVIOUS REQUESTS AND DATA AVAILABILITY**

In completing this form, the **sponsor, data provider, or supporting Member** of a request set out in Annex 3 can indicate if the request is still in effect, and if the data to support the request are currently available. The opportunity to later confirm or discontinue the requests will still be available at the in-session working group of the JECFA Priority List. In case any of the **sponsor, data provider, or supporting Member** cannot physically attend the meeting, please complete the form and please note one form per request.

And indication of "no" to any of the questions will result in the deletion of the request at the following session of the CCFA. In response to the circular letter, separate tables should be prepared for separate requests.

<b>Confirmation of previous request and data availability</b>	
<b>Name of Substance (as it appears in Annex 3):</b>	
<b>Is the request still in effect? (yes / no)</b>	
<b>Are the data available? (yes / no)</b>	<If yes, specify the earliest date on which the data can be made available>
<b>Change to data provider? (yes/no)</b>	<If yes, specify the new data provider including contact person>

(Data shall only be submitted in response to a JECFA call for data; do **NOT** add data intended for JECFA to this form)