



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

FROM: Secretariat, Joint FAO/WHO Food Standards Programme,
Codex Alimentarius Commission,
Viale delle Terme di Caracalla,
00153 Rome, Italy

SUBJECT: Request for information and comments on the priority list of substances proposed for
evaluation by JECFA

DEADLINE: 15 January 2023

COMMENTS: **To:** Secretariat
Codex Committee on Food Additives
China National Center for Food Safety Risk
Assessment (CFSA),
Building 2, No. 37 Guangqu Road, Chaoyang
District, Beijing 100022, China, E-mail:
ccfa@cfsa.net.cn

Copies to: Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards
Programme
Viale delle Terme di Caracalla
00153 Rome, Italy
E-mail: codex@fao.org

REQUEST FOR INFORMATION AND COMMENTS

1. Members and Observers are invited to: i) provide comments on substances already included in the priority list of substances proposed for evaluation by JECFA, ii) submit information on new substances for inclusion in the priority list; and/or iii) confirm previous requests and data availability.
2. Information and comments should be submitted on the basis of the following attached Annexes to this Circular Letter:
 - 2.1 For submitting information on new substances, refer to:
 - Annex 1** - Criteria for the inclusion of substances in the priority list;
 - Annex 2** - Form for the submission of substances to be evaluated by JECFA.
 - 2.2 For information of the priority list, to which comments may be made, refer to:
 - Annex 3** - Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up;
 - 2.3 To confirm previous requests, refer to:
 - Annex 4** - Confirmation of previous requests and data availability.
3. Information and comments, submitted in response to this Circular Letter, will be considered at the 53rd Session of the Codex Committee on Food Additives.

CRITERIA FOR THE INCLUSION OF SUBSTANCES IN THE PRIORITY LIST

(Codex Procedural Manual – *Risk Analysis Principles applied by the Codex Committee on Food Additives*)

The Codex Committee on Food Additives (CCFA) shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCFA's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e. magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations.

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Substance(s):	
Question(s) to be answered by JECFA <i>(Provide a brief justification of the request in case of re-evaluations)</i>	

1. Proposal for inclusion submitted by:
2. Name of substance; trade name(s); chemical name(s), 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)
Toxicological 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)	
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	
Dietary 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.	
Other information: (please specify)	

12. 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 3

(Appendix XI of REP21/FA)

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

TABLE 1 LIST OF SUBSTANCES USED AS FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA

No.	Substance(s)	General information	Comments about the request	Priority*
1.	Anionic methacrylate copolymer (AMC) (INS 1207)	<p>Type of request: Data pending to finalize safety evaluation Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3) Additional data is required to clarify the <i>in vivo</i> carcinogenic potential of the residual monomer methyl acrylate. Possible issues for trade: currently unidentified</p>	2
	Neutral methacrylate copolymer (NMC) (INS 1206)	<p>Type of request: Data pending – suitable method of assay Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>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</p>	3
2.	Aspartame (INS 951)	<p>Type of request: Re-evaluation of safety Proposed by: ICBA Supported by: Colombia; Costa Rica; United States of America Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: <i>Dietary Intake Assessment</i> Exponent Nga Tran, Dr.P.H., M.P.H. ntran@exponent.com Intertek Scientific & Regulatory Consultancy Danika Martyn, Ph.D. Danika.martyn@intertek.com <i>Systematic Assessment of Mechanistic Data in context of overall carcinogenicity assessment</i></p>	<p>Basis for request: The request for re-evaluation is supported by the following:</p> <ol style="list-style-type: none"> i. Refined intake assessments reflective of actual uses weighted according to market volume data to ensure quantitative representativeness for corresponding beverage types. ii. A systematic assessment of all available mechanistic data in the context of an overall carcinogenicity assessment for aspartame. <p>The re-evaluation of this substance is subject to the advice from JECFA on sweeteners and colours, as described for INS 950, 954(i)-(iv), 123, and 160b(ii).</p> <p>Possible issues for trade: currently unidentified</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
		<p>ToxStrategies, Inc. Daniele Wikoff, Ph.D. dwikoff@toxstrategies.com</p> <p>ICBA, Maia Jack, Ph.D., mjack@americanbeverage.org</p>		
	<p>Acesulfame potassium (INS 950), Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), Annatto extracts, norbixin based (INS 160b(ii))</p>	<p>Type of request: Re-evaluation of exposure Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: Not applicable Data provider: ICBA, Maia Jack, Ph.D., mjack@americanbeverage.org</p>	<p>Basis for request: Based on CRD2, Recommendation 27, the JECFA has been asked the following questions:</p> <p>The VWG on the GSFA requests that the WG on the JECFA Priority List to CCFA52 consider inclusion of the following request into the Priority List of Substances proposed for evaluation by JECFA:</p> <p>Part 1: CCFA requests JECFA to comment on and discuss the following questions regarding the refined Budget Method and tiered-intake assessment approach presented by ICBA:</p> <p>a. Is the approach proposed by ICBA scientifically sound? How conservative is the dietary exposure assessment presented when applied to the sweeteners Acesulfame potassium (INS 950), Saccharins (INS 954(i)-(iv)), and the colours Amaranth (INS 123) and Annatto extracts, norbixin based (INS 160b(ii))?</p> <p>b. How appropriate is it to apply multiple refinement parameters (such as market share, the percentage of products containing the substance, etc.) into a Budget Method calculation?</p> <p>c. Are there any limitations, uncertainties, and applicability of the approach proposed by ICBA that CCFA should be made aware of?</p> <p>d. Is the approach presented by ICBA suitable for determining dietary exposure to colors and sweeteners in non-milk beverages for the purpose of comparing against the JECFA ADI to determine if a proposed maximum use level is safe?</p> <p>e. Is it appropriate for CCFA to use dietary exposure estimates provided for non-milk beverages from the refined Budget Method and the tiered-intake assessments as presented by ICBA to determine maximum use levels for sweeteners in GSFA Food Category 14.1.4 and 14.1.5, and colors in GSFA Food Category 14.1.4, to determine that the exposure would be below the established JECFA ADI?</p> <p>Part 2: CCFA requests that JECFA perform a dietary exposure estimate for Acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5, and Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), and Annatto norbixin, based (INS 160b(ii)) in food category 14.1.4 to verify whether the</p>	

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>max use levels under consideration do not result in an exceedance of the ADI in the context of overall exposure from all uses of the additive in the diet. While in general, lower levels of the food additives will be used, the proposed maximum levels are 600 mg/kg for Acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5 and 300 mg/kg ("on a sodium saccharin basis") for Saccharins (INS 954(i)-(iv)), 100 mg/kg for Amaranth (INS 123) and 50 mg/kg ("on a norbixin basis") for Annatto norbixin, based (INS 160b(ii)) in food category 14.1.4. A proposal has been made to reduce the use levels for Saccharins (INS 954(i)-(iv)) to 230 mg/kg, Amaranth (INS 123) to 50 mg/kg and Annatto, norbixin based (INS 160b(ii)) to 30 mg/kg as norbixin in food category 14.1.4. Any comments from JECFA on the safety of these maximum use levels would be helpful.</p> <p>Possible issues for trade: currently unidentified</p>	
3.	Azodicarbonamide (INS 927a)	<p>Type of request: safety assessment and establishment of specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>Basis for request: The Physical Working Group on Alignment noted the safety concern on this food additive and request the re-evaluation of this food additive.</p>	1
4.	Bentonite (INS 558)	<p>Type of request: Establishment of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53</p>	<p>Basis for request: In view of the <i>Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004)</i>, the CCCF14 recommended that the JECFA:</p> <ul style="list-style-type: none"> i. review the lead specifications for diatomaceous earth and activated carbon and ii. evaluate available data to support development of a lead specification for bentonite. <p>(Note: also captured under item 11 of Table 2 below, as it is used in fruit juice as a processing aid during clarification)</p> <p>Possible issues for trade: currently unidentified</p>	3
5.	Black carrot extract (INS 163(vi))	<p>Type of request: Data pending – characterization and toxicological information Proposed by: JECFA Year requested: 2021 (CCFA52)</p>	<p>Basis for request: JECFA prepared tentative specifications for black carrot extract as the powder form, at its 87th meeting. However, JECFA could not conclude on its safety or</p>	2

No.	Substance(s)	General information	Comments about the request	Priority*
		Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53	establish specifications. Additional characterization and toxicological data are required, namely: <ul style="list-style-type: none"> i. data regarding full characterization of the protein, carbohydrate, lipid, fibre, mineral and non-anthocyanin polyphenol components in five lots each of the liquid and powder forms of black carrot extract; and ii. at least a 90-day toxicological study on a well-characterized extract representative of the material in commerce. Possible issues for trade: currently unidentified	
6.	Butterfly Pea Flower Extract	Type of request: Safety assessment and establishment of specifications Proposed by: IACM Supported by: Canada Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: IACM Sarah Codrea scodrea@iacmcolor.org Sensient Colors LLC Sue Ann McAvoy Sueann.macavoy@sensient.com	Basis for request: Safety assessment and establishment of specifications for use as a colour. Possible issues for trade: currently unidentified	2
7.	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
8.	L-cysteine hydrochloride (INS 920)	Type of request: safety evaluation and establishment of specifications	Basis for request: (see CX/FA 19/51/6) It notes that two food additives, listed as flour	3

No.	Substance(s)	General information	Comments about the request	Priority*
		Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53	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	
9.	Dioctyl sodium sulfosuccinate (INS 480)	Type of request: Exposure assessment Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53	Basis 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 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.	1
10.	Flavouring substances (129 for safety evaluations + 29 for specifications updates = 158 total)	Type of request: Safety assessment and establishment of specifications Proposed by: International Organization of the Flavour Industry (IOFI) Supported by: United States of America Year requested: 2019 to 2021 (CCFA51, CCFA52) Data availability: December 2021 Data provider: IOFI Sean V. Taylor, Ph.D. staylor@vertosolutions.net	Basis for request: Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable <i>Refer to tables of flavourings directly following Table 1</i> Possible issues for trade: currently unidentified	Not applicable
	Flavouring agents: (+)Carvone (no. 380.1) and (-)-Carvone (No. 380.2)	Type of request: Data pending to finalize exposure assessment and revise the JECFA specifications Proposed by: JECFA Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: Japan and IOFI codex@mext.go.jp Sean V. Taylor, Ph.D. staylor@vertosolutions.net	Basis for request: (see JECFA86 report or Table 2 of CX/FA 19/51/3) Additional data are required to complete the exposure assessment: <ul style="list-style-type: none"> (+)-carvone: data on the oral exposure from all sources; 	

No.	Substance(s)	General information	Comments about the request	Priority*
	Flavouring agents:(Ethyl 2-methyl pentanoate (No.214), cis-3-Hexen-1-ol (No.315), Menthol (No.427), l-Menthyl l-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))	<p>Type of request: revise the JECFA specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: April 2019 Data provider: Japan and IOFI codex@mext.go.jp</p> <p>Sean V. Taylor, Ph.D. staylor@vertosolutions.net</p>	<ul style="list-style-type: none"> (-)-carvone: data on the oral exposure from all sources and toxicological data. <p>Possible issues for trade: currently unidentified</p> <p>Basis for request: (see CX/FA 19/51/4 add.2) Requests reconsideration of the specifications for 16 flavouring agents that were considered at the 86th JECFA meeting (listed in either Annex 1 or Annex 2 of CX/FA 19/51/4) due to introduced gaps between the JECFA specification (some items therein) and the commercially available products for each compound.</p>	
11.	Fulvic acid (carbohydrate derived)	<p>Type of request: Data pending – (1) toxicological data required; and (2) data on manufacturing processes and chemical characterization of the products in commerce Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>Basis for request: The 89th meeting of JECFA concluded that the toxicological information provided were inadequate to complete the safety evaluation, and that the chemical and technical information were insufficient to prepare specifications. The JECFA requests that additional data be provided.</p> <p>The toxicological data required include:</p> <ol style="list-style-type: none"> Absorption, distribution, metabolism and excretion; repeated-dose 90-day oral toxicity in rodents; two-generation reproductive toxicity or extended one-generation reproductive toxicity; prenatal developmental toxicity; additional studies, including an in vitro micronucleus test in mammalian cells, might be required, depending on elucidation of the 	2

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>article(s) of commerce and the provision of full information on their composition; vi. information on the potential of the material to induce antimicrobial resistance; and, vii. Levels of use should be provided for estimating dietary exposure.</p> <p>The characterization data required include:</p> <ul style="list-style-type: none"> i. Data on manufacturing processes; and, ii. Chemical characterization of the article(s) of commerce. <p>Possible issues for trade: currently unidentified</p>	
12.	Fungal amylase from <i>Aspergillus niger</i>	<p>Type of request: safety assessment and establishment of specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>Basis for request: During the discussions on the alignment of the food-additive provision in CXS 152-1985 with the relevant provisions of the GSFA, CCFA51 agreed to include the substance as flour treatment agent to the list.</p>	2
13.	Gellan gum (INS 418)	<p>Type of request: Data pending – data characterizing the three forms of gellan gum used in commerce. Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: EU Specialty Food Ingredients</p>	<p>Basis for request: JECFA developed tentative specifications and ADI at its 87th meeting; however, characterization data are required to finalize the specifications. JECFA is requesting the additional data be available by December 2021.</p> <p>The information must address:</p> <ul style="list-style-type: none"> i. a method to differentiate the three commercial forms of gellan gum ii. a method to determine the degree of acylation iii. validation data for the above methods, including detailed description of the sample preparation iv. data from five non-consecutive commercial batches of material using the proposed validated methods for all three forms of gellan gum. 	3

No.	Substance(s)	General information	Comments about the request	Priority*
14.	Lycopene (synthetic, INS 160d(i)); and from <i>Blakeslea trispora</i> , INS 160d(iii))	<p>Type of request: Revision of JECFA specifications with regard to the parameter “solubility”</p> <p>Proposed by: EU Specialty Food Ingredients</p> <p>Supported by: United Kingdom</p> <p>Year requested: 2021 (CCFA52)</p> <p>Data availability: December 2021</p> <p>Data provider: BASF SE Nicola Leinwetter Nicola.leinwetter@basf.com</p> <p>DSM Dirk Cremer dirk.cremer@dsm.com</p>	<p>Possible issues for trade: currently unidentified</p> <p>Basis for request: Presently the specifications require the use of chloroform when determining this parameter of the specifications. As the use of chloroform should be avoided where possible, and a more suitable alternative had been identified, the applicants wish to get the monographs revised regarding this parameter. The solubility data of lycopene in an alternative solvent are available. Chloroform had been evaluated by JECFA at its 23rd session (TRS Report 648), a toxicological monograph been prepared (FAS 14-JECFA 23/24) and the ADI been determined as: “not to be used”.</p> <p>Possible issues for trade: currently unidentified</p>	3
15.	Natamycin (INS 235)	<p>Type of request: Re-evaluation of safety and revision of specifications</p> <p>Proposed by: Russian Federation</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: To be confirmed at CCFA53</p> <p>Data provider: Russian Federation Codex Contact Point codex@gse.ru</p>	<p>Basis for request: The appropriateness of retaining natamycin in the GSFA should be re-evaluated, due to to emerging data on natamycin's role in: (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora. 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>	1
	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>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</p>	

No.	Substance(s)	General information	Comments about the request	Priority*
		<p>Data availability: To be confirmed at CCFA53 Data provider: Russian Federation Codex Contact Point codex@gse.ru</p>	<p>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>	
16.	ortho-Phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232)	<p>Type of request: Re-evaluation of ADI Proposed by: JECFA Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>Basis for request: (see Appendix 1 of CX/FA 19/51/2 Add. 1)</p> <p>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.</p> <p>Possible issues for trade: currently unidentified</p>	1
17.	Pentasodium triphosphate (INS 451(i))	<p>Type of request: Revision of specifications with regards to (1) revising the assay as P₂O₅ to “not more than 59.0%”; and revising the maximum pH value to 10.2 Proposed by: CEFIC Supported by: Colombia; European Union Year Requested: 2021 (CCFA52) Data availability: December 2021 Data provider:</p>	<p>Basis for request:</p> <p>i. Align the assay as P₂O₅ to “not more than 59.0%”</p> <p>In the Pentasodium Triphosphate monograph prepared at the 55th JECFA (2000) and published in FNP 52 Add 8 (2000) the Assay values expressed as P₂O₅ not less than 56.0 % and not more than 58.0 %. This maximum value</p>	3

No.	Substance(s)	General information	Comments about the request	Priority*
		Frederic Martens Prayon S.A. rue Joseph Wauters 144 4480 Engis Belgique	<p>of 58.0 % is not realistic because it is the theoretical P₂O₅ content of 100% pure Pentasodium triphosphate. In practice this value might be often exceeded. The request is to align the maximum value to 59.0 % P₂O₅ as mentioned in the EU Commission Regulation No EU/231/20125.</p> <p>ii. Align the maximum pH value to 10.2</p> <p>The pH value in the FNP 52 Add 8 is 9.1 – 10.1 whereas the pH value in the EU legislation is 9.1 – 10.2. The difference in maximum value can mislead and it is requested to align the maximum value to 10.2 as mentioned in the EU commission Regulation EU/231/2012.</p> <p>Possible issues for trade: currently unidentified</p>	
18.	Polyglycerol esters of fatty acids (INS 475)	<p>Type of request: The completeness of the information for safety assessment Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: December 2021 Data provider: to be confirmed at CCFA52</p>	<p>Basis 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.</p>	3
19.	Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)	<p>Type of request Re-evaluation of safety Proposed by: FoodDrinkEurope Supported by: Colombia; European Union Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: None identified – basis for re-evaluation subject to available data evaluated in EFSA 2017 re-evaluation</p>	<p>Basis for request: In 2017, the European Food Safety Authority (EFSA) has re-evaluated polyglycerol polyricinoleate (E 476) as a food additive, and considered that the available dataset give reason to revise the ADI of 7.5 mg/kg bw per day allocated by Scientific Committee for Foods (SCF) in 1978, to a new ADI of 25 mg/kg bw per day.</p> <p>Possible issues for trade: currently unidentified</p>	1
20.	Polyoxyethylene (20) sorbitan monolaurate (INS 432), Polyoxyethylene (20) sorbitan monooleate (INS 433), Polyoxyethylene (20) sorbitan monopalmitate (INS 434), Polyoxyethylene (20) sorbitan	<p>Type of request: Re-evaluation of safety Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53</p>	<p>Basis for request: JECFA noted during its 89th meeting that five polyoxyethylene sorbitan esters polysorbates) were evaluated by JECFA at its 17th meeting, and specifications were established. JECFA recommends that a new call for data be issued for their full evaluation.</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
	monostearate (INS 435), Polyoxyethylene (20) sorbitan tristearate (INS 436)		Possible issues for trade: currently unidentified	
21.	Proteolytic enzyme from <i>Bacillus subtilis</i>	Type of request: safety assessment and establishment of specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53	Basis for request: During the discussions on the alignment of the food-additive provision in CXS 152-1985 with the relevant provisions of the GSFA, CCFA51 agreed to include the substance as flour treatment agent to the list.	2
22.	Rosemary extract (INS 392)	Type of request Data pending – studies required for (1) the developmental toxicity of rosemary extract; and (2) determining whether the effects noted on rodent pup thyroid hormone levels can be replicated. Proposed by: JECFA Year requested: 2021(CCFA52) Data availability: December 2022 Data provider: To be confirmed at CCFA53	Basis for request: Additional studies on developmental toxicity and on noted effects on rodent pup thyroid hormone levels are required to complete the evaluation. <u>JECFA requests a deadline of data submission by December 2021 for the additional data, or its ADI will be withdrawn.</u> Possible issues for trade: currently unidentified	1
23.	Sorbitan monostearate (INS 491); Sorbitan tristearate (INS 492); Sorbitan monolaurate (INS 493), Sorbitan monooleate (INS 494); Sorbitan monopalmitate (INS 495)	Type of request: Safety re-evaluation and revision of specifications Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53	Basis for request: Previously, a request was made to revise the specifications for INS 491, 492 and 495 to replace the congealing range identification method as reported in the JECFA monographs for INS 491, 492 and 495 with the identification test “acid value, iodine value, gas chromatography”. However, JECFA recommends that a call for data be issued to conduct a safety re-evaluation of the group Sorbitan esters of fatty acids (INS 491 to 495). The specifications for the group can be revised pending the outcome of the safety re-evaluation. Possible issues for trade: currently unidentified	1
24.	Spirulina extract (INS 134)	Type of request: Data pending – analytical data Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51)	Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3) JECFA86 received limited analytical data on	2

No.	Substance(s)	General information	Comments about the request	Priority*
		<p>Data availability: December 2019 Data provider: NATCOL secretariat@natcol.org</p>	<p>spirulina extract. To remove the tentative designation from the specifications, the following information on the products of commerce is requested by December 2019:</p> <ul style="list-style-type: none"> • Full compositional characterization of commercial products in both liquid and powder forms. • Full compositional characterization of the aqueous extract before formulation/standardization. • Validated analytical methods for identification of the substance with a suitable specificity (including validation data and representative batch data). • Validated analytical methods for the determination of the purity of the substance with a suitable specificity (including validation data and representative batch data). <p>Possible issues for trade: currently unidentified</p>	
25.	Steviol glycosides	<p>Type of request: Safety assessment Proposed by: ISC Supported by: Colombia; Peru Year requested: 2021 (CCFA52) Data availability: December 2021 (already provided to JECFA) Data provider: ISC Maria Teresa Scardigli globaloffice@internationalsteviacouncil.org</p>	<p>Basis for request: The request is for the completion of the safety evaluation of those steviol glycosides produced via novel technologies that was initiated during the 87th JECFA meeting including bioconversion, fermentation and glucosylation. Nine (9) separate monographs were submitted to JECFA for review at the 87th meeting to support a “framework” for future safety evaluations and for the preparation of specifications for each new technology. These monographs were evaluated by the Committee and as part of this process “A framework was adopted for developing specifications for steviol glycosides by four different methods of production”. As a consequence, specifications for those steviol glycosides produced by novel production methods were developed. In addition, the Committee determined at the 87th meeting</p>	2

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>that “no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% purity as per existing specifications”. While the Committee supported the fact that “no safety concerns exist” a formal safety opinion for each new technology was not conducted. The re-evaluation is therefore requested to build upon the extensive work conducted by the JECFA at the 87th meeting regarding the safety of each of the individual dossiers produced using the novel technologies.</p> <p>Possible issues for trade: currently unidentified.</p>	
26.	Sucroglycerides (INS 474)	<p>Type of request: exposure assessment Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52</p>	<p>Basis for request: During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment.</p>	1
27.	Sucrose esters of fatty acids (INS 473)	<p>Type of request: Data pending - exposure assessment Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2023 Data provider: Japan codex@mext.go.jp</p>	<p>Basis for request: During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment.</p> <p>At the 89th JECFA meeting, JECFA considered that more refined dietary exposures should be provided. Specifically, JECFA recommends that sponsors provide information on:</p> <ul style="list-style-type: none"> i. typical or mean and high use levels for foods in which the food additives are used; and ii. foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used. <p>The information should be as specific as possible, and the foods should be classified</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>according to the FoodEx2 classification system, or another appropriate system. JECFA recommends that the data should be presented in tabular format by mapping the foods recorded in both the FoodEx2 to the GSFA food categories. This exercise can improve mapping consistency for all meetings. <u>Given the extent of the request for information, the JECFA proposes that the data be available 2 years after the date of confirmation.</u></p> <p>Possible issues for trade: currently unidentified</p>	
28.	Sucrose oligoesters ,type I and type II (INS 473a)	<p>Type of request: Data pending - exposure assessment Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2023 Data provider: Japan codex@mext.go.jp</p>	<p>Basis for request: During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment.</p> <p>At the 89th JECFA meeting, JECFA considered that more refined dietary exposures should be provided. Specifically, JECFA recommends that sponsors provide information on:</p> <ul style="list-style-type: none"> i. typical or mean and high use levels for foods in which the food additives are used; and ii. foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used. <p>The information should be as specific as possible, and the foods should be classified according to the FoodEx2 classification system, or another appropriate system. JECFA recommends that the data should be presented in tabular format by mapping the foods recorded in both the FoodEx2 to the GSFA food categories. This exercise can improve mapping consistency for all meetings. Given the extent of the request for information, the JECFA proposes</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>that the data be available 2 years after the date of confirmation.</p> <p>Possible issues for trade: currently unidentified</p>	
29.	Tannins (oenological tannins)	<p>Type of request: Data pending to complete evaluation – Evaluation by JECFA84 Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52</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>	2
30.	THAUMATIN II	<p>Type of request: Safety evaluation Proposed by: CCC Supported by: Colombia; United States of America Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: NOMAD Bioscience GmbH Jurijus (Yuri) Gleba, Ph.D. gleba@nomadbioscience.com</p> <p>Centre for regulatory Services Inc. Kristi O. Smedley, Ph.D. smedley@cfr-services.com</p>	<p>Basis for request: THAUMATIN II protein is a non-caloric natural sweetener and flavor enhancer produced recombinantly in green plants by NOMAD Bioscience. The vast majority of commercially available thaumatin are extracted from <i>Thaumatococcus daniellii</i> trees, which are not cultivated. Natural thaumatin mixtures are obtained by extraction of the aryls of the tree's fruit, which are harvested in the wild. Unpredictable supply and environmental concerns regarding current production practices have limited the expanded use of thaumatin, especially as sweeteners. NOMAD's manufacturing process does not deplete natural</p>	2

No.	Substance(s)	General information	Comments about the request	Priority*
		<p>DT/Consulting Group Daniel Tusé, Ph.D. daniel@dt-cg.com</p> <p>Calorie Control Council Robert Rankin rrankin@caloriecontrol.org</p>	<p>resources and can be scaled to meet increasing demand for thaumatin. THAUMATIN II is NOMAD Bioscience's single thaumatin-family protein produced recombinantly in green plants such as spinach, lettuce, red beet and <i>Nicotiana benthamiana</i>; all of which can be cultivated sustainably and in large scale. NOMAD's production process yields THAUMATIN II with the identical amino acid sequence as the thaumatin II (also referred to as thaumatin 2 or thaumatin B in the literature) in commercial products. NOMAD's process yields a highly pure product that meets the existing specifications and includes some trace impurities that have been demonstrated to be safe at the levels present. NOMAD requests an opinion from JEFCA with respect to the possibility of modifying the definition and expanding the specification of the current thaumatin compositions to also include the specification of THAUMATIN II.</p> <p>Although thaumatin II (thaumatin 2) is a component of thaumatin mixtures approved for marketing in the EU and is encompassed by the specification of E957, the process used by NOMAD for manufacturing THAUMATIN II recombinantly is different than the process employed to produce E957, albeit the thaumatin 2/THAUMATIN II proteins responsible for functionality are identical. The different processes yield thaumatin 2/II with different impurity profiles. NOMAD's product (THAUMATIN II and its associated impurities) has received GRAS classification by US FDA and is considered safe for use in all food classes defined for E957 and at the same rates of application (GRN 738). Thaumatin produced recombinantly has not been evaluated by EFSA. As such, it is NOMAD Bioscience's intent to seek review by JECFA of NOMAD's specification and</p>	

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>safety determination, so that other regulatory jurisdictions can rely on this assessment</p> <p>Possible issues for trade: currently unidentified.</p>	
31.	Titanium dioxide (INS 171)	<p>Type of request: Re-evaluation of safety, and revision of specifications if necessary Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: Not applicable Data provider: Not applicable</p>	<p>Basis for request: The EFSA has recently published a re-evaluation of titanium dioxide, with the key messages:</p> <ul style="list-style-type: none"> • Taking into account all available scientific studies and data, the Panel concluded that titanium dioxide can no longer be considered safe as a food additive. • The assessment was conducted following a rigorous methodology and taking into consideration many thousands of studies, including new scientific evidence and data on nanoparticles. • Although the evidence for general toxic effects was not conclusive, on the basis of the new data and strengthened methods the panel could not rule out a concern for genotoxicity and consequently could not establish a safe level for daily intake of the food additive. <p>The JECFA Secretariat has clarified since the publication of CL 2021/61-FA that JECFA aims first to establish criteria for the data necessary for the re-evaluation of titanium dioxide (likely in 2022) and then issue a corresponding call for data (likely in 2023).</p> <p>Possible issues for trade: The use of titanium dioxide as a food additive is expected to be banned in the European Union. The EU will soon inform trading partners via a Sanitary and Phytosanitary (SPS) Notification advising of measures to be taken. This revocation presents significant potential for trade disruption.</p>	1

* CCFA50¹ endorsed the ranking system for prioritization of entries, in order from highest (1) to lowest (3) 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.

Priority list of 61 flavourings proposed for inclusion on the JECFA Priority List to be considered at the 52nd session of the Codex Committee on Food Additives submitted in reply to CL 2019/41-FA

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA52	4902		22122-36-7	3-Methyl-2(5H)-furanone	III
Submitted at CCFA52	4915		2142634-65-7	(5Z)-3,4-Dimethyl-5-propylidene2(5H)-furanone	III
Submitted at CCFA52	4927		934534-30-2	4,7-Decadienal	I
Submitted at CCFA52	4887		56219-03-5	<i>cis</i> -9-Dodecenal	I
Submitted at CCFA52	4918		68820-38-2	Tridec-5-enal	I
Submitted at CCFA52	4886		126745-61-7	<i>cis</i> -6-Dodecenal	I
Submitted at CCFA52	4904		115018-39-8	<i>trans</i> -Tetradec-4-enal	I
Submitted at CCFA52	4905		2119671-25-7	2,6-Dimethylheptenyl formate	I
Submitted at CCFA52	4885		68820-34-8	<i>trans</i> -5-Dodecenal	I
Submitted at CCFA52	4898		41547-29-9	<i>trans</i> -5-Octenal	I
Submitted at CCFA52	4891		2088117-65-9	(<i>E</i>)-3-Methyl-4-dodecenoic acid	I
Submitted at CCFA52	4917		22032-47-9	(<i>Z</i>)-9-Dodecenoic acid	I
Submitted at CCFA52	4926		65398-36-9	(<i>Z</i>)-8-Pentadecenal	I
Submitted at CCFA52	4841		16676-96-3	<i>cis</i> -5-Dodecanyl acetate	I
Submitted at CCFA52	4784		57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	I
Submitted at CCFA52	4939		2180135-09-3	S-Methyl 5-(1-ethoxyethoxy)decanethioate	I
Submitted at CCFA52	4894		116229-37-9	2-Mercapto-3-methyl-1-butanol	I
Submitted at CCFA52	4883		556-27-4	S-Allyl-L-cysteine sulfoxide	II
Submitted at CCFA52	4935		98139-71-0	3-Methylbutane-1,3-dithiol	III
Submitted at CCFA52	4916		124831-34-1	2-Methyl-3-butene-2-thiol	I
Submitted at CCFA52	4938		2180135-08-2	S-Methyl 5-(1-ethoxyethoxy)tetradecanethioate	I
Submitted at CCFA52	4901		2097608-89-2	O-Ethyl S-(3-methylbut-2-en-1-yl)thiocarbonate	I
Submitted at CCFA52	4900		64580-54-7	Hexyl propyl disulphide	I
Submitted at CCFA52	4914		24963-39-1	bis-(3-Methyl-2-butenyl)disulphide	III
Submitted at CCFA52	4889		3877-15-4	Methyl propyl sulphide	I
Submitted at CCFA52	4903		26516-27-8	Ethyl 3-methyl-2-oxopentanoate	I
Submitted at CCFA52	4804		61789-44-4	Mixture of Ricinoleic acid, Linoleic acid, and Oleic acid	
Submitted at CCFA52	4930		159017-89-7	4-Isopropoxycinnamaldehyde	I

¹ REP 18/FA, para 156.

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA52	4888		1945993-01-0; 828265-08-3	Mixture of 5-hydroxy-4-(4'-hydroxy3'-methoxyphenyl)-7-methylchroman-2-one and 7-hydroxy-4-(4'-hydroxy3'-methoxyphenyl)-5-methylchroman-2-one	III
Submitted at CCFA52	4879		21145-77-7	1-(3,5,5,6,8,8-Hexamethyl-5,6,7,8-tetrahydronaphthalen-2-yl)ethanone	II
Submitted at CCFA52	4893		4912-58-7	2-Ethoxy-4-(hydroxymethyl)phenol	I
Submitted at CCFA52	4892		4707-61-3	<i>cis</i> -2-Hexylcyclopropaneacetic acid	II
Submitted at CCFA52	4890		27841-22-1	3- <i>p</i> -Menthen-7-al	I
Submitted at CCFA52	4928		554-14-3	2-Methylthiophene	II
Submitted at CCFA52	4839		163460-99-9; 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	II
Submitted at CCFA52	4813		1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	II
Submitted at CCFA52	4884		1569-60-4	6-Methyl-5-hepten-2-ol	I
Submitted at CCFA52	4827		6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	I
Submitted at CCFA52	4869		886449-15-6	4-(<i>L</i> -Menthoxyl)-2-butanone	II
Submitted at CCFA52	4844		118026-67-8	(<i>2E,4E</i>)-2,4-Decadien-1-ol acetate	I
Submitted at CCFA52	4747		91212-78-1	(±)-2,5-Undecadien-1-ol	II
Submitted at CCFA52	4913		18478-46-1	3,7-Dimethyl-2-methyleneoct-6-en-1-ol	II
Submitted at CCFA52	4785		25234-33-7	2-Octyl-2-dodecenal	II
Submitted at CCFA52	4786		13893-39-5	2-Hexyl-2-decenal	II
Submitted at CCFA52	4929		60857-05-8	4-Methylidene-2-(2-methylprop-1-enyl)oxane	III
Submitted at CCFA52	4920		220462-51-9	1-Ethyl-2-(1-pyrrolylmethyl)pyrrole	III
Submitted at CCFA52	4832		108715-62-4	2-(3-Benzoyloxypropyl)pyridine	III
Submitted at CCFA52	4829		616-45-5	2-Pyrrolidone	I
Submitted at CCFA52	4818		1370711-06-0	<i>trans</i> -1-ethyl-2-methylpropyl 2-2-butenoate	I
Submitted at CCFA52	4867		18374-76-0	(3 <i>S</i> ,5 <i>R</i> ,8 <i>S</i>)-3,8-Dimethyl-5-prop-1-en-2-yl-3,4,5,6,7,8-hexahydro-2 <i>H</i> -azulen-1-one	II
Submitted at CCFA52	4840		38427-80-4	Tetrahydronootkatone	II
Submitted at CCFA52	4807		1078-95-1	Pinocarvyl acetate	II
Submitted at CCFA52	4906		36687-82-8	<i>L</i> -Carnitine tartrate	III
Submitted at CCFA52	4868		61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5 <i>H</i>)-furanone	III
Submitted at CCFA52	4896		2186611-08-3	<i>N</i> -(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	III
Submitted at CCFA52	4882		1857330-83-9	<i>N</i> -(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at CCFA52	4899		1622458-34-7; 2079034-28-7	<i>N</i> -(1-((4-amino-2,2-dioxido-1 <i>H</i> -benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)-2,6-dimethylisonicotinamide	III
Submitted at CCFA52	4880		2015168-50-8	2-(4-Ethylphenoxy)- <i>N</i> -(1 <i>H</i> -pyrazol-3-yl)- <i>N</i> -(thiophen-2-ylmethyl)acetamide	III
Submitted at CCFA52	4881		1857331-84-0	<i>N</i> -(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at CCFA52	4877		76733-95-4	(<i>E</i>)-3-(3,4-Dimethoxyphenyl)- <i>N</i> -[2-(3-methoxyphenyl)-ethyl]-acrylamide	III

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA52	4835		877207-36-8	2,4-Dihydroxy- <i>N</i> -[(4-hydroxy-3-methoxyphenyl)methyl]benzamide	III

Priority list of 68 flavours previously proposed for inclusion on the JECFA Priority List to be considered for safety evaluation at the 52nd session of the Codex Committee on Food Additives, identified in reply to CL 2020/37-FA

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA43	4074		6321-45-5	Allyl valerate	II
Submitted at CCFA43	4072		20474-93-5	Allyl crotonate	II
Submitted at CCFA45	4688		105-82-8	1,1-Dipropoxyethane	I
Submitted at CCFA43	4432		25334-93-4	(±) Acetaldehyde ethyl isopropyl acetal	I
Submitted at CCFA43	4528		6986-51-2	Acetaldehyde ethyl isobutyl acetal	I
Submitted at CCFA43	4527		5669-09-0	Acetaldehyde di-isobutylacetal	I
Submitted at CCFA43	4335		10486-19-8	Tridecanal	I
Submitted at CCFA43	4334		1002-84-2	Pentadecanoic acid	I
Submitted at CCFA43	4336		638-53-9	Tridecanoic acid	I
Submitted at CCFA43	4010		123-63-7	Paraldehyde	III
Submitted at CCFA45	4685		7370-92-5	(±)-6-Octahyltetrahydro-2 <i>H</i> -pyran-2-one	I
Submitted at CCFA45	4673		7370-44-7	<i>delta</i> -Hexadecalactone	I
Submitted at CCFA45	4749		35852-42-7	4-Methylpentyl-4-methylvalerate	I
Submitted at CCFA45	4346		180348-60-1	5-Methylhexyl acetate	I
Submitted at CCFA45	4347		850309-45-4	4-Methylpentyl isovalerate	I
Submitted at CCFA45	4343		25415-67-2	Ethyl 4-methylpentanoate	I
Submitted at CCFA45	4344		2983-38-2	Ethyl 2-ethylbutyrate	I
Submitted at CCFA45	4345		2983-37-1	Ethyl 2-ethylhexanoate	I
Submitted at CCFA45	4735		13552-95-9	(4 <i>Z</i> , 7 <i>Z</i>)-Trideca-4,7-dienal	I
Submitted at CCFA45	4682		23333-91-7	Octahydro-4,8a-dimethyl-4a(2 <i>H</i>)-naphthol	I
Submitted at CCFA45	4742		917750-72-2	1-(2-Hydroxy-4-methylcyclohexyl)ethanone	III
Submitted at CCFA45	4687		544409-58-7	(±)-3-Hydroxy-3-methyl-2,4-nonanedione	II
Submitted at CCFA51	4836		137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol	III
Submitted at CCFA51	4842		911212-28-7	2,4,5-Trithiaoctane	III
Submitted at CCFA51	4817		38634-59-2	<i>S</i> -[(methylthio)methyl]thioacetate	I
Submitted at CCFA51	4870		17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane	II
Submitted at CCFA51	4828		729602-98-6	1,1-Propanedithioacetate	III
Submitted at CCFA51	4824		1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate	III
Submitted at CCFA51	4843		1838169-65-5	3-(Allyldithio)butan-2-one	III
Submitted at CCFA51	4822		61407-00-9	2,6-Dipropyl-5,6-dihydro-2 <i>H</i> -thiopyran-3-carboxaldehyde	II

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA51	4823		33368-82-0	1-Propenyl 2-propenyl disulfide	II
Submitted at CCFA51	4782		1679-06-7; 1633-90-5	2(3)-Hexanethiol	I
Submitted at CCFA51	4779		1416051-8-1	(±)-2-Mercapto-5-methylheptan-4-one	I
Submitted at CCFA51	4792		548740-99-4	(±)-3-Mercapto-1-pentanol	I
Submitted at CCFA51	4791		22236-44-8	3-(Acetylthio)hexanal	III
Submitted at CCFA51	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone	I
Submitted at CCFA51	4730		1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate	III
Submitted at CCFA51	4734		1256932-15-6	3-(Methylthio)-decanal	I
Submitted at CCFA51	4733		1006684-20-3	(±)-2-Mercaptoheptan-4-ol	III
Submitted at CCFA51	4761		75631-91-3	Prenyl thioisovalerate	I
Submitted at CCFA51	4760		53626-94-1	Prenyl thioisobutyrate	I
Submitted at CCFA45	4745		62439-41-2	(±)-6-Methoxy-2,6-dimethylheptanal	I
Submitted at CCFA45	4765		1367348-37-5	Ethyl 5-formyloxydecanoate	III
Submitted at CCFA45	4719		110-15-6	Succinic acid	I
Submitted at CCFA51	4871		1962956-83-7	2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate	I
Submitted at CCFA51	4826		10525-99-8	3-Phenylpropyl 2-(4-hydroxy-3-methoxy-phenyl)acetate	I
Submitted at CCFA51	4810		60563-13-5	Ethyl-2-(4-hydroxy-3-methoxy-phenyl)acetate	I
Submitted at CCFA45	4750		65405-77-8	<i>cis</i> -3-Hexenyl salicylate	I
Submitted at CCFA45	4700		614-60-8	<i>o-trans</i> -Coumaric acid	III
Submitted at CCFA43	4622		61683-99-6	Piperonal propyleneglycol acetal	III
Submitted at CCFA43	4606		930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate	I
Submitted at CCFA43	4627		6414-32-0	Anisaldehyde propyleneglycol acetal	III
Submitted at CCFA43	4435		673-22-3	2-Hydroxy-4-methoxybenzaldehyde	I
Submitted at CCFA43	4430		99-50-3	3,4-Dihydroxybenzoic acid	I
Submitted at CCFA43	4431		99-06-9	3-Hydroxybenzoic acid	I
Submitted at CCFA43	4618		23495-12-7	2-Phenoxyethyl propionate	III
Submitted at CCFA43	4625		6314-97-2	Phenylacetaldehyde diethyl acetal	I
Submitted at CCFA43	4629		5468-05-3	Phenylacetaldehyde propyleneglycol acetal	III
Submitted at CCFA43	4620		122-99-6	2-Phenoxyethanol	III
Submitted at CCFA43	4619		92729-55-0	Propyl 4- <i>tert</i> -butylphenylacetate	I
Submitted at CCFA43	4314		61810-55-7	Phenethyl decanoate	I
Submitted at CCFA43	2860		94-47-3	Phenethyl benzoate	I
Submitted at CCFA43	4438		591-11-7	<i>beta</i> -Angelicalactone	I
Submitted at CCFA43	4195		87-41-2	Phthalide	III
Submitted at CCFA45	4768		67936-13-4	2,6,10-Trimethyl-9-undecenal	I
Submitted at CCFA45	4612		645-62-5	2-Ethyl-2-hexenal	II
Submitted at CCFA45	4616		13019-16-4	2-Hexylidenehexanal	II

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA45	4486		5694-82-6	Citral glyceryl acetal	I

Priority list of 29 flavours proposed for inclusion on the JECFA Priority List to be considered for revision of specifications at the 52nd session of the Codex Committee on Food Additives submitted in reply to CL 2020/37-FA

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	3862	489		S-Methyl hexanethioate	2003 (session 61)	CAS number should be 2432-77-1; update the chemical formula and molecular weight
Old	4047	1383	67746-30-9	(E)-2-hexenal diethyl acetal	2004 (Session 63)	The specification requires clarity. 92% 2E-isomer and 3-5% 2Z-isomer
Old	3333	1170	551-08-6	3-Butylidenephthalide	2003 (Session 61)	The assay value is currently not reflective of the material in commerce
Old	2962	755		Isopulegol	2000 (Session 55)	The currently listed CAS number is for the L-isomer but the substance is a mixture of D and L-isomers, which are better represented by CAS 7786-67-6
Old	3658	1233	470-67-7	1,4-Cineole	2003 (Session 61)	The Specific Gravity and Refractive index do not reflect the material currently in commerce.
Old	3791	1166	4430-31-3	Octahydrocoumarin	2003 (Session 61)	Specific gravity in the database does not reflect the material currently in commerce
Old	3849	1411	195863-84-4	3-(L-Menthoxy)-2- methylpropane-1,2-diol	2004 (Session 63)	Specific gravity in the database does not reflect the material currently in commerce
Old	4053	1416	42822-86-6	p-Menthane-3,8-diol	2004 (Session 63)	Specific gravity in the database does not reflect the material currently in commerce.
Old	3927	808	645-13-6	p-Isopropylacetophenone	2001 (Session 57)	Clarity on the positional isomer description
Old	2005	810	100-06-1	Acetanisole	2001 (Session 57)	Clarity on the positional isomer description
Old	3839	1343	502-61-4	Farnesene (alpha and beta)	2004 (Session 63)	The CAS number 688330-26-9 better described the mixture of alpha and beta-farnesene
Old	3478	511		1-Butanethiol	1999 (Session 53)	The CAS number currently in the database does not represent 1-Butanethiol. The CAS no. That does is 109-79-5
Old	3886	1226		8-Ocimenyl acetate	2003 (Session 61)	The CAS number for this substance is 197098-61-0. There currently is not one listed in the database

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	3790	493		Methylthio 2-(propionyloxy)propionate	2002 (Session 59)	The CAS number for this substance is 93940-60-4. There currently is not one listed in the database
Old	3503	520		2, 3, or 10-Mecaptopinane	2000 (Session 55)	The CAS numbers for this substance are 23832-18-0; 6588- 78-9; 72361-41-2. There currently is not one listed in the database
Old	3865	571		Methyl 3-methyl-1-butenyl disulfide	2003 (Session 61)	The CAS number for this substance is 233666-09-6. There is currently not one listed in the database
Old	3752	933		Potassium 2-(1'- ethoxy)ethoxypropanoate	2001 (Session 57)	The CAS number for this substance is 100743-68-8. There is currently not one listed in the database
Old	3806	444	156329-82-2	(-)-Menthol 1- and 2-propylene glycol carbonate	1998 (Session 51)	The CAS number currently listed in the database has been deleted by the registry. The current CAS No. is 30304-82-6
Old	2611	930	598-82-3	Lactic acid	2001 (Session 57)	The CAS number currently listed in the database has been deleted by the registry. The CAS Nos. that represent this substance are 10326-41-7; 79-33-4; 50-21-5
Old	2044	9	7439-76-7	Allyl 10-undecenoate	1996 (Session 46)	There is a typographical error in the CAS number. It should be 7493-76-7
Old	2514	54	1005-86-2	Geranyl formate	2003 (Session 61)	There is a typographical error in the CAS number. It should be 105-86-2
Old	2031	4	142-91-8	Allyl heptanoate	1996 (Session 46)	There is a typographical error in the CAS number. It should be 142-19-8
Old	2040	1	2408-70-0	Allyl propionate	2000 (Session 55)	There is a typographical error in the CAS number. It should be 2408-20-0
Old	3353	1272	151824	3-Hexenyl formate (<i>cis</i> and <i>trans</i> mixture)	2003 (Session 61)	There is a data error in the CAS number field. The correct CAS number is 33467-73-1
Old	3493	135	34942-91-1	<i>trans</i> -3-Heptenyl acetate	1997 (Session 49)	The CAS number for the <i>trans</i> -isomer is 1576-77-8
Old	4479	1973	5413-49-0	Ethyl levulinate propylene glycol	2010 (Session 73)	The correct CAS number is 57197-36-1
Old	2721	216	2412-24-1	Methyl 4-methylvalerate	2000 (Session 55)	The correct CAS number is 2412-80-8
Old	2390	273	1321-89-7	2,6-Dimethyloctanal	2001 (Session 57)	The correct CAS number is 7779-07-9
Old	3809	506	109-79-5	Menthone-8-thioacetate	1999 (Session 53)	The current CAS number in the database is for a different substance. The correct CAS number is 94293-57-9

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

No	Substance(s)	General information	Comments about the request
1.	Acid prolyl endopeptidase from <i>Aspergillus niger</i> expressing a gene from <i>Aspergillus niger</i>	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 Mrs. Paola Montaguti paola.montaguti@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
2.	Activated carbon (activated charcoal)	Type of request: Revision of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53	Basis for request: In view of the <i>Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004)</i> , the CCCF14 recommended that the JECFA: <ol style="list-style-type: none"> i. review the lead specifications for diatomaceous earth and activated carbon and ii. evaluate available data to support development of a lead specification for bentonite. Possible issues for trade: currently unidentified
3.	Adenosine-5'-monophosphate deaminase from <i>Aspergillus oryzae</i>	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 <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. Possible issues for trade: currently unidentified
4.	Alpha-amylase from <i>Bacillus licheniformis</i> expressing a modified alpha-amylase gene from <i>Geobacillus stearothermophilus</i>	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
5.	Alpha-amylase from <i>Bacillus</i>	Type of request: Safety assessment and establishment of specifications	Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.

	<i>stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>	Proposed by: European Union Year requested: 2015 (CCFA47) Data availability: December 2018 Data provider: Novozymes A/S Tine Vitved Jensen tvit@novozymes.com	Possible issues for trade: currently unidentified
6.	Alpha-amylase from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>	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.	Amyloglucosidase from <i>Talaromyces emersonii</i> expressed in <i>Aspergillus niger</i>	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
8.	Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i>	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
9.	Asparaginase from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>	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	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

		Tine Vitved Jensen tvit@novozymes.com	
10.	Beta-amylase from <i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i>	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
11.	Bentonite (INS 558)	Type of request: Establishment of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53	Basis for request: In view of the <i>Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004)</i> , the CCCF14 recommended that the JECFA: i. review the lead specifications for diatomaceous earth and activated carbon and ii. evaluate available data to support development of a lead specification for bentonite. (Note: also captured under item 3 of Table 1 above) Possible issues for trade: currently unidentified
12.	Chymosin from <i>Camelus dromedaries</i> expressed in <i>Aspergillus niger</i>	Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: Chr-Hansen A/S Christina Westphal Christensen dkchwe@chr-hansen.com	Basis for request: The chymosin catalyze the hydrolysis, at a very particular site in the amino acid chain, of κ-casein - the main protein in milk. This is the absolute first key step in all cheese-making, through which the liquid milk is coagulated (precipitated) and converted to a semi-solid form by the catalytic action of coagulants, such as chymosin. Therefore, the most important production process in which chymosin is used is the production of cheese. Moreover, chymosin can be used in the production of fermented milk products, where it can be used to increase the viscosity of the preparation. Quarg (quark) is an example of fermented milk product in which coagulants, like chymosins, are used to increase the final viscosity of the product. Possible issues for trade: currently unidentified
13.	Diatomaceous earth	Type of request: Revision of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: to be confirmed at CCFA53	Basis for request: In view of the <i>Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004)</i> , the CCCF14 recommended that the JECFA:

		Data provider: to be confirmed at CCFA53	<p>i. review the lead specifications for diatomaceous earth and activated carbon and</p> <p>ii. evaluate available data to support development of a lead specification for bentonite.</p> <p>Possible issues for trade: currently unidentified</p>
14.	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</p> <p>Proposed by: European Union</p> <p>Year requested: 2016 (CCFA48)</p> <p>Data availability: December 2018</p> <p>Data provider: Puratos NV Mr. Olivier Maigret omaigret@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>
15.	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</p> <p>Proposed by: European Union</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Puratos NV Mr. Olivier Maigret omaigret@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>
16.	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</p> <p>Proposed by: European Union</p> <p>Year requested: 2017 (CCFA49)</p> <p>Data availability: December 2018</p> <p>Data provider: Puratos NV Mr. Olivier Maigret omaigret@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>
17.	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</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>

		jack.reuvers@dsm.com	
18.	Glutaminase from <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: Nobuo Okado, Shin Nihon Chemical Co., Ltd. c/o: Intertek Shahrzad Tafazoli, MASc (Eng.), MSc, PhD +1 905 542-2900 ext. 0268</p>	<p>Basis for request: The enzyme catalyzes the conversion L-glutamine to L-glutamate, and is used in the manufacture of glutamic acid-rich yeast extracts and glutamic acid-rich protein hydrolysates. These, in turn, are added to other foods, including beverages, to impart savoury or umami taste. Possible issues for trade: currently unidentified</p>
19.	Inulinase from <i>Aspergillus ficuum</i> produced by <i>Aspergillus oryzae</i> , strain MUCL 44346	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. Olivier Maignret omaignret@puratos.com</p>	<p>Basis for request: The enzyme catalyzes the hydrolysis of inulin to produce fructo-oligosaccharides, theoretically from all food materials that naturally contain inulin. Possible issues for trade: currently unidentified</p>
20.	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: Novozymes A/S Mr. Peter Hvass phva@novozymes.com</p>	<p>Basis for request: The lactase enzyme preparation is used as a processing aid during food manufacture for hydrolysis of lactose during processing of milk and other lactose containing dairy products, e.g. in order to obtain lactose-reduced milk products for lactose-intolerant individuals as well as dairy products with better consistency and increased sweetness due hydrolysis of lactose to form glucose and galactose. Possible issues for trade: currently unidentified</p>
21.	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: Novozymes A/S Mr. Peter Hvass phva@novozymes.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. Possible issues for trade: currently unidentified</p>
22.	Phosphodiesterase from <i>Penicillium citrinum</i>	<p>Type of request: Safety assessment and establishment of specifications</p>	<p>Basis for request: The enzyme is used in processing yeast products by hydrolysing RNA, thereby increasing</p>

		<p>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>ribonucleotide levels and improving umami flavour. Possible issues for trade: currently unidentified</p>
23.	<p>Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i></p>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2014 (CCFA46) Data availability: December 2018 Data provider: DSM Food Specialties Dr. Mariella Kuilman mariella.kuilman@dsm.com</p>	<p>Basis for request: The enzyme hydrolyzes natural phospholipids present in foodstuffs resulting in the formation of lyso-phospholipids that have emulsifying properties. This may be of benefit in baking and in egg processing for superior emulsifying properties (e.g. useful in dressings, spreads, sauces). In addition, the enzyme preparation is used during degumming of vegetable oils, where phospholipids can be separated more effectively from the oil. Possible issues for trade: currently unidentified</p>
24.	<p>Protease Aqualysin 1 from <i>Thermus aquaticus</i> produced by <i>B. subtilis</i>, strain LMGS 25520</p>	<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. Olivier Maignet omaignet@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>
25.	<p>Transglucosidase/alpha-glucosidase from <i>Trichoderma reesei</i> expressing an Alpha-glucosidase gene from <i>Aspergillus niger</i></p>	<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-glucosyl-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. Possible issues for trade: currently unidentified</p>

26.	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. Possible issues for trade: currently unidentified</p>
27.	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. Possible issues for trade: currently unidentified</p>

Annex 4

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 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 yes, specify the earliest date on which the data can be made available>
Change to data provider? (yes/no)	<If yes, specify the new data provider including contact person>

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