



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifteenth Session

REPORT OF THE IN-SESSION WORKING GROUP ON PRIORITIES FOR EVALUATION BY JECFA

(CX/FA 18/50/12; CX/FA 18/50/3 Rev.1; CRDs 15, 16, 20, 22, 23, 27, 29, 30, 36)

I. Introduction

1. The in-session working group (WG) was chaired by Mr. Steve Theriault (Canada). Mr. John van den Beuken (New Zealand) served as Rapporteur, and Dr. Angelika Tritscher (JECFA, WHO), Dr. Markus Lipp (JECFA, FAO) and Kim Petersen (JECFA, WHO) assisted the Chair. The following members and organisations participated: Australia, Belgium, Brazil, Bulgaria, Canada, China, Costa Rica, Denmark, European Union, France, Germany, Ghana, India, Ireland, Italy, Japan, New Zealand, Nigeria, Palestine, Philippines, Poland, Republic of Korea, Russian Federation, Singapore, South Africa, Sudan, Switzerland, Thailand, United Kingdom, United States of America, Vietnam, AIDGUM, AIPG, AMFEP, CCC, ESFI, ETA, FIA, IACM, IADSA, ICA/IOCCC, ICBA, ICGA, ICGMA, IFAC, IFT, IGTC, ILSI, IOFI, ISC, ISDI, OENOPPIA, OFCA, OIV, USP.

II. Adoption of the agenda

2. The agenda was adopted without changes.

III. Notes

3. The Chair also stated the WG's Terms of Reference. These being:

To consider and prepare recommendations for the Plenary on:

- i. To consider and prepare recommendations for the Plenary on proposals for additions and changes to the Priority List of Substances Proposed for Evaluation by JECFA (CX/FA 18/50/12; CX/FA 18/50/3 Rev.1; CRDs 15, 16, 20, 22, 23, 27, 29, 30, 36); and
 - ii. Matters referred by Agenda item 2: note 301 "interim maximum level until CCFA50" associated with benzoate in FC 14.1.4 in the GSFA (CX/FA 18/50/2 add.1, paras 2-3).
4. Requests for work by JECFA need to be made using the form on which information on the compound to be evaluated by JECFA is provided.
 - i. All requests are to be in by the cut-off date of January 15, and late requests will not be considered;
 - ii. New paragraph added to CL (refer to CX/FA 18/50/3 Rev.1);
 - iii. Proposal to amend the Circular Letter *Request for information and comments on the priority list of substances proposed for evaluation by JECFA* to allow for confirmation of the request and data availability by response to the letter (see Annex 1).
 5. The Chair clarified that the purpose of the proposal to amend the circular letter is two-fold: (1) to expedite the process of confirming the requests in the following session of the in-session working group, as this step takes up the most time of the working group; and (2) to provide a mechanism for Members to confirm requests without having to attend the in-session working group. As a result of an intervention seeking clarification on the proposal, it was indicated that there was no requirement to confirm requests ahead of time, and that there will continue to be an opportunity to confirm requests at the following in-session working group.

Recommendation 1

The In-Session WG recommends that the 50th session of the CCFA amend the Circular Letter *Request for information and comments on the priority list of substances proposed for evaluation by JECFA* as shown in Annex 1.

6. The JECFA Secretariat clarified that being on the Priority List means there will be a call for data and emphasized that it is the sponsor's responsibility to ensure that data are available and that they be responsive to the call for data.
7. To help JECFA prioritize requests, it is proposed that providing further information on the requests is beneficial. To this end, changes to the Priority List table have been introduced to include a summary of information about the request such as its basis and possible trade issues. The Chair noted that information on trade issues has not been populated at this time but may be considered in the future.
8. The Chair of the in-session working group did not discuss any recommendations to the setting of priorities for the evaluation of substances on the Priority List given that discussion on the relevant issue under Agenda item no. 8 has yet to occur.

IV. Working group recommendations to the 50th CCFA on proposals for additions and changes to the priority list of food additives proposed for evaluation by JECFA

9. There were substances that were carried over from the 49th CCFA, and new requests were considered for the Priority List.
10. For those substances that were carried over from the 49th CCFA, confirmation was made that data would be available by December 2018, for consideration by JECFA.
11. The availability of data by December 2018 was confirmed for a number of substances included in the new requests for substances to be added to the Priority List.
12. With respect to benzoic acid and salts (INS 210-213), the availability of new toxicological data was confirmed by the data sponsor. The data will be available by December 2019. Thus, the request will remain on the JECFA priority list for now. In reference to the second term of reference to the in-session working group, the Chair also recommended that the interim ML for INS 210-213 in FC 14.1.4 be extended to CCFA53 without changes to any provisions under consideration in the GSFA. The Chair clarified that CCFA53 is the earliest session by which JECFA could provide advice to the Committee on this issue.

Recommendation 2

The In-Session WG recommends that CCFA50 revise Note 301 to read "Interim maximum level until CCFA53".

13. As a matter of referral from the Plenary discussion of Agenda item 2 from CCFA49, gold (INS 175) and silver (INS 174) were added to the JECFA priority list for a safety assessment and the establishment of specifications with the availability of data to be confirmed by CCFA50. Although a Member noted that industry was actively working on this matter, no data was confirmed to be available. Thus, the Chair of the in-session working group recommended that gold (INS 175) and silver (INS 174) be removed from the JECFA priority list.
14. As a matter of referral from the Plenary discussion of Agenda item 3(a) (see CX/FA 18/50/3 Rev. 1), the completion of certain evaluations by JECFA from the 84th meeting are pending the provision of additional data. Confirmation of data for the following substances is due by the session indicated:
 - i. Jagua (Genipin-Glycine) Blue by CCFA51
 - ii. Metatartaric acid (INS 353) by CCFA50
 - iii. Tannins (oenological tannins) by CCFA51
 - iv. Yeast extracts containing mannoproteins CCFA51
15. With respect to Red 2G (INS 128), a commitment to provide data was not confirmed for this additive, thus the request is proposed to be removed from the Priority List. Consequently, the specifications and the ADI for Red 2G will be withdrawn.

16. With respect to gum Arabic (INS 414), the request was to revise the specifications of this additive to add the functional class of prebiotic. The Chair noted that there is no recognized INS functional class of prebiotic, and thus the proposed use is not as a food additive. The JECFA Secretariat clarified that a functional class not consistent with a food additive function could not be added to the specifications. However, if the request went to an appropriate Committee such as CCNSFDU, then JECFA could consider a request put forward by that Committee. Consequently, the request is proposed for removal from the JECFA Priority List.
17. With respect to sodium sorbate (INS 201), commitment to provide data was not confirmed for this additive, thus the request is proposed to be removed from the Priority List. Consequently, sodium sorbate will need to be removed from the additive grouping for sorbates. In addition, the provisions will need to be removed from the relevant Codex standards and the Codex Committees on Processed Fruits and Vegetables (CCPFV) and Asia (CCASIA).
18. With respect to beta-carotene-rich extract from *Dunaliella salina*, a request was added to the Priority List because of the information presented in Agenda item 3(a) (CX/FA 18/50/3 Rev.1). However, the JECFA Secretariat indicated that this is a JECFA related matter and does not need to be on the Priority List. Thus, the Chair of the in-session working group recommended removing this request from the Priority List.
19. With respect to Steviol glycosides, there were 2 requests carried over from CCFA49, and 3 new requests for the JECFA Priority List. For one of the previous requests noted as requiring additional data, it was clarified that the data had already been provided. Consequently, the request is proposed for removal from the Priority List. The other request is proposed to be retained on the Priority List.
20. Among the new requests, the European Union withdrew their support for the request to revise the specifications for Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*. Switzerland confirmed their support for this request, so the proposal of the in-session working group is to add the request to the Priority List. A duplicate request as the above was submitted by the EU Specialty Food Ingredients, so the proposal of the in-session working group is to not include this request.
21. Finally, the request for steviol glycosides produced through enzyme modification or bioconversion was supported by the United States of America, and so the proposal for the in-session working group is to add the request to the Priority List.
22. With respect to carob bean gum (INS 410) and rosemary extract (INS 392), there are ongoing discussions between JECFA and the data providers. JECFA asked that the requests be maintained on the Priority List.
23. With respect to the request for gellan gum (INS 418) submitted at CCFA48, it has been confirmed that this is an ongoing request pending the outcome of further work on the framework for technological justification by the CCNSFDU. The proposal to retain the request on the JECFA Priority List was agreed to by the in-session working group.
24. The outcome of the in-session working group's deliberations is presented in the table attached to this report (Annex 2).

Recommendation 3

The in-session working group recommends that CCFA50 consider including the substances identified in the table attached to this report (Annex 2) on the Priority List of Food Additives Proposed for Evaluation by JECFA.

Annex 1**Proposal to add Annex 4 to the circular letter *Request for information and comments on the priority list of substances proposed for evaluation by JECFA***

In order to improve the efficient use of the limited time allotted for the physical working group of the JECFA Priority List, and to avoid the possible situation where a request is inadvertently removed from the JECFA Priority List due to an unintended lack of confirmation on the status of the request or the availability of data, it is proposed to revise the circular letter as follows:

1. Modify the cover page as follows (added text underlined):

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;

Annex 4 – Confirmation of previous requests and data availability.

2. Add Annex 4, as follows:

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.

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

ANNEX 2 - PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA
(Recommended by the in-session WG on priorities for evaluation by JECFA for consideration by the 48th CCFA)

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 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 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 Proposed by: European Union Year requested: 2016 (CCFA48) 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 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 Proposed by: Japan Year requested: 2018 (CCFA50) Data availability: December 2018 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>
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 Proposed by: United States of America Year requested: 2016 (CCFA48) Data availability: December 2018 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>

Substance(s)	General information	Comments about the request
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>
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>

Substance(s)	General information	Comments about the request
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 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 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 Proposed by: European Union Year requested: 2015 (CCFA47) Data availability: December 2018 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>
Benzoic acid and its salts (INS 210-212)	<p>Type of request: Safety assessment and establishment of specifications Proposed by: International Council of Beverages Associations (ICBA) Year requested: 2018 (CCFA50) Data availability: December 2019 Data provider: 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: ICBA is requesting that CCFA50 extend the interim level of 250 ppm (as benzoic acid) for the beverage category 14.1.4 to CCFA53.</p>
Beta-amylase from <i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2016 (CCFA48) Data availability: December 2018 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.</p> <p>Possible issues for trade: currently unidentified</p>
Black carrot extract	<p>Type of request: Safety assessment and establishment of specifications Proposed by: International Association of Color Manufacturers (IACM) Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: 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 vegetable juice color and is allowed under the group color name “Anthocyanins” (E163) or “vegetable juice” color depending on the countries.</p> <p>Possible issues for trade: currently unidentified</p>
Carob bean gum (INS 410)	<p>Type of request: Data pending – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas Proposed by: JECFA Year requested: 2016 (CCFA48) Data availability: ongoing discussion with JECFA 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>
Collagenase from <i>Streptomyces violaceoruber</i> expressed in <i>S. violaceoruber</i>	<p>Type of request: Safety evaluation when used as a processing aid 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.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
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.</p> <p>Possible issues for trade: currently unidentified</p>
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.</p> <p>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.</p> <p>Possible issues for trade: currently unidentified</p>
Flavouring substances (3 new + 27 from previous Priority Lists + 9 for re-evaluation + 39 for which JECFA requested additional info = 78 total)	<p>Type of request: Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable Proposed by: International Organization of the Flavor Industry (IOFI) Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: IOFI Dr. Sean V. Taylor (staylor@vertosolutions.net)</p>	<p>Basis for request: Flavouring ingredients in foods for human consumption. Chair's comment: this entry is a duplication of the entry in Annex 2.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Gellan gum (INS 418)	<p>Type of request: Safety assessment for use in infant formula, formula for special medical purposes for infants, and follow-up formula</p> <p>Proposed by: United States of America</p> <p>Year requested: 2016 (CCFA48) - ongoing</p> <p>Data availability: December 2018</p> <p>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.</p> <p>Possible issues for trade: currently unidentified</p>
Gellan gum (INS 418)	<p>Type of request: For JECFA to consider revising the limit for ethanol from the specifications</p> <p>Proposed by: China</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2018</p> <p>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.</p> <p>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</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 baking, as it forms inter-protein bonds in dough, strengthening the dough and increasing its gas-retaining capacity and improving its handling properties.</p> <p>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</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 catalyzes the hydrolysis of inulin to produce fructo-oligosaccharides, theoretically from all food materials that naturally contain inulin.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Jagua (Genipin-Glycine) Blue	<p>Type of request: Data pending – Evaluation by JECFA 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: Information of characterization is needed on:</p> <ul style="list-style-type: none"> • Characterization of the low molecular weight components of the “<i>blue polymer</i>”; • 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>
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.</p> <p>Possible issues for trade: currently unidentified</p>
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 Proposed by: European Union Year requested: 2016 (CCFA48) Data availability: December 2018 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 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 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>

Substance(s)	General information	Comments about the request
Metatartaric acid (INS 353)	<p>Type of request: Data pending – Evaluation by JECFA Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed by CCFA50 by Australia Data provider: To be confirmed by CCFA50 by Australia</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>
Natamycin (INS 235)	<p>Type of request: Re-evaluation of safety and revision of specifications Proposed by: Russian Federation Year requested: 2017 (CCFA49) Data availability: December 2018 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 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. It is suggested that previous evaluations were specific to chemical toxicology and did not adequately take into account antimicrobial effects. 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>

Substance(s)	General information	Comments about the request
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>
Phosphodiesterase from <i>Penicillium citrinum</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 processing yeast products by hydrolysing RNA, thereby increasing ribonucleotide levels and improving umami flavour.</p> <p>Possible issues for trade: currently unidentified</p>

Substance(s)	General information	Comments about the request
Phospholipase A2 from pig pancreas 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. 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.</p> <p>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</p> <p>Proposed by: Japan</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>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.</p> <p>Possible issues for trade: currently unidentified</p>
Potassium polyaspartate	<p>Type of request: Safety assessment and establishment of specifications</p> <p>Proposed by: European Union</p> <p>Year requested: 2018 (CCFA50)</p> <p>Data availability: December 2018</p> <p>Data provider: Nanochem Solutions Ms. Grace Fan (lqfan@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.</p> <p>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 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 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>
Rosemary extract (INS 392)	<p>Type of request: Data pending Evaluation by JECFA Proposed by: CCFA Year requested: 2017 (CCFA49) Data availability: ongoing discussion with JECFA Data provider: ongoing discussion with JECFA</p>	<p>Basis for request: (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</p> <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 Proposed by: Switzerland Year requested: 2018 (CCFA50) Data availability: December 2018 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 Proposed by: United States of America Year requested: 2017 (CCFA49) Data availability: December 2018 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 Proposed by: International Stevia Council (ISC) Year requested: 2018 (CCFA50) Data availability: December 2018 Data provider: Blue California Mr. Hadi Omrani (email address)</p> <p>Cargill Incorporated Ms. Nicole Cuellar-Kingston nicole_cuellar-kingston@cargill.com</p> <p>DSM Food Specialties Ms. Jeanine A. G. van de Wiel Jeanine.Wiel-van-de@DSM.com</p> <p>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>
Tannins (oenological tannins)	<p>Type of request: Data pending – Evaluation by JECFA 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>

Substance(s)	General information	Comments about the request
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 Proposed by: European Union Year requested: 2016 (CCFA48) Data availability: December 2018 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 Proposed by: European Union Year requested: 2015 (CCFA47) Data availability: December 2018 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>
*Xylanase from <i>Talaromyces emersonii</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 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>
Yeast extracts containing mannoproteins	<p>Type of request: Data pending – Evaluation by JECFA 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>
Colours for re-evaluation		

Substance(s)	General information	Comments about the request
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