

**REVISION TO THE CIRCULAR LETTERS
PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA
AND**

**CHANGE AND/OR ADDITION TO SECTION 3 OF THE CLASS NAMES AND INTERNATIONAL
NUMBERING SYSTEM FOR FOOD ADDITIVES (CAC/GL 36-1989)**

(For Information only)

**PART A: REQUEST FOR INFORMATION AND COMMENTS ON THE PRIORITY LIST OF SUBSTANCES
PROPOSED FOR EVALUATION BY JECFA**

Note: New text is presented in **bold and underlined** font; deletion in ~~strike through~~ font

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 (No amendment);

Annex 2 - Form for the submission of substances to be evaluated by JECFA (Amended)

Annex 3 - Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up. (No amendment);

Annex 4 – Confirmation of previous requests and data availability (New).

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 (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)

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 and such data/information could include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances etc

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 4**CONFIRMATION OF PREVIOUS REQUESTS AND DATA AVAILABILITY**

In completing this form, the sponsor 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.

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.

<u>Confirmation of previous requests and data availability</u>	
<u>Name of Substance(s):</u>	
<u>Is the request still in effect? (yes / no)</u>	
<u>Are the data available? (yes / no)</u>	
<u>Change to data provider? (yes/no)</u>	<u><Specify if “yes”></u>

PART B: REQUEST FOR PROPOSALS FOR CHANGE AND/OR ADDITION TO SECTION 3 OF THE CLASS NAMES AND INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES (CAC/GL 36-1989)

Note: New text is presented in **bold and underlined** font; deletion in ~~striketrough~~ font

PRINCIPLES FOR CHANGES/ADDITIONS TO SECTION 3 OF CLASS NAMES AND INTERNATIONAL NUMBERING SYSTEM (CAC/GL 36-1989)**Annex 1****5. Deletion of an additive from the INS list**

Proposals for deletion of INS entries cannot be submitted to this circular letter if there are existing provisions (adopted or in the Step Process) for the additive in the General Standard for Food Additives (CODEX STAN 192-1995). The Codex Committee on Food Additives must first remove those provisions from the GSFA prior to the submission of proposals to delete a corresponding INS entry.

Proposals for deletion of INS entries should be accompanied by a suitable justification.

Annex 2

Justification for the requested INS change in Section 3: deletion of additive purpose (*Please select only the appropriate option and provide details in the space below, **Proposals for deletion of INS entries cannot be submitted to this circular letter if there are existing provisions (adopted or in the Step Process) for the additive in the General Standard for Food Additives (CODEX STAN 192-1995).***)