CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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CL 2017/48-FA
April 2017

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 the priority list of substances proposed for evaluation by JECFA**

DEADLINE: **15 January 2018**

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: ccfa@cfsa.net.cn

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 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;

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.

2. Information and comments, submitted in response to this Circular Letter, will be considered at the 50th 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 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)

   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 3

(Appendix XI of REP17/FA)

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

Substance(s)	***Question(s) to be answered***	***Data availability (when, what)***	***Proposed by***	***Data provider***
5'-Deaminase from *Streptomyces murinus*	Safety evaluation when used as a processing aid and establishment of specifications	December 2017	Japan	Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)
Acid prolyl endopeptidase from *Aspergillus niger* expressing a gene from *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	DSM Food Specialties Dr. Jack Reuvers (jack.reuvers@dsm.com)
D-Allulose 3-epimerase from *Arthrobacter globiformis* expressed in *Escherichi coli*	Safety assessment and establishment of specifications	December 2017	United States of America	Matsutani Chemical Industry Co. Ltd. Mr. Yuma Tani (yuma-tani@matsutani.co.jp)
Alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus*	Safety assessment and establishment of specifications	December 2017	European Union	Danisco US Inc Ms. Lisa Jensen (lisa.jensen@dupont.com)
Alpha-amylase from *Bacillus stearothermophilus* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2017	European Union	Danisco US Inc Ms. Lisa Jensen (lisa.jensen@dupont.com)
Alpha-amylase from *Rhizomucor pusillus* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)
Amyloglucosidase from *Talaromyces emersonii* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes A/S Mr. Peter Hvass (phva@novozymes.com)
Asparaginase from *Aspergillus niger* expressing a modified gene from *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)
Asparaginase from *Pyrococcus furiosus* expressed in *Bacillus subtilis*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)
Beta-amylase from *Bacillus flexus* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes A/S Mr. Peter Hvass (phva@novozymes.com)
Beta-glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*	Safety assessment and establishment of specifications	December 2017	Japan	Nagase ChemteX Corporation Mr. Kensaku Uzura (kensaku.uzura@ncx.nagase.co.jp)

Substance(s)	***Question(s) to be answered***	***Data availability (when, what)***	***Proposed by***	***Data provider***
Carob bean gum (INS 410)	Data pending – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas	To be confirmed during CCFA50	CCFA49	
Citric and Fatty Acid Esters of Glycerol (INS 472 c)	Revision of specifications to allow for salts of sodium, potassium, and calcium as neutralizing agents for CITREM	December 2017	European Union	EFEMA Ms. Caroline Rey (efema@ecco-eu.com)
Collagenase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*	Safety evaluation when used as a processing aid and establishment of specifications	December 2017	Japan	Nagase ChemteX Corporation Mr. Kensaku Uzura (kensaku.uzura@ncx.nagase.co.jp)
Endo-1,4-ß-xylanase from *Bacillus subtilis* produced by *B. subtilis* LMG S-28356	Safety evaluation when used as a processing aid	December 2017	European Union	Puratos NV Bas Verhagen (bverhagen@puratos.com)
Endo-1,4-ß-xylanase from *Pseudoalteromonas haloplanktis* produced by *B. subtilis*, strain LMG S-24584	Safety evaluation when used as a processing aid	December 2017	European Union	Puratos NV Bas Verhagen (bverhagen@puratos.com)
Endo-1,4-ß-xylanase from *Thermotoga maritima* produced by *B. subtilis*, strain LMG S-27588	Safety evaluation when used as a processing aid	December 2017	European Union	Puratos NV Bas Verhagen (bverhagen@puratos.com)
Flavouring substances (3 new + 27 from previous Priority Lists + 1 for re-evaluation + 39 for which JECFA requested additional info = 70 total)	Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable	December 2017	United States of America	IOFI Dr. Sean V. Taylor (staylor@vertosolutions.net)
Gellan gum (INS 418) (Pending confirmation of technological justification from CCNFSDU)	Safety assessment for use in infant formula, formula for special medical purposes for infants, and follow-up formula	To be confirmed during CCFA50	United States of America	Abbott Nutrition Mr. Paul Hanlon (paul.hanlon@abbott.com)
Glucose oxidase from *Penicillium chrysogenum* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	DSM Food Specialties Dr. Jack Reuvers (jack.reuvers@dsm.com)
Glycerol ester of wood rosin (GEWR) (INS445(iii))	Revision of specifications to allow for additional species of pine as source materials	December 2017	European Union	Resinas Sineticas Mr. Vasilios Fotopoulos (vasilios@trchemicals.com) (IFAC will also provide data.)
Gold (INS 175)	Safety assessment and establishment of specifications	To be confirmed by CCFA50	CCFA49	
Basic methacrylate copolymer (INS 1205)	Safety assessment on use as a glazing/coating agent on food supplements (FC 13.6), and establishment of specifications	December 2017	European Union	Evonik Nutrition & Care GmbH Dr. Uta Deiting (uta.deiting@evonik.com)

Substance(s)	***Question(s) to be answered***	***Data availability (when, what)***	***Proposed by***	***Data provider***
Neutral methacrylate copolymer (INS 1206)	Safety assessment on use as a glazing/coating agent on food supplements (FC 13.6), and establishment of specifications	December 2017	European Union	Evonik Nutrition & Care GmbH Dr. Uta Deiting (uta.deiting@evonik.com)
Anionic Methacrylate copolymer (INS 1207)	Safety assessment on use as a glazing/coating agent on food supplements (FC 13.6), and establishment of specifications	December 2017	European Union	Evonik Nutrition & Care GmbH Dr. Uta Deiting (uta.deiting@evonik.com)
Inulinase from *Aspergillus ficuum* produced by *Aspergillus oryzae*, strain MUCL 44346	Safety evaluation when used as a processing aid	December 2017	European Union	Puratos NV Bas Verhagen (bverhagen@puratos.com)
Lactase from *Bifidobacterium bifidum* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes Mr. Peter Hvass (phva@novozymes.com)
Lipase from *Aspergillus oryzae* expressing a modified gene from *Thermomyces lanuginosus*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes Mr. Peter Hvass (phva@novozymes.com)
Lipase from *Mucor javanicus*	Safety evaluation when used as processing aid and establishment of specifications.	December 2017	Japan	Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)
Lutein from *Tagetes erecta* (INS 161b(i))	Re-evaluation of safety to extend the ADI of 'not specified' for Lutein esters of *Tagetes erecta* to Lutein from *Tagetes erecta,* and revision of specifications Revision of specifications with respect to “melting range”.	December 2017	Switzerland	DSM Nutritional Products Europe Ltd Mr. Dirk Cremer (dirk.cremer@dsm.com)
Natamycin (INS 235)[1]	Re-evaluation of safety and revision of specifications due to emerging data on natamycin's role in promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens	December 2017	Russian Federation	Federal Research Centre of Nutrition, Biotechnology and Food Safety (codex@ion.ru)
Nisin (INS 234) [7]	Re-evaluation of safety and revision of specifications due to emerging data on nisin's role in promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens	December 2017	Russian Federation	Federal Research Centre of Nutrition, Biotechnology and Food Safety (codex@ion.ru)
Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of *Pseudomonas fluorescens*	Safety assessment and establishment of specifications	December 2017	European Union	DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)

[1] To be addressed by JECFA or other mechanisms through the FAO/WHO Scientific Advice Programme

Substance(s)	***Question(s) to be answered***	***Data availability (when, what)***	***Proposed by***	***Data provider***
Phosphodiesterase from *Penicillium citrinum*	Safety evaluation when used as processing aid and establishment of specifications.	December 2017	Japan	Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)
Phospholipase A2 from pig pancreas expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)
Phospholipase A2 from *Streptomyces violaceoruber* expressed in *S. violaceoruber*	Safety assessment and establishment of specifications	December 2017 2015	Japan	Nagase ChemteX Corporation Mr. Kensaku Uzura (kensaku.uzura@ncx.nagase.co.jp)
Protease Aqualysin 1 from *Thermus aquaticus* produced by *B. subtilis*, strain LMGS 25520	Safety evaluation when used as a processing aid	December 2017	European Union	Puratos NV Bas Verhagen (bverhagen@puratos.com)
Rosemary extract (INS 392)	(1) Data pending – studies to elucidate the potential developmental and reproductive toxicity (2) Data pending – validation information on the method of determination of residual solvents (3) Data pending – data on typical use-levels in food	To be confirmed by CCFA50	CCFA49	
Silver (INS 174)	Safety assessment and establishment of specifications	To be confirmed by CCFA50	CCFA49	
Sodium sorbate (INS 201)	Safety assessment and establishment of specifications	To be confirmed by CCFA50	CCFA 49	
Spirulina extract	Safety assessment and establishment of specifications for use as a colour	December 2017	United States of America	IACM Sarah Codrea (scodrea@vertosolutions.net)
Steviol glycosides (INS 960)	(1) Data pending – method of assay to replace the existing method of, to include as many steviol glycosides as possible, along with supporting validation information and chromatograms (2) Data pending – analysis of at least 5 batches of commercial samples, including chromatograms	December 2017	CCFA49	CCC Ms Allison Cooke (acooke@caloriecontrol.org)
Steviol Glycosides (Rebaudioside M)	Safety evaluation of Rebaudioside M manufactured from two strains of yeast from the *saccharomyces* family, and establishment of standalone specifications	December 2017	United States of America	Intertek Scientific & Regulatory Consultancy Dr. Ashley Roberts (ashley.roberts@intertek.com)
Transglucosidase/alpha-glucosidase from *Trichoderma reesei* expressing an Alpha-glucosidase gene from *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	Danisco US Inc Dr. Vincent J. Sewalt (vincent.sewalt@dupont.com)

Substance(s)	***Question(s) to be answered***	***Data availability (when, what)***	***Proposed by***	***Data provider***
Xylanase from *Bacillus licheniformis* expressed in *B. licheniformis*	Safety assessment and establishment of specifications	December 2017	European Union	Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)
Xylanase from *Talaromyces emersonii* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2017	European Union	DSM Food Specialties Dr. Jack Reuvers (jack.reuvers@dsm.com)
Colours for re-evaluation				
Brilliant Black	Re-evaluation of safety and specifications	To be confirmed by CCFA50	CCFA49	
Erythrosine (INS 127)	Re-evaluation of safety and specifications	December 2017	CCFA46 (data from Japan; IACM; EU)	
Indigotine (INS 132)	Re-evaluation of safety and specifications	December 2017	CCFA46 (data from Japan; IACM; EU)	
Red 2G	Re-evaluation of safety and specifications	To be confirmed by CCFA50	CCFA49	

PENDING DATA REQUIREMENTS FOR 13 MODIFIED STARCHES

(1) All modified starches require data on the method of manufactured

(2) The following table lists data requirements for each modified starches

#	**Modified starch**	**Pending data requirement**	**Data provider**
1	Dextrin roasted starch (INS 1400)	Suitable method for the Dispersion or Reducing Sugars Distinguishing Test	Richard L Barndt LLC Richard Barndt (rbarndt49@gmail.com)
2	Acid treated starch (INS 1401)	Suitable method for the Dispersion or Reducing Sugars Distinguishing Test	
3	Alkaline treated starch (INS 1402)	Suitable method for the Dispersion or Reducing Sugars Distinguishing Test	
4	Bleached starch (INS1403)	Typical levels of residual reagents or by-products	
5	Enzyme-treated starch (INS 1405)	Suitable method for the Dispersion or Reducing Sugars Distinguishing Test	
6	Monostarch phosphate (INS 1410)	Suitable test for the identification of the phosphate groups	
7	Distarch phosphate (INS 1412)	Suitable test for the identification of the phosphate groups and of crosslinking	
8	Phosphated distarch phosphate (INS 1413)	Suitable test for the identification of the phosphate groups and of crosslinking	
9	Acetylated distarch phosphate (INS 1414)	Suitable test for the identification of the phosphate groups and of crosslinking	
10	Acetylated distarch adipate (INS 1422)	Suitable test for the identification of the adipate groups; Levels of adipic acid	
11	Hydroxypropyl starch (INS 1440)	Suitable method for the determination of propylene chlorohydrin	
12	Hydroxypropyl distarch phosphate (INS 1442)	Suitable method for the determination of propylene chlorohydrin; Suitable test for the identification of the phosphate groups	
13	Starch sodium octenyl succinate (INS 1450)	Suitable test for the identification of octenylsuccinate groups	