

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

CL 2018/28-FA
April 2018

TO: Codex Contact Points
Contact Points of international organizations having observer status with Codex

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 2019

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 are invited to: i) provide comments on substances already included in the priority list of substances proposed for evaluation by JECFA, ii) submit information on new substances for inclusion in the priority list; and/or iii) confirm previous requests and data availability.
2. Information and comments should be submitted on the basis of the following attached Annexes to this Circular Letter:
 - 2.1 For submitting information on new substances, refer to:
 - 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.
 - 2.2 For information of the priority list, to which comments may be made, refer to:
 - Annex 3** - Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up;
 - 2.3 To confirm previous requests, refer to:
 - Annex 4** - Confirmation of previous requests and data availability.
3. Information and comments, submitted in response to this Circular Letter, will be considered at the 51st Session of the Codex Committee on Food Additives.

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.

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 <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):
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 3

(Appendix X of REP18/FA)

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

Substance(s)	General information	Comments about the request
5'-Deaminase from <i>Streptomyces murinus</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: Japan</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)</p>	<p>Basis for request: The enzyme is used in the processing of yeast and like products to promote the conversion of adenosine monophosphate (generally tasteless) to inosine monophosphate ("umami" flavour), thereby enhancing the flavour of the products.</p> <p>Possible issues for trade: currently unidentified</p>
Acid prolyl endopeptidase from <i>Aspergillus niger</i> expressing a gene from <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: DSM Food Specialties Dr. Jack Reuvers (jack.reuvers@dsm.com)</p>	<p>Basis for request: The enzyme is used in the processes of: brewing beer to reduce the amount gluten/gliadins; potable alcohol production to optimize fermentation; protein processing to produce protein hydrolysates without bitter flavour; starch processing to degrade peptides which would negatively affect the production process and reduce the amount of gluten/gliadins.</p> <p>Possible issues for trade: currently unidentified</p>
Adenosine-5'-monophosphate deaminase from <i>Aspergillus oryzae</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: Japan</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2018</p> <p>Data provider: Shin Nihon Chemical Co., Ltd. Dr. Ashley Roberts (ashley.roberts@intertek.com)</p>	<p>Basis for request: AMP deaminase from <i>Aspergillus oryzae</i> is intended for use during food and beverage processing to increase the content of 5'-monophosphate (5'-IMP) in food, beverages or food ingredients to impart or enhance flavour.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
D-Allulose 3-epimerase from <i>Arthrobacter globiformis</i> expressed in <i>Escherichia coli</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: United States of America</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Matsutani Chemical Industry Co. Ltd. Mr. Yuma Tani (yuma-tani@matsutani.co.jp)</p>	<p>Basis for request: The enzyme is used in the production of D-allulose or ketose sugars from D-fructose.</p> <p>Possible issues for trade: currently unidentified</p>
Alpha-amylase from <i>Bacillus licheniformis</i> expressing a modified alpha-amylase gene from <i>Geobacillus stearothermophilus</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Danisco US Inc Ms. Lisa Jensen (lisa.jensen@dupont.com)</p>	<p>Basis for request: The enzyme is a thermostable starch hydrolysing alpha-amylase, which quickly reduced viscosity of gelatinized starch, allowing for processing of materials with high solid levels.</p> <p>Possible issues for trade: currently unidentified</p>
Alpha-amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2015 (CCFA47)</p> <p>Data availability: December 2018</p> <p>Data provider: Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)</p>	<p>Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.</p> <p>Possible issues for trade: currently unidentified</p>
Alpha-amylase from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2015 (CCFA47)</p> <p>Data availability: December 2018</p> <p>Data provider: Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)</p>	<p>Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Amyloglucosidase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Novozymes A/S Mr. Peter Hvass (phva@novozymes.com)</p>	<p>Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.</p> <p>Possible issues for trade: currently unidentified</p>
Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2014 (CCFA46)</p> <p>Data availability: December 2018</p> <p>Data provider: DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)</p>	<p>Basis for request: The enzyme is used in cereal- and potato-based products to convert asparagine to aspartic acid, to reduce acrylamide formation during processing.</p> <p>Possible issues for trade: currently unidentified</p>
Asparaginase from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2015 (CCFA47)</p> <p>Data availability: December 2018</p> <p>Data provider: Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)</p>	<p>Basis for request: The enzyme is indicated as a thermotolerant enzyme used to convert asparagine to aspartic acid to reduce acrylamide formation in the course of baking processes, cereal-based processes, fruit and vegetable processing, and coffee and cocoa processing.</p> <p>Possible issues for trade: currently unidentified</p>
Beta-amylase from <i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Novozymes A/S Mr. Peter Hvass (phva@novozymes.com)</p>	<p>Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Beta-glucanase from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2016 (CCFA48) Data availability: December 2018 Data provider: Nagase ChemteX Corporation Mr. Kensaku Uzura (kensaku.uzura@ncx.nagase.co.jp)</p>	<p>Basis for request: The enzyme is used in the production of yeast extract products. It is indicated that by disrupting cell walls, an increased yield of yeast extract can be obtained, and bacterial contamination during manufacturing is reduced. Possible issues for trade: currently unidentified</p>
Black carrot extract	<p>Type of request: Safety assessment and establishment of specifications Proposed by: United States of America Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: International Association of Color Manufacturers (IACM) Mrs. Sarah Codrea (scodrea@iacmcolor.org)</p>	<p>Basis for request: To be used as a food color. Black carrot extract is an anthocyanin-based color and is allowed under the group color name “Anthocyanins” (E163) or “vegetable juice” color depending on the countries. Possible issues for trade: currently unidentified</p>
Collagenase from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2016 (CCFA48) Data availability: December 2018 Data provider: Nagase ChemteX Corporation Mr. Kensaku Uzura (kensaku.uzura@ncx.nagase.co.jp)</p>	<p>Basis for request: The enzymes is used in meat and sausage casing processing to hydrolyze collagen, thereby reducing connective tissue toughness and improving meat tenderness. Possible issues for trade: currently unidentified</p>
Endo-1,4-β-xylanase from <i>Bacillus subtilis</i> produced by <i>B. subtilis</i> LMG S-28356	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2016 (CCFA48) Data availability: December 2018 Data provider: Puratos NV Mr. Bas Verhagen (bverhagen@puratos.com)</p>	<p>Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Endo-1,4- β -xylanase from <i>Pseudoalteromonas haloplanktis</i> produced by <i>B. subtilis</i> , strain LMG S-24584	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. Bas Verhagen (bverhagen@puratos.com)</p>	<p>Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified</p>
Endo-1,4- β -xylanase from <i>Thermotoga maritima</i> produced by <i>B. subtilis</i> , strain LMG S-27588	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. Bas Verhagen (bverhagen@puratos.com)</p>	<p>Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified</p>
Flavouring substances (8 for re-evaluation)	<p>Type of request: Revision of specifications Proposed by: United States of America Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: International Organization of the Flavor Industry (IOFI) Dr. Sean V. Taylor (staylor@vertosolutions.net)</p>	
Gellan gum (INS 418) (Pending confirmation of technological justification from CCFNSDU)	<p>Type of request: Safety assessment for use in infant formula, formula for special medical purposes for infants, and follow-up formula Proposed by: United States of America Year requested: 2016 (CCFA48) - ongoing Data availability: December 2018 Data provider: Abbott Nutrition Mr. Paul Hanlon (paul.hanlon@abbott.com)</p>	<p>Basis for request: Gellan gum acts as a stabilizer in ready-to-feed infant formula, or concentrated liquid products to improve physical stability through mechanisms such as maintaining homogeneity or minimizing ingredient sedimentation. Gellan gum helps to keep minerals such as calcium and phosphorus in suspension and prevents physical separation of the product. Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Gellan gum (INS 418)	<p>Type of request: For JECFA to consider revising the limit for ethanol from the specifications Proposed by: China Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: Zhejiang DSM Zhongken Biotechnology Co Ltd Mr. Wen Fang wen.fang@dsmzk.com</p>	<p>Basis for request: A limit of 50 mg/kg for ethanol in gellan gum was set by JECFA79 although ethanol is considered a GMP solvent. No other specifications (Chinese legal specifications, 10th edition of the FCC, EU E 418 purity criteria) have set a numerical limit for residual ethanol. Possible issues for trade: currently unidentified</p>
Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2014 (CCFA46) Data availability: December 2018 Data provider: DSM Food Specialties Dr. Jack Reuvers jack.reuvers@dsm.com</p>	<p>Basis for request: The enzyme is used in baking, as it forms inter-protein bonds in dough, strengthening the dough and increasing its gas-retaining capacity and improving its handling properties. Possible issues for trade: currently unidentified</p>
Inulinase from <i>Aspergillus ficuum</i> produced by <i>Aspergillus oryzae</i> , strain MUCL 44346	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Bas Verhagen bverhagen@puratos.com</p>	<p>Basis for request: The enzyme catalyzes the hydrolysis of inulin to produce fructo-oligosaccharides, theoretically from all food materials that naturally contain inulin. Possible issues for trade: currently unidentified</p>
Lactase from <i>Bifidobacterium bifidum</i> expressed in <i>Bacillus licheniformis</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Bas Verhagen bverhagen@puratos.com</p>	<p>Basis for request: The lactase enzyme preparation is used as a processing aid during food manufacture for hydrolysis of lactose during processing of milk and other lactose containing dairy products, e.g. in order to obtain lactose-reduced milk products for lactose-intolerant individuals as well as dairy products with better consistency and increased sweetness due hydrolysis of lactose to form glucose and galactose. Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Lipase from <i>Aspergillus oryzae</i> expressing a modified gene from <i>Thermomyces lanuginosus</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Puratos NV Bas Verhagen (bverhagen@puratos.com)</p>	<p>Basis for request: The enzyme is used as a processing aid during food manufacture for hydrolysis of lipids during processing of lipid-containing foods, e.g., in order to improve dough strength and stability in baking and other cereal based processes.</p> <p>Possible issues for trade: currently unidentified</p>
Lipase from <i>Mucor javanicus</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: Japan</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)</p>	<p>Basis for request: The enzyme catalyzes the hydrolysis of mono-, di- and triglycerides containing short-, medium-, and long-chain fatty acid moieties, providing various sensory benefits in processed dairy products, processed baking products, and processed egg products.</p> <p>Possible issues for trade: currently unidentified</p>
Metatartaric acid (INS 353)	<p>Type of request: <u>Data pending</u> to finalize specifications – Evaluation by JECFA84</p> <p>Proposed by: Australia</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2018</p> <p>Data provider: currently unidentified</p>	<p>Basis for request: JECFA received limited analytical data on metatartaric acid. In order to remove the tentative designation from the specifications, the following information on the products of commerce is requested:</p> <ul style="list-style-type: none"> • Characterization of the products (optical rotation, content of free tartaric acid, degree of esterification and molecular weight distribution) and the corresponding analytical methods; • Infrared spectrum (in a suitable medium); and • Analytical results including the above parameters from a minimum of five batches of products currently available in commerce, along with quality control data. <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Natamycin (INS 235)	<p>Type of request: Re-evaluation of safety and revision of specifications</p> <p>Proposed by: Russian Federation</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Russian Federation Codex Contact Point (codex@gse.ru)</p>	<p>Basis for request: The appropriateness of retaining natamycin in the GSFA should be re-evaluated, due to to emerging data on natamycin's role in: (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora.</p> <p>It is suggested that previous evaluations were specific to chemical toxicology and did not adequately take into account antimicrobial effects.</p> <p>Comments in opposition to the request note that the antimicrobial effects against a variety of Gram-positive bacteria and their spores are important in maintaining product shelf-life and ensuring food safety.</p> <p>Possible issues for trade: currently unidentified</p>
Nisin (INS 234)	<p>Type of request: Re-evaluation of safety and revision of specifications</p> <p>Proposed by: Russian Federation</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Russian Federation Codex Contact Point (codex@gse.ru)</p>	<p>Basis for request: The appropriateness of retaining nisin in the GSFA should be re-evaluated, due to to emerging data on nisin role in: (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora.</p> <p>It is suggested that previous evaluations were specific to chemical toxicology and did not adequately take into account antimicrobial effects.</p> <p>Comments in opposition to the request note that the antimicrobial effects against a variety of Gram-positive bacteria and their spores are important in maintaining product shelf-life and ensuring food safety.</p> <p>Possible issues for trade: currently unidentified</p>
Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of <i>Pseudomonas fluorescens</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)</p>	<p>Basis for request: The enzyme hydrolyzes phosphatidylinositol present in vegetable oil, thereby reducing its concentration. PI negatively impacts taste, colour, and stability of vegetable oil, while the hydrolytic products do not.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Phosphodiesterase from <i>Penicillium citrinum</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)</p>	<p>Basis for request: The enzyme is used in processing yeast products by hydrolysing RNA, thereby increasing ribonucleotide levels and improving umami flavour. Possible issues for trade: currently unidentified</p>
Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2014 (CCFA46) Data availability: December 2018 Data provider: DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)</p>	<p>Basis for request: The enzyme hydrolyzes natural phospholipids present in foodstuffs resulting in the formation of lyso-phospholipids that have emulsifying properties. This may be of benefit in baking and in egg processing for superior emulsifying properties (e.g. useful in dressings, spreads, sauces). In addition, the enzyme preparation is used during degumming of vegetable oils, where phospholipids can be separated more effectively from the oil. Possible issues for trade: currently unidentified</p>
Phospholipase A2 from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2016 (CCFA48) Data availability: December 2018 Data provider: Nagase ChemteX Corporation Mr. Kensaku Uzura (kensaku.uzura@ncx.nagase.co.jp)</p>	<p>Basis for request: The enzyme preparation helps to improve emulsification properties of modified lipids increasing yield and texture of the final food in dairy and bakery. The enzyme preparation can also be used for degumming of vegetable oil. In general, the phospholipase A2 does not exert any enzymatic activity in the final food. Possible issues for trade: currently unidentified</p>
Potassium polyaspartate	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: Nanochem Solutions Ms. Grace Fan (Igfan@nanochems.com)</p>	<p>Basis for request: Potassium polyaspartate is a new food additive to be used as a stabilizer to prevent tartrate crystal precipitation in wine. This additive is (1) strongly effective even in unstable wines, (2) stable over time in wine and (3) shows no sensory effects. Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Protease Aqualysin 1 from <i>Thermus aquaticus</i> produced by <i>B. subtilis</i> , strain LMG5 25520	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Puratos NV Bas Verhagen (bverhagen@puratos.com)</p>	<p>Basis for request: The enzyme preparation is used as a processing aid during production of bakery products. The food enzyme catalyses hydrolyzes of the peptide bonds. The addition of enzyme provides several benefits during the production of bakery products:</p> <ul style="list-style-type: none"> - Faster dough development upon mixing; - Better dough machinability; - Reduced dough rigidity; - Improved dough's structure and extensibility during the shaping or moulding step; - Uniform shape of the bakery product; - Regular batter viscosity, and - Improved short-bite of certain products like hamburger breads <p>Possible issues for trade: currently unidentified</p>
Steviol Glycosides (Rebaudioside A and M, respectively, from Multiple Gene Donors Expressed in <i>Yarrowia lipolytica</i>) (INS 960)	<p>Type of request: Revision of specifications</p> <p>Proposed by: Switzerland</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2018</p> <p>Data provider: DSM Food Specialties Ms. Jeannine van de Wiel (Jeanine.Wiel-van-de@DSM.com)</p>	<p>Basis for request: To include data on Rebaudioside M and to rename the specifications as appropriate (e.g., Steviol glycosides produced by <i>Yarrowia lipolytica</i>).</p> <p>Possible issues for trade: currently unidentified</p>
Steviol Glycosides (Rebaudioside M manufactured from two strains of yeast from the <i>Saccharomyces</i> family)	<p>Type of request: Safety assessment and establishment of standalone specifications</p> <p>Proposed by: United States of America</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Intertek Scientific & Regulatory Consultancy Dr. Ashley Roberts (ashley.roberts@intertek.com)</p>	<p>Basis for request: An amendment to the JECFA specification is justified based on the commercial availability of rebaudioside M, manufactured using a novel fermentation process. Rebaudioside M was included within the 2016 JECFA evaluation and incorporated within the 2016 JECFA specification.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Steviol glycosides (Steviol Glycosides, Rebaudioside A, Rebaudioside D, Rebaudioside M; Enzyme Modified Steviol Glycosides, Enzyme Modified Stevia Leaf Extract)	<p>Type of request: Re-evaluation and establishment of specifications</p> <p>Proposed by: United States of America</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2018</p> <p>Data provider: Blue California Mr. Hadi Omrani (hadi@bluecal-ingredients.com) Cargill Incorporated Ms. Nicole Cuellar-Kingston (nicole_cuellar-kingston@cargill.com) DSM Food Specialties Ms. Jeanine A. G. van de Wiel (Jeanine.Wiel-van-de@DSM.com) PureCircle Limited Dr. Sidd Pukayastha (sidd.pukayastha@purecircle.com)</p>	<p>Basis for request: An amendment to the current JECFA specifications is justified based upon the commercial availability of a number of steviol glycoside preparations that contain for example a high proportion of singular steviol glycosides such as rebaudiosides A, D or M from fermentation or bioconversion and glycosides containing additional glucose units that are produced through enzyme modification.</p> <p>Possible issues for trade: currently unidentified</p>
Transglucosidase/alpha-glucosidase from <i>Trichoderma reesei</i> expressing an Alpha-glucosidase gene from <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Danisco US Inc Dr. Vincent J. Sewalt (vincent.sewalt@dupont.com)</p>	<p>Basis for request: The food enzyme catalyzes both hydrolytic and transfer reactions on incubation with α-D-gluco-oligosaccharides. In molasses, non-fermentable sugars including raffinose and stachyose are converted to sucrose, galactose, glucose and fructose, which can then be fermented into alcohol. The enzyme preparation is intended for use in the production of isomalto-oligosaccharides and in the manufacture of potable alcohol, lysine, lactic acid and MSG.</p> <p>Possible issues for trade: currently unidentified</p>
Xylanase from <i>Bacillus licheniformis</i> expressed in <i>B. licheniformis</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2015 (CCFA47)</p> <p>Data availability: December 2018</p> <p>Data provider: Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)</p>	<p>Basis for request: The enzyme catalyzes the endo-hydrolysis of 1,4-beta-D-xylosidic linkages in xylans, including arabinoxylans in various plant materials including the cell walls and endosperm of cereals, such as wheat, barley, oats and malt. It is used in baking processes and other cereal based processes where it improves characteristics and handling of the dough.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Xylanase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2014 (CCFA46)</p> <p>Data availability: December 2018</p> <p>Data provider: DSM Food Specialties Dr. Jack Reuvers (jack.reuvers@dsm.com)</p>	<p>Basis for request: The enzyme is used in brewing processes to hydrolyze arabinoxylans in cereal cell walls, to reduce wort viscosity and improve filtration. The enzyme is also used in baking processes to improve dough characteristics and handling.</p> <p>Possible issues for trade: currently unidentified</p>
Benzoic acid and its salts (INS 210-212)	<p>Type of request: Safety assessment</p> <p>Proposed by: CCFA49</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2019</p> <p>Data provider: International Council of Beverages Associations (ICBA) Ms. Katherine Loatman (Kate@icba-net.org)</p>	<p>Basis for request: To confirm ICBA's commitment to provide new toxicological evaluation of benzoates. The studies include extended one-generational reproductive toxicity testing (EOGRT Study, OECD 443) and findings relative to benzoate's chemical-specific adjustment factor, default uncertainty factors and intake assessment assumptions.</p> <p>Possible issues for trade: Identified: CCFA50 suggested extending the interim level of 250 ppm (as benzoic acid) for the beverage category 14.1.4 to CCFA53.</p>
Carob bean gum (INS 410)	<p>Type of request: <u>Data pending</u> – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas</p> <p>Proposed by: JECFA</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: ongoing discussion with JECFA</p> <p>Data provider: ongoing discussion with JECFA</p>	<p>Basis for request: Although no confirmation was provided for carob bean gum (INS 410), JECFA indicated that there was ongoing discussion with industry and that the deadline for the submission of data could be extended and therefore carob bean gum was retained on the JECFA priority list subject to confirmation of provision of data by CCFA50.</p> <p>Possible issues for trade: currently unidentified</p>
Jagua (Genipin-Glycine) Blue	<p>Type of request: <u>Data pending</u> to finalize safety evaluation and establishment of specifications – Evaluation by JECFA84</p> <p>Proposed by: CCFA50</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: To be confirmed by CCFA51</p> <p>Data provider: To be confirmed by CCFA51</p>	<p>Basis for request: (see JECFA84 report) Additional biochemical and toxicological data. Information of characterization of food additive is needed on:</p> <ul style="list-style-type: none"> • Characterization of the low molecular weight components of the “blue polymer”; • A validated method for the determination of dimers; and • Data on concentrations of dimers from five batches of the commercial products <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Rosemary extract (INS 392)	<p>Type of request: <u>Data pending</u> to complete evaluation – Evaluation by JECFA82 Proposed by: CCFA Year requested: 2017 (CCFA49) Data availability: ongoing discussion with JECFA Data provider: ongoing discussion with JECFA</p>	<p>Basis for request: Temporary ADI and specifications. (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 Possible issues for trade: currently unidentified</p>
Tannins (oenological tannins)	<p>Type of request: <u>Data pending</u> to complete evaluation – Evaluation by JECFA84 Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed by CCFA51 Data provider: To be confirmed by CCFA51</p>	<p>Basis for request: In order to complete its evaluation, JECFA requires information on :</p> <p>The following information is required:</p> <ul style="list-style-type: none"> • Composition of tannins derived from the full range of raw materials as well as the processes used in their manufacture; • Validated analytical method(s) and relevant quality control data; • Analytical data from five batches of each commercial product including information related to impurities such as gums, resinous substances, residual solvents, sulfur dioxide content and metallic impurities (arsenic, lead, iron, cadmium and mercury); • Solubility of the products in commerce, according to JECFA terminology; and • Use levels, natural occurrence and food products in which tannins are used. <p>Possible issues for trade: currently unidentified</p>
Yeast extracts containing mannoproteins	<p>Type of request: <u>Data pending</u> to finalize specifications – Evaluation by JECFA84 Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed by CCFA51 Data provider: To be confirmed by CCFA51</p>	<p>Basis for request: In order to revise its tentative specifications, JECFA requires information on:</p> <ul style="list-style-type: none"> • Composition of yeast extracts containing mannoproteins as well as the processes used in their manufacture; • Analytical data from five batches of each commercial product, including information related to impurities; and • Data on concentrations of yeast mannoproteins in wine in which yeast extracts containing mannoproteins have been used. <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
<i>Colour for re-evaluation</i>		
Brilliant Black	Type of request: Re-evaluation of safety and specifications Proposed by: CCFA46 Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: IACM	Basis for request: One of the two remaining priority colours identified for re-evaluation as set out in CX/FA 13/45/17, and amended by the 45 th CCFA. Possible issues for trade: currently unidentified

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.

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