# CODEX ALIMENTARIUS COMMISSION





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Agenda Item 7

CRD 5

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

**Fifty-First Session** 

Jinan, China, 25-29 March 2019

# Report of the 51<sup>st</sup> CCFA's Physical Working Group on Priorities for Evaluation by JECFA 25 March 2019

#### I. INTRODUCTION

1. The in-session physical working group (WG) was chaired by China with the assistance from JECFA and CODEX Secretariat. New Zealand delegation and CCFA Secretariat served as rapporteurs. The following members and organisations participated: Austria, Australia, Belgium, Brazil, China, Chile, Colombia, Croatia, Denmark, Estonia, European Union, Finland, France, Germany, India, Indonesia, Israel, Italy, Japan, Kazakhstan, Kenya, Netherlands, New Zealand, Nigeria, Norway, Paraguay, Philippines, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Senegal, Singapore, Slovakia, Spain, Switzerland, Tanzania, Thailand, Uganda, United Kingdom, United States of America, AIDGUM, AMFEP, EFEMA, ETA, FIA, IACM, IADSA, ICA, ICBA, ICGA, ICGMA, IDF, IFAC, IFT, IGTC, ILSI, IOFI, ISA, ISDI, NATCOL, OIV.

#### II. ADOPTION OF THE AGENDA

2. The Chair presented the provisional agenda of the physical working group for discussion. The physical working group agreed to proceed with the proposed agenda.

### III. NOTES

- 3. The Chair introduced the terms of reference of this working group as following:
  - 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, in consideration of CX/FA 19/51/13 and matters referred in CX/FA 19/51/2 Add.1; CX/FA 19/51/3; CX/FA 19/51/4; CX/FA 19/51/4 add.1; CX/FA 19/51/4 add.2; CX/FA 19/51/6; CX/FA 19/51/7; and CRDs 6, 17, 29);
  - ii. To consider and prepare recommendations for the Plenary on revisions to Annexes 2 and 4 of the circular letter for Requests for information and comments on the priority list of substances proposed for evaluation by JECFA.
- 4. The Chair noted that the revised format of Priority List in accordance with the conclusions of REP18/FA paragraphs 156 and 160 consisted with two tables. Table 1 is the List of substances used as food additives proposed for evaluation by JECFA, with the ranking system for placement on the Priority List for those food additives intended for inclusion in the GSFA, in order from highest to lowest priority:
  - (1) Re-evaluation of an additive, based on an identified safety concern;
  - (2) Evaluation of a new additive that is intended to be included in the GSFA; and
  - (3) Evaluation of a change to the specifications.
- 5. The Chair noted that Table 2 is the List of substances used as processing aids proposed for evaluation by JECFA, based on the conclusion in REP18/FA that processing aids would be included in the Priority List but not ranked.

6. The Chair explained that the Annex 2 of CL 2018/28-FA in CRD6 amended the circular letter template for the Form for the submission of substances to be evaluated by JECFA. The aim of the changes is (i) to ensure that the available data are directly relevant to the substance of interest in the request, in particular, for substances obtained from natural resources, (ii) to clarify that data shall only be submitted in response to a JECFA call for data, not the Circular Letter.

#### **Recommendation 1**

The In-Session WG recommends that the 51<sup>st</sup> session of the CCFA adopt the *Form for the submission* of substances to be evaluated by JECFA as shown in Annex 1.

7. The Chair explained that the Annex 4 of CL 2018/28-FA in CRD6 confirmed the circular letter template for the Form for confirmation of previous requests and data availability for the substances listed in Priority list. The aim of the template is to acquire only the information indicating if the request is still in effect, and if the data to support the request are currently available.

### **Recommendation 2**

The In-Session WG recommends that the 51<sup>st</sup> session of the CCFA adopt the *Form for the confirmation* of previous requests and data availability as shown in Annex 2.

- 8. The Chair introduced Table 1 of CRD29 substance by substance.
- 9. During the discussion of Table 1, the working group agreed that (i) no support from member countries was necessary for the requests of the evaluation on the substances proposed by JECFA itself, (ii) where data availability of a general request is to be confirmed, the data availability of such request will be revisited during the next session before a proposal is made.
- 10. During the discussion of Table 1, JECFA Secretariat explained that for the evaluation and re-evaluation requests on any substances by JECFA, raw data were required for submission.
- 11. During the discussion of the requests for the evaluation on anionic methacrylate copolymer (AMC) (INS 1207) and neutral methacrylate copolymer (NMC) (INS 1206), the working group agreed to combine both requests as a group request due to the similarity of the substances and the requests on general information.
- 12. During the discussion of flavouring substances/agents listed in Table 1, several member countries and observers proposed that the flavouring substances/agents to be combined as a group request due to the similarity of the functional class and the requests on general information.
- 13. During the discussion of gellan gum (INS 418), the working group noted that JECFA had scheduled the substance for evaluation in its next session.

#### **Recommendation 3**

The In-Session WG recommends that the 51<sup>st</sup> session of the CCFA remove gellan gum (INS 418) from Table 1 the List of substances used as food additives proposed for evaluation by JECFA as shown in Annex 3.

14. The substances L-cysteine hydrochloride (INS 920) and potassium ascorbate (INS 303) were forwarded by the Working Group on Alignment. The Chair noted that both substances needed evaluation by JECFA due to the lack of specifications.

### **Recommendation 4**

The In-Session WG recommends that the 51<sup>st</sup> session of the CCFA include the requests for the evaluations on L-cysteine hydrochloride (INS 920) and potassium ascorbate (INS 303) in Table 1 the List of substances used as food additives proposed for evaluation by JECFA as shown in Annex 3.

15. During the discussion of nisin (INS 234) and natamycin (INS 235), the working group agreed to combine both requests as a group request due to the high similarity of the functional classes of the substances and the requests on general information, as well as the basis of the request.

#### **Recommendation 5**

The In-Session WG recommends that the 51<sup>st</sup> session of the CCFA adpot Table 1 the List of substances used as food additives proposed for evaluation by JECFA as shown in Annex 3.

16. The Chair presented Table 2 of CRD29 as a group request for substances intended to be used as processing aids. Member countries and observers confirmed the requests for the evaluation of the substances at their current status.

### **Recommendation 6**

The In-Session WG recommends that the 51<sup>st</sup> session of the CCFA adopt Table 2 List of substances used as processing aids proposed for evaluation by JECFA as shown in Annex 4.

- Annex 1: Form for the Submission of Substances to be Evaluated by JECFA
- Annex 2: Form for Confirmation of Previous Requests and Data Availability
- Annex 3: Table 1 List of Substances Used as Food Additives Proposed for Evaluation by JECFA
- Annex 4: Table 2 List of Substances Used as Processing Aids Proposed for Evaluation by JECFA

# ANNEX 1 - 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), IUPAC name, C.A.S number (as applicable):
- 3. Names and addresses of basic producers:
- 4. Identification of the manufacturer that will be providing data (Please indicate contact person):
- 5. Justification for use:
- 6. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):
- 7. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))
- 8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.
- 9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.
- 10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries.

11. Please indicate the type of data that are available in the table below.

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

		Data available? (Y/N)
To	xicological data	
(i)	Metabolic and pharmacokinetic studies (please specify)	
(ii)	Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	
(iii)	Epidemiological and/or clinical studies and special considerations (please specify)	
(iv)	Other data (please specify)	
Ted	chnological 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	
Die	etary exposure 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 exposures based on food consumption data for foods in which the substance may be used.	
Otl	ner information: (please specify)	

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

# ANNEX 2 - FORM FOR CONFIRMATION OF PREVIOUS REQUESTS AND DATA AVAILABILITY

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

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

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

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

# ANNEX 3 - TABLE 1 LIST OF SUBSTANCES USED AS FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA

<u>Bold</u> - Changes made to Table 1 in Annex 1 of CRD29 <del>Strike through - Removal of contents in Table 1 in Annex 1 of CRD29</del>

	Substance(s)	General information	Comments about the request	Priority*
1.	Anionic methacrylate	Type of request: Data pending to finalize safety	Basis for request: (see JECFA86 report or	2
	copolymer (AMC) (INS	evaluation	Table 1 of CX/FA 19/51/3)	
	1207)	Proposed by: JECFA	Additional data is required to clarify the in vivo	
		Supported by: N/A	carcinogenic potential of the residual monomer	
		Year requested: 2019 (CCFA51)	methyl acrylate.	
		Data availability: To be confirmed at CCFA51	Possible issues for trade: currently	
		Data provider: To be confirmed at CCFA51	unidentified	
	Neutral methacrylate	Type of request: Data pending – suitable method	Basis for request: (see JECFA86 report or	3
	copolymer (NMC) (INS	of assay	Table 1 of CX/FA 19/51/3)	
	1206)	Proposed by: JECFA	A suitable validated method for its assay is	
		Supported by: N/A	required to remove the tentative status of the	
		Year requested: 2019 (CCFA51)	specifications developed by JECFA.	
		Data availability: To be confirmed at CCFA51	Possible issues for trade: currently	
		Data provider: To be confirmed at CCFA51	unidentified	
2.	Azodicarbonamide (INS	Type of request: safety assessment	Basis for request: The Physical Working	1
	927a)	Proposed by: CCFA 51	Group on Alignment noted the safety concern	
		Year requested: 2019 (CCFA51)	on this food additive and request the re-	
		Data availability: To be confirmed at CCFA52	evaluation of this food additive.	
		Data provider: To be confirmed at CCFA52		
3.	Benzoic acid and its salts	Type of request: Data pending – safety	Basis for request: To confirm ICBA's	1
	(INS 210-212)	assessment	commitment to provide new toxicological	
		Proposed by: CCFA49	evaluation of benzoates. The studies include	
		Year requested: 2018 (CCFA50)	extended one-generational reproductive toxicity	
		Data availability: December 2020	testing (EOGRT Study, OECD 443) and findings	
		Data provider:	relative to benzoate's chemical-specific	
		International Council of Beverages Associations	adjustment factor, default uncertainty factors	
		(ICBA)	and intake assessment assumptions.	
		Ms. Katherine Loatman	Possible issues for trade: Identified: CCFA50	
		(Kate@icba-net.org)	suggested extending the interim level of 250	

	Substance(s)	General information	Comments about the request	Priority*
			ppm (as benzoic acid) for the beverage category 14.1.4 to CCFA53.	
4.	Carob bean gum (INS 410)	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	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.  Possible issues for trade: currently unidentified	1
5.	Citric and fatty acid esters of glycerol (INS 472c)	Type of request: Data pending to designate specifications as FULL Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: Japan and EFEMA	<ul> <li>Basis for request: (see JECFA86 report or Annex 2 of CX/FA 19/51/4)</li> <li>To remove the tentative designation from the specifications, the following information is requested by December 2019:</li> <li>Validated analytical method to replace the obsolete packed column gas chromatographic method for the determination of total citric acid;</li> <li>Validated analytical method that eliminates the use of chloroform for the determination of total glycerol.</li> <li>Amendment to the specification based on the compositions/characteristics of the product commercially available</li> <li>Possible issues for trade: currently unidentified</li> </ul>	2
6.	Dioctyl sodium sulfosuccinate(INS 480)	Type of request: Safety assessment Exposure  assessment Proposed by: CCFA51  Year requested: 2019 (CCFA51)  Data availability: to be confirmed at CCFA52	Basic for request: The Physical Working Group on GSFA discussed exposure to this food additive, some members noted that exposure of a small child could exceed the ADI. One observer noted that they had performed a	1

	Substance(s)	General information	Comments about the request	Priority*
		Data provider: to be confirmed at CCFA52	budget calculation and that the calculation could be made available upon request. The WG agreed to request JECFA review the calculation, to be submitted by the observer, as well as other exposure information that maybe available.	
7.	Flavouring substances (45 new + 1 for re-evaluation + 14 for updates = 60 total)  See Annex 2	Type of request: Safety assessment and establishment of specifications  Proposed by: International Organization of the Flavour Industry (IOFI)  Supported by: the United States of America Year requested: 2019 (CCFA51)  Data availability: December 2019  Data provider: IOFI Sean V. Taylor, Ph.D. (staylor@vertosolutions.net)	Basis for request: Safety assessment or reassessment, and establishment of specifications or revision of specifications, as applicable Possible issues for trade: currently unidentified	Not applicable
	Flavouring agents: (+)Carvone (no. 308.1) and (-)-Carvone (No. 380.2)	Type of request: Data pending to finalize exposure assessment and revise the JECFA specifications Proposed by: JECFA Supported by: Japan Year requested: 2019 (CCFA51) Data availability: April 2019 Data provider: Japan	Basis for request: (see JECFA86 report or Table 2 of CX/FA 19/51/3) Additional data are required to complete the exposure assessment:  (+)-carvone: data on the oral exposure from all sources;  (-)-carvone: data on the oral exposure from all sources and toxicological data.  Possible issues for trade: currently unidentified	
	Flavouring agents:(Ethyl 2-methyl pentanoate (No.214), cis-3-Hexen-1-ol (No.315), d-Carvone (No.380.1), l-Carvone (No.380.2), Menthol (No.427), l-Menthyl	Type of request: to finalize exposure  assessment and revise the JECFA specifications  Proposed by: CCFA 51  Supported by: Japan  Year requested: 2019 (CCFA51)  Data availability: April 2019	Basis for request: (see CX/FA 19/51/4 add.2) Requests reconsideration of the specifications for 16 flavouring agents that considered at the 86th JECFA meeting (listed in either Annex 1 or Annex 2 of CX/FA 19/51/4).,because the reorganization some gaps between the JECFA	

	Substance(s)	General information	Comments about the request	Priority*
	I-lactate (No.433), Myrcene (No.1327), Maltol (No.1480), 2-pentylfuran (No.1491), 3- (2-Furyl)acrolein (No.1497), 3-(5-Methyl-2-furyl)-butanal (No.1500), 2-Furyl methyl ketone (No.1503), 3-Acetyl-2,5-dimethylfuran (No.1506), (2-Furyl)-2-propanone (No.1508), 4-(2-furyl)-3-buten-2-one (No.1511), and Furfuryl methyl ether (No.1520))	Data provider: <u>Japan</u>	specification (some items therein) and the commercially available products for each compound.	
8.	Fulvic acid	Type of request: Safety assessment and establishment of specifications Proposed by: South Africa Supported by: to be added Year requested: 2019 (CCFA51) Data availability: already available Data provider: Fulvimed SA Stefan Coetzee (stefan@fulvimed.co.za)	Basis for request: Carbohydrate-Derived Fulvic Acid (CHD-FA®) is described as a novel, pure, biologically-active organic acids embedded in a supramolecular structure, free from heavy metals and safe for human and animal consumption. CHD-FA® liquid would be a suitable preservative for acidic foods such as jams, salad dressings, fruit and vegetable juices, pickles and carbonated drinks. Fulvate (CHD-FA® powder) would be a suitable preservative in dry products, such as cereals, maize, soup powders and meal replacements. Possible issues for trade: currently unidentified	2
9.	Gellan gum (INS 418) (Pending confirmation of technological justification from CCNFSDU)	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	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	4

	Substance(s)	General information	Comments about the request	Priority*
		Data provider: Abbott Nutrition Mr. Paul Hanlon (paul.hanlon@abbott.com)	keep minerals such as calcium and phosphorus in suspension and prevents physical separation of the product.  Possible issues for trade: currently unidentified	
10.	Jagua (Genipin-Glycine) Blue	Type of request: Data pending to finalize safety evaluation and establishment of specifications – Evaluation by JECFA84 Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: December 2019 Data provider: Colombia	Basis for request: (see JECFA84 report)     Additional biochemical and toxicological data.     Information of characterization of food additive is needed on:	2
11.	Magnesium stearate (INS 470(iii))	Type of request: Amendment of JECFA monograph with regards to method of assay Proposed by: APAG – the European Oleochemicals & Allied Products group, a sector group of CEFIC Supported by: European Union Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: CEFIC -The European Chemical Industry Council Sofia Serafim (sse@cefic.be)	Basis for request: The method of assay for magnesium (an ICP-AES technique) referred to in the monograph for INS 470(iii), prepared by JECFA80, is considered inappropriate for determination of magnesium content and should be replaced by the titration method reported in the Food Chemical Codex monograph or other pharmacopoeia monographs.  Possible issues for trade: currently unidentified	3
12.	Natamycin (INS 235)	Type of request: Re-evaluation of safety and revision of specifications Proposed by: Russian Federation Year requested: 2017 (CCFA49)	Basis for request: The appropriateness of retaining natamycin in the GSFA should be reevaluated, due to to emerging data on natamycin's role in: (i) promoting antimicrobial	1

Substance(s)	General information	Comments about the request	Priority*
	Data availability: December 2018	resistance, as well as speeding up virulence	
	Data provider:	and pathogenic potential of food-borne human	
	Russian Federation Codex Contact Point	pathogens; and (ii) unbalancing the immunity	
	(codex@gsen.ru)	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.	
		Possible issues for trade: currently	
		unidentified	
Nisin (INS 234)	Type of request: Re-evaluation of safety and	Basis for request: The appropriateness of	
	revision of specifications	retaining nisin in the GSFA should be re-	
	Proposed by: Russian Federation	evaluated, due to to emerging data on nisin role	
	Year requested: 2017 (CCFA49)	in: (i) promoting antimicrobial resistance, as well	
	Data availability: December 2018	as speeding up virulence and pathogenic	
	Data provider:	potential of food-borne human pathogens; and	
	Russian Federation Codex Contact Point	(ii) unbalancing the immunity and other bodily	
	(codex@gsen.ru)	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	

	Substance(s)	General information	Comments about the request	Priority*
			important in maintaining product shelf-life and ensuring food safety.  Possible issues for trade: currently unidentified	
13.	Neutral methacrylate copolymer (NMC) (INS 1206)	Type of request: Data pending — suitable method of assay Proposed by: JECFA Supported by: to be added Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA51 Data provider: To be confirmed at CCFA51	Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3) A suitable validated method for its assay is required to remove the tentative status of the specifications developed by JECFA. Possible issues for trade: currently unidentified	2
14.	Nisin (INS 234)	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@gsen.ru)	Basis for request: The appropriateness of retaining nisin in the GSFA should be reevaluated, 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.  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.  Possible issues for trade: currently unidentified	1

	Substance(s)	General information	Comments about the request	Priority*
15.	ortho-Phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232)	Type of request: Re-evaluation of ADI Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA51CCFA52 Data provider: To be confirmed at CCFA51CCFA52	Basis for request: (see Appendix 1 of CX/FA 19/51/2 Add. 1) Analysis of all group food additives in the GSFA: The Codex Secretariat, in consultation with the JECFA Secretariats, undertake a review of all group food additives in the GSFA and prepare a more comprehensive document for consideration at CCFA51 including proposals on how to deal with the issue. It was noted that a re-evaluation of INS 231 and INS 232 may be needed as some studies indicate that the salt might be more toxic for human health than previously estimated.  Possible issues for trade: currently unidentified	1
16.	Polyglycerol esters of fatty acids(INS 475)	Type of request: The completeness of the information for safety assessment Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA52 Data provider: to be confirmed at CCFA52	Basic for request:  The Physical Working Group on GSFA of CCFA 51 noted that there may be new information available which could raise the ADI of this food additive, request for eventual re-evaluation and a potential increase in the ADI.	4 <u>.3</u>
17.	Polyvinyl alcohol (INS 1203)	Type of request: Amendment of JECFA monograph Revise JECFA specification with regards to solubility of polyvinyl alcohol Proposed by: European Union Supported by: IFAC Year requested: 2019 (CCFA51) Data availability: already available Data provider: Ales Bartl Tel: 0032 2 645 1452 (abartl@jonesday.com)	Basis for request: This is to request a change of the JECFA monograph with regards to the solubility of polyvinyl alcohol (PVOH) in ethanol from "sparingly soluble in ethanol" to "practically insoluble or insoluble in ethanol".  In 2011, a solubility testing for PVOH was carried out by Nippon and the test results were interpreted as PVOH being "practically insoluble or insoluble in ethanol".  Possible issues for trade: currently unidentified	3

	Substance(s)	General information	Comments about the request	Priority*
18.	Riboflavin from <i>Ashbya</i> gossypii	Type of request: Safety assessment and establishment of specifications Proposed by: EU Specialty Food Ingredients Supported by: European Union Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: BASF SE Nicola Leinwetter (nicola.leinwetter@basf.com)	Basis for request: Alternative source of riboflavin for colouring purposes and as nutrient source Possible issues for trade: currently unidentified	2
19.	Sorbitan monostearate (INS 491); Sorbitan tristearate (INS 492); Sorbitan monopalmitate (INS 495)	Type of request: Revision of specifications with regards to the congealing range identification method  Proposed by: European Food Emulsifier Manufacturers' Association (EFEMA)  Supported by: European Union  Year requested: 2019 (CCFA51)  Data availability: Immediately  Data provider:  EFEMA  Caroline Rey (efema@ecco-eu.com)	Basis for request: The congealing range identification method as reported in the JECFA monographs for INS 491, 492 and 495 is obsolete, difficult to work with due to poor reproducibility, and irrelevant. This identification parameter should be replaced by the identification test "acid value, iodine value, gas chromatography".  Possible issues for trade: currently unidentified	3
20.	Spirulina extract (INS 134)	Type of request: Data pending – analytical data Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: IACM	Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3) JECFA86 received limited analytical data on spirulina extract. To remove the tentative designation from the specifications, the following information on the products of commerce is requested by December 2019:  • Full compositional characterization of commercial products in both liquid and powder forms.	2

	Substance(s)	General information	Comments about the request	Priority*
			<ul> <li>Full compositional characterization of the aqueous extract before formulation/standardization.</li> <li>Validated analytical methods for identification of the substance with a suitable specificity (including validation data and representative batch data).</li> <li>Validated analytical methods for the determination of the purity of the substance with a suitable specificity (including validation data and representative batch data).</li> </ul>	
			Possible issues for trade: currently unidentified	
21.	Sucroglycerides(INS 474)	Type of request: safety evaluation exposure	Basis for request: During the discussion on the	1
		assessment	use of this food additive in FC 05.1.4, one	
		Proposed by: CCFA 51	member country concern that the proposed use	
		Year requested: 2019 (CCFA51)	would result in exposures which exceed the	
		Data availability: To be confirmed at CCFA52  Data provider: To be confirmed at CCFA52	ADI, the physical Working Group on GSFA of	
22.	Sucrose esters of fatty	Type of request: safety evaluation exposure	CCFA51 to request for exposure assessment.  Basis for request: During the discussion on the	1
22.	acids(INS 473)	assessment	use of this food additive in FC 05.1.4, one	'
	acius(1145 475)	Proposed by: CCFA 51	member country concern that the proposed use	
		Year requested: 2019 (CCFA51)	would result in exposures which exceed the	
		Data availability: December 2019	ADI, the physical Working Group on GSFA of	
		Data provider: <u>Japan</u>	CCFA51 to request for exposure assessment.	
23.	Sucrose oligoesters ,type I	Type of request: safety evaluation exposure	Basis for request: During the discussion on the	1
	and type II (INS 473a)	assessment	use of this food additive in FC 05.1.4, one	·
		Proposed by: CCFA 51	member country concern that the proposed use	
		Year requested: 2019 (CCFA51)	would result in exposures which exceed the	
		Data availability: <u>December 2019</u>	ADI, the physical Working Group on GSFA of	
		Data provider: Japan	CCFA51 to request for exposure assessment.	

	Substance(s)	General information	Comments about the request	Priority*
24.	Tannins (oenological tannins)	Type of request: Data pending to complete evaluation – Evaluation by JECFA84 Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed by CCFA51 at CCFA52 Data provider: To be confirmed by CCFA51 at CCFA52	<ul> <li>Basis for request: In order to complete its evaluation, JECFA requires information on:</li> <li>The following information is required: <ul> <li>Composition of tannins derived from the full range of raw materials as well as the processes used in their manufacture;</li> <li>Validated analytical method(s) and relevant quality control data;</li> <li>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);</li> <li>Solubility of the products in commerce, according to JECFA terminology; and</li> <li>Use levels, natural occurrence and food products in which tannins are used.</li> </ul> </li> <li>Possible issues for trade: currently unidentified</li> </ul>	2
25.	L-cysteine hydrochloride (INS 920)	Type of request: Establishment of specifications Proposed by: CCFA51 Supported by: to be confirmed Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA52 Data provider: to be confirmed at CCFA52	Basis for request: (see CX/FA 19/51/6) It notes that two food additives, listed as flour treatment agents in CXS 152-1985 have not been added to the GSFA provisions as part of the alignment work. These are L- cysteine hydrochloride (INS 920) and potassium ascorbate (INS 303). It agrees that both cannot be added to the GSFA since they do not have a JECFA specification.  Possible issues for trade: currently unidentified	<u>3</u>

303) specifications It notes that two food additives, listed as Froposed by: CCFA51 flour treatment agents in CXS 152-1985 have		Substance(s)	General information	Comments about the request	Priority*
Year requested: 2019 (CCFA51)  Data availability: to be confirmed at CCFA52  Data provider: to be confirmed at CCF	26.	Potassium ascorbate (INS	specifications Proposed by: CCFA51 Supported by: to be confirmed Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA52	Basis for request: (see CX/FA 19/51/6) It notes that two food additives, listed as flour treatment agents in CXS 152-1985 have not been added to the GSFA provisions as part of the alignment work. These are L-cysteine hydrochloride (INS 920) and potassium ascorbate (INS 303). It agrees that both cannot be added to the GSFA since they do not have a JECFA specification.  Possible issues for trade: currently	3

# Priority list of 46 flavours proposed for inclusion on the JECFA Priority List to be considered at the 51st session of the Codex Committee on Food Additives

CCFA Listing History	FEM A No	JECFA No	CAS	Principle Name	Group No	TRS No
SIMPLE ALIPHATIC AND AROMA		ATIC AND AROM	ATIC SULFIDES AND THIOLS	J20	TRS 896 TRS 922 TRS 947 TRS 960 TRS 974	
Submitted at CCFA51	4730		1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate		
Submitted at CCFA51	4733		1006684-20-3	(±)-2-Mercaptoheptan-4-ol		
Submitted at CCFA51	4734		1256932-15-6	3-(Methylthio)-decanal		
Submitted at CCFA51	4760		53626-94-1	Prenyl thioisobutyrate		
Submitted at CCFA51	4761		75631-91-3	Prenyl thioisovalerate		
Submitted at CCFA51	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone		
Submitted at CCFA51	4779		1416051-88-1	(±)-2-Mercapto-5-methylheptan-4-one		
Submitted at CCFA51 4782 1679-06-7; 1633-90-5		· ·	2(3)-Hexanethiol			
Submitted at CCFA51	4791	_	22236-44-8	3-(Acetylthio)hexanal		
Submitted at CCFA51	4792		548740-99-4	(±)-3-Mercapto-1-pentanol		
Submitted at CCFA51	4817	_	38634-59-2	S-[(methylthio)methyl]thioacetate		
Submitted at CCFA51	4822		61407-00-9	2,6-Dipropyl-5,6-dihydro-2 <i>H</i> -thiopyran-3-carboxaldehyde		

CCFA Listing History	FEM A No	JECFA No	CAS	Principle Name	Group No	TRS No
Submitted at CCFA51	4823		33368-82-0	1-Propenyl 2-propenyl disulfide		
Submitted at CCFA51	4824		1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate		
Submitted at CCFA51	4828		729602-98-6	1,1-Propanedithioacetate		
Submitted at CCFA51	4836		137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol		
Submitted at CCFA51	4842		911212-28-7	2,4,5-Trithiaoctane		
Submitted at CCFA51	4843		1838169-65-5	3-(Allyldithio) butan-2-one		
Submitted at CCFA51	4870		17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane		
	PHEN	OL AND P	HENOL DERIVA	TIVES	J24	TRS 901 TRS 960 TRS 974
Submitted at CCFA51	4228		462631-45-4	(-)-Homoeriodictyol, sodium salt		
Submitted at CCFA51	4797		480-41-1	(±)-Naringenin		
Submitted at CCFA51	4799		1449417-52-0	(2R)-3',5-Dihydroxy-4'-methoxyflavanone		
Submitted at CCFA51	4830		38183-03-8	7,8-Dihydroxyflavone		
Submitted at CCFA51	4833		87733-81-1	(2S)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan		
Submitted at CCFA51	4834		1796034-68-2	(R)-5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7- methylchroman-2-one		
Submitted at CCFA51	4872		35400-60-3	3-(3-Hydroxy-4-methoxy-phenyl)-1-(2,4,6-trihydroxyphenyl)propan-1-one		
	HYDR	OXY- AND	ALKOXY-SUBS	STITUTED BENZYL DERIVATIVES	J29	TRS 909 TRS 952
Submitted at CCFA51	4430		99-50-3	3,4-Dihydroxybenzoic acid		
Submitted at CCFA51	4431		99-06-9	3-Hydroxybenzoic acid		
Submitted at CCFA51	4435		673-22-3	2-Hydroxy-4-methoxybenzaldehyde		
Submitted at CCFA51	4606		930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate		
Submitted at CCFA51	4622		61683-99-6	Piperonal propyleneglycol acetal		
Submitted at CCFA51	4627		6414-32-0	Anisaldehyde propyleneglycol acetal		
Submitted at CCFA51	4700		614-60-8	o-trans-Coumaric acid		
Submitted at CCFA51	4750		65405-77-8	cis-3-Hexenyl salicylate		
Submitted at CCFA51	4810		60563-13-5	Ethyl-2-(4-hydroxy-3-methoxy-phenyl)acetate		
Submitted at CCFA51	4826		10525-99-8	3-Phenylpropyl 2-(4-hydroxy-3-methoxy-phenyl)acetate		
Submitted at CCFA51	4871		1962956-83-7	2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate		
ALICYCLIC KETONES, SECONDARY ALCOHOLS AND RELATED ESTERS		J36	TRS 913 TRS 960			
Submitted at CCFA51	4724		21862-63-5	trans-4-tert-Butylcyclohexanol		
Submitted at CCFA51	4780		38284-26-3	Caryophylla-3(4),8-dien-5-ol		

CCFA Listing History	FEM A No	JECFA No	CAS	Principle Name	Group No	TRS No
	AMINO ACIDS AND RELATED SUBSTANCES				J49	TRS 928 TRS 974
Submitted at CCFA51	4223		107-43-7	Betaine		
Submitted at CCFA51	4738		16869-42-4	Glutamyl-2-aminobutyric acid		
Submitted at CCFA51	4739		38837-71-7	Glutamyl-norvalyl-glycine		
Submitted at CCFA51	4740		71133-09-0	Glutamyl-norvaline		
Submitted at CCFA51	4752		1188-37-0	N-Acetyl glutamate		
Submitted at CCFA51	4781		18598-63-5	L-Cysteine methyl ester hydrochloride		

CCFA Listing	FEMA	JECFA	CAS	Principle Name	Grou	TRS
History	No	No			p No	No
	ALICYC EVALUA		ARY ALCOHOLS	, ALDEHYDES, ACIDS AND RELATED ESTERS (RE-	J32	TRS 913 TRS 960 TRS 1009
Old	3557	973	2111-75-3	p-Mentha-1,8-dien-7-al (Perillaldehyde)		

# Priority list of 14 compounds proposed for specifications modification by JECFA Priority List to be considered at the 51st session of the Codex Committee on Food Additives

History	FEMA No	JECFA No	CAS	Principle Name	Most recent Specification Evaluation	Status	Update
Old	4050	2002	774-64-1	3,4-Dimethyl-5-pentylidene- 2(5H)-furanone	73 <sup>rd</sup> JECFA	Full	Secondary components
Old	4085	1575	1139-30-6	<i>beta</i> -Caryophyllene oxide	65 <sup>th</sup> JECFA	Full	Updated isomeric composition
Old	4249	1604	99583-29-6	2-Acetylpyrroline	65 <sup>th</sup> JECFA	II-1111	Updated assay value, CAS number and secondary components
Old	4668	171177	504-48-3; 25394-57-4	(2E,6E/Z,8E)-N-(2- Methylpropyl)-2,6,8- decatrienamide	76 <sup>th</sup> JECFA	Full	Updated isomeric mixture

Old	3352	1125	2497-21-4	4-Hexen-3-one	59 <sup>th</sup> JECFA	11-1111	Updated assay value and isomeric composition
Old	2249	380.1	2244-16-8	d-Carvone	86th JECFA	Tentative	Updated refractive index
Old	3317	1491	3777-69-3	2-Pentylfuran	86 <sup>th</sup> JECFA	IF UII	Updated specific gravity range and assay value
Old	2494	1497	623-30-3	3-(2-Furyl)acrolein	86th JECFA	Full	Updated melting point range
Old	3586	1502	65545-81-5	2-Phenyl-3-(2-furyl)prop-2-enal	86 <sup>th</sup> JECFA		UpddatedAssay value and physical and odor descriptions
Old	3609	1504	1193-79-9	2-Acetyl-5-methylfuran	86 <sup>th</sup> JECFA	II-1111	Updated Physical appearance description; specific gravity
Old	3391	1506	10599-70-9	3-Acetyl-2,5-dimethylfuran	86th JECFA		Updated Specific gravity range
Old	2495	1511	623-15-4	4-(2-Furyl)-3-buten-2-one	86 <sup>th</sup> JECFA		Updated Physical appearance and melting point range
Old	2435	1513	10031-90-0	Ethyl 3-(2-furyl)propanoate	86 <sup>th</sup> JECFA		Updated Physical form, refractive index and specific gravity
Old	2865	1517	7149-32-8	Phenethyl 2-furoate	86 <sup>th</sup> JECFA		Updated Refractive index and specific gravity ranges; physical appearance

Annex 4 - TABLE 2 LIST OF SUBSTANCES USED AS PROCESSING AIDS PROPOSED FOR EVALUATION BY JECFA

No	Substance(s)	General information	Comments about the request
1.	5'-Deaminase from Streptomyces murinus	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)	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.  Possible issues for trade: currently unidentified
2.	Acid prolyl endopeptidase from Aspergillus niger expressing a gene from Aspergillus niger	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)	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.  Possible issues for trade: currently unidentified
3.	Adenosine-5'- monophosphate deaminase from Aspergillus oryzae	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)	Basis for request: AMP deaminase from Aspergillus oryzae 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.  Possible issues for trade: currently unidentified
4.	D-Allulose 3-epimerase from <i>Arthrobacter</i> globiformis expressed in Escherichi coli	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)	Basis for request: The enzyme is used in the production of D-allulose or ketose sugars from D-fructose.  Possible issues for trade: currently unidentified NOTE: Confirmation of data was provided in response to CL 2018/28-FA.

No	Substance(s)	General information	Comments about the request
5.	Alpha-amylase from Bacillus licheniformis expressing a modified alpha-amylase gene from Geobacillus stearothermophilus	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 Ms. Lisa Jensen (lisa.jensen@dupont.com)	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.  Possible issues for trade: currently unidentified
6.	Alpha-amylase from Bacillus stearothermophilus expressed in Bacillus licheniformis	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)	Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  Possible issues for trade: currently unidentified
7.	Alpha-amylase from Rhizomucor pusillus expressed in Aspergillus niger	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)	Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  Possible issues for trade: currently unidentified
8.	Amyloglucosidase from Talaromyces emersonii expressed in Aspergillus niger	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)	Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  Possible issues for trade: currently unidentified

No	Substance(s)	General information	Comments about the request
9.	Asparaginase from Aspergillus niger expressing a modified gene from Aspergillus niger	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)	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. Possible issues for trade: currently unidentified
10.	Asparaginase from Pyrococcus furiosus expressed in Bacillus subtilis	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)	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.  Possible issues for trade: currently unidentified
11.	Beta-amylase from Bacillus flexus expressed in Bacillus licheniformis	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)	Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  Possible issues for trade: currently unidentified
12.	Beta-glucanase from Streptomyces violaceoruber expressed in S. violaceoruber	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)	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

No	Substance(s)	General information	Comments about the request
13.	Collagenase from Streptomyces violaceoruber expressed in S. violaceoruber	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)	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
14.	Endo-1,4-ß-xylanase from <i>Bacillus subtilis</i> produced by <i>B. subtilis</i> LMG S-28356	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)	Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking.  Possible issues for trade: currently unidentified
15.	Endo-1,4-ß-xylanase from <i>Pseudoalteromonas</i> haloplanktis produced by <i>B. subtilis</i> , strain LMG S- 24584	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)	Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking.  Possible issues for trade: currently unidentified
16.	Endo-1,4-ß-xylanase from <i>Thermotoga</i> <i>maritima</i> produced by <i>B.</i> <i>subtilis</i> , strain LMG S- 27588	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)	Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking.  Possible issues for trade: currently unidentified

No	Substance(s)	General information	Comments about the request
17.	Glucose oxidase from Penicillium chrysogenum expressed in Aspergillus niger	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)	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
18.	Inulinase from Aspergillus ficuum produced by Aspergillus oryzae, strain MUCL 44346	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)	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
19.	Lactase from Bifidobacterium bifidum expressed in Bacillus licheniformis	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)	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
20.	Lipase from Aspergillus oryzae expressing a modified gene from Thermomyces lanuginosus	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)	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.  Possible issues for trade: currently unidentified

No	Substance(s)	General information	Comments about the request
21.	Lipase from <i>Mucor</i> javanicus	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)	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.  Possible issues for trade: currently unidentified
22.	Phosphatidyl inositol- specific phospholipase C from a genetically modified strain of Pseudomonas fluorescens	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. Mariella Kuilman (mariella.kuilman@dsm.com)	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.  Possible issues for trade: currently unidentified
23.	Phosphodiesterase from Penicillium citrinum	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)	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
24.	Phospholipase A2 from pig pancreas expressed in Aspergillus niger	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)	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

No	Substance(s)	General information	Comments about the request
25.	Phospholipase A2 from Streptomyces violaceoruber expressed in S. violaceoruber	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)	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
26.	Protease Aqualysin 1 from <i>Thermus aquaticus</i> produced by <i>B. subtilis</i> , strain LMGS 25520	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)	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:  - Faster dough development upon mixing;  - Better dough machinability;  - Reduced dough rigidness;  - 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  Possible issues for trade: currently unidentified
27.	Transglucosidase/alpha-glucosidase from Trichoderma reesei expressing an Alpha-glucosidase gene from Aspergillus niger	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)	Basis for request: The food enzyme catalyzes both hydrolytic and transfer reactions on incubation with α-D-gluco-oligosaccharides. In molasses, nonfermentable 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.  Possible issues for trade: currently unidentified

No	Substance(s)	General information	Comments about the request
28.	Xylanase from Bacillus licheniformis expressed in B. licheniformis	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)	Basis for request: The enzyme catalyzes the endohydrolysis 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.  Possible issues for trade: currently unidentified
29.	Xylanase from Talaromyces emersonii expressed in Aspergillus niger	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)	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.  Possible issues for trade: currently unidentified