CODEX ALIMENTARIUS COMMISSION E





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CL 2021/61-FA August 2021

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 comments on the priority list of substances proposed for evaluation by

JECFA

DEADLINE: 25 August 2021

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

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BACKGROUND

- 1. CCFA52 has been postponed to September 2021 due to the Covid-19 pandemic. In order to maintain the momentum of the Codex standard setting work and to minimize the impact of the pandemic, it was agreed that in addition to CL 2019/41-FA, one new Circular Letter (i.e. CL 2020/37-FA) should be distributed for collection of additional proposals on the priority list of substances proposed for evaluation by JECFA (hereafter referred to as the "Priority List").
- 2. Replies to CL 2019/41-FA and CL 2020/37-FA have been compiled in CX/FA 21/52/12. For inclusion of requests submitted by Observers in the Priority List, it is required to obtain support from Members.
- 3. Canada who has normally been the chair for the in-session Working Group meeting on this matter (hereafter referred to as the working group chair), based on the available documents (e.g. CX/FA 21/52/2 Add.1, CX/FA 21/52/3, CX/FA 21/52/3 Add.1, CX/FA 21/52/4, CX/FA 21/52/4 Add.1, CX/FA/21/52/4 Add.2, CX/FA 21/52/12), has prepared an updated Priority List (Annex 1). In addition, the call for data¹ for the 92nd JECFA meetings and the conclusions of the 92nd JECFA meeting have been considered.²
- 4. In view of the virtual nature for CCFA52, in order to facilitate the preparatory work on this subject, it was decided to distribute this Circular Letter to collect comments in advance.

REQUEST FOR COMMENTS

- 5. Members and Observers are invited to provide comments on the updated Priority List (Annex 1). It is advised that data providers and sponsors ensure that all revisions relevant to their request are accurate. Please consider the following in preparing your comments:
 - It is not expected that there will be an in-session working group during CCFA52 to discuss the Priority List, therefore it is critical to receive comments in response to this circular letter in order to prepare the report for endorsement by CCFA52;
 - ii. Observers must provide Member support in response to this circular letter, or the request may not be included in the Priority List submitted for endorsement by CCFA52;

¹ Call for Data – JECFA 92 meeting: https://www.who.int/news-room/articles-detail/call-for-data-jecfa-92-meeting.

² Summary and Conclusions of the 92nd JECFA meeting: http://www.fao.org/3/cb5597en/cb5597en.pdf.

iii. Given the delay since the CCFA51 meeting, it is requested that Members and Observers, as applicable, provide confirmation of current requests set out in the Tables to Annex 1, even if previous confirmation has been provided in reply to CX/FA 21/52/12;

- iv. New requests in the Priority List are in blue font (example), while deletions are struck through (example);
- v. Requests have been deleted if JECFA has issued a call for data;
- vi. Certain new entries are in response to JECFA requiring additional data, denoted by the entry "Proposed by: JECFA", and such entries require a commitment to provide data;
- vii. A ranked prioritization of new entries from 1 (highest) to 3 (lowest) has been proposed based on the system endorsed during CCFA50³;
- viii. The updated requests for flavourings submitted by IOFI have been presented in the unnumbered tables directly following Table 1 of Annex 1, and reflect the listings provided in CX/FA 21/52/12; and consequently, the previous tables of flavourings are proposed for deletion; and
- ix. Table 2, the LIST OF SUBSTANCES USED AS PROCESSING AIDS PROPOSED FOR EVALUATION BY JECFA, follows the tables of flavourings.
- 6. Lead specifications for diatomaceous earth, charcoal (activated carbon), and bentonite: As described in CX/FA 21/52/2 Add.1, the CCCF is recommending that **CCFA consider** the recommendation that JECFA review the lead specifications for diatomaceous earth and charcoal, and develop a lead specification for bentonite. This request to JECFA has not been added to the draft Priority List, but will be considered for inclusion pending discussion of this agenda item at CCFA52. Given that there will not be an opportunity to comment on this request between discussion of this agenda item and the presentation of the report of the working group on JECFA priorities, the addition of this request to the Priority List might need to be delayed until CCFA53.
- 7. THAUMATIN II: The request for THAUMATIN II, submitted as part of CX/FA 21/52/12, is for thaumatin II sourced from recombinant plant technologies. The request is therefore for a re-evaluation of the current specifications for thaumatin, to expand the definition and accommodate any relevant specifications for the new source. The working group chair is seeking comments as to whether this request is appropriate as a re-evaluation of the existing specifications, or if the substance should be treated as a distinct entity, requiring its own INS number and independent safety assessment or a determination that the existing safety assessment is suitable to account for the new source. Further, with respect to the revision of specifications, the working group chair asks if it is appropriate to revise the specifications in a manner similar to the approach taken at the 87th JECFA meetings regarding the tentative specifications for steviol glycosides.
- 8. <u>Titanium dioxide</u>: This listing is not based on any available document. Due to the recent EFSA reevaluation of titanium dioxide, JECFA will issue a call for data in the summer of 2021 for the purpose of conducting a re-evaluation. This is an open call for data, and the details of the toxicological data will be described therein. Comments are welcome on the listing for titanium dioxide in Table 1 of Annex 1.
- 9. <u>Alpha-amylase from Bacillus licheniformis expressing a modified alpha-amylase gene from Geobacillus stearothermophilus</u>: As part of the call for data for the 92nd JECFA meeting, information was requested for the listing for "alpha-amylase from *Bacillus stearothermophilus* expressed in *Bacillus licheniformis*". The working group chair is seeking clarification on whether or not this call for data applies to the similar entry for "alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus*" in Table 2. The European Union proposed the request in question.
- 10. Comments submitted in response to this Circular Letter will be considered at CCFA52 and used to prepare the report for endorsement by CCFA52.

³ REP 18/FA, Paragraph 156

Annex 1

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

	Substance(s)	General information	Comments about the request	Priority*
1.	Anionic methacrylate copolymer (AMC) (INS 1207)	olymer (AMC) (INS 1207) evaluation	Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3)	2
		Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability	Additional data is required to clarify the <i>in vivo</i> carcinogenic potential of the residual monomer methyl acrylate.	
		Data provider	Possible issues for trade: currently unidentified	
	Neutral methacrylate copolymer (NMC) (INS 1206)	Type of request: Data pending – suitable method of assay Proposed by: JECFA	Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3)	3
		Supported by: N/A Year requested: 2019 (CCFA51) Data availability: Data provider	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.	Aspartame (INS 951)	Type of request: Re-evaluation of safety Proposed by: ICBA Supported by: to be confirmed at CCFA52 Year requested: 2021 (CCFA52) Data availability: Data provider: Dietary Intake Assessment Exponent Nga Tran, Dr.P.H., M.P.H. ntran@exponent.com Intertek Scientific & Regulatory Consultancy Danika Martyn, Ph.D.	Basis for request: The request for re-evaluation is supported by the following: 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. Possible issues for trade: currently unidentified	1
		Danika.martyn@intertek.com Systematic Assessment of Mechanistic Data in context of overall carcinogenicity assessment ToxStrategies, Inc.		

	Substance(s)	General information	Comments about the request	Priority*
		Daniele Wikoff, Ph.D. <u>dwikoff@toxstrategies.com</u>		
3.	Azodicarbonamide (INS 927a)	Type of request: safety assessment and establishment of specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	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.	1
4.	Benzoic acid and its salts (INS 210-212)	Type of request: Data pending – safety assessment Proposed by: CCFA49 Year requested: 2018 (CCFA50) Data availability: December 2020 Data provider: International Council of Beverages Associations (ICBA) Ms. Katherine Loatman (Kate@icba-net.org)	Basis for request: To confirm ICBA's commitment to provide new toxicological evaluation of benzoates. The studies include extended one-generational reproductive toxicity testing (EOGRT Study, OECD 443) and findings relative to benzoate's chemical-specific adjustment factor, default uncertainty factors and intake assessment assumptions. Possible issues for trade: Identified: CCFA50 suggested extending the interim level of 250 ppm (as benzoic acid) for the beverage category 14.1.4 to CCFA53.	1
5.	Black carrot extract (INS 163(vi)	Type of request: Data pending – characterization and toxicological information Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: to be confirmed at CCFA52 Data provider: to be confirmed at CCFA52	Basis for request: JECFA prepared tentative specifications for black carrot extract as the powder form, at its 87 th meeting. However, JECFA could not conclude on its safety or establish specifications. Additional characterization and toxicological data are required, namely: 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	2

	Substance(s)	General information	Comments about the request	Priority*
6.	Butterfly Pea Flower Extract	Type of request: Safety assessment and establishment of specifications Proposed by: IACM Supported by: To be confirmed at CCFA52 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.	1
8.	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 codex@mext.go.jp ema@ecco-eu.com	Possible issues for trade: currently unidentified Basis for request: (see JECFA86 report or Annex 2 of CX/FA 19/51/4) To remove the tentative designation from the specifications, the following information is requested by December 2019: Validated analytical method to replace the obsolete packed column gas chromatographic method for the determination of total citric acid; Validated analytical method that eliminates the use of chloroform for the determination of total glycerol.	2

	Substance(s)	General information	Comments about the request	Priority*
			Amendment to the specification based on the compositions/characteristics of the product commercially available	
			Possible issues for trade: currently unidentified	
9.	L-cysteine hydrochloride (INS 920)	Type of request: safety evaluation and 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.	3
10.	Dioctyl sodium sulfosuccinate(INS 480)	Type of request: Exposure assessment Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA52 Data provider: to be confirmed_at CCFA52	Possible issues for trade: currently unidentified 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 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
11.	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: the 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 reassessment, and establishment of specifications or revision of specifications, as applicable Refer to tables of flavourings directly following Table 1 Possible issues for trade: currently unidentified	Not applicable
	Flavouring agents:	Type of request: Data pending to finalize exposure	Basis for request: (see JECFA86 report or	

	Substance(s)	General information	Comments about the request	Priority*
	(+)Carvone (no. 380.1) and (-)-Carvone (No. 380.2)	assessment and revise the JECFA specifications Proposed by: JECFA Supported by: Japan Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: Japan and IOFI codex@mext.go.jp (staylor@vertosolutions.net	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.	
	Flavouring agents:(Ethyl 2-methyl pentanoate (No.214), cis-3-Hexen-1-ol (No.315), Menthol (No.427), I-Menthyl 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))	Type of request: revise the JECFA specifications Proposed by: CCFA 51 Supported by: Japan Year requested: 2019 (CCFA51) Data availability: April 2019 Data provider: Japan codex@mext.go.jp	Possible issues for trade: currently unidentified 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 specification (some items therein) and the commercially available products for each compound.	
12.	` ','	Type of request: Safety assessment and establishment of specifications Proposed by: South Africa 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.	2

	Substance(s)	General information	Comments about the request	Priority*
			Possible issues for trade: currently unidentified	
13.	Fulvic acid (carbohydrate derived)	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: To be confirmed at CCFA52 Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	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. The toxicological data required include:	2
			 i. Absorption, distribution, metabolism and excretion; ii. repeated-dose 90-day oral toxicity in rodents; iii. two-generation reproductive toxicity or extended one-generation reproductive toxicity; iv.prenatal developmental toxicity; v. additional studies, including an in vitro micronucleus test in mammalian cells, might be required, depending on elucidation of the 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. 	
			The characterization data required include:	
			i. Data on manufacturing processes; and,ii. Chemical characterization of the article(s) of commerce.	
			Possible issues for trade: currently unidentified	
14.	Fungal amylase from Aspergillus niger	Type of request: safety assessment and establishment of specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51)	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	2

	Substance(s)	General information	Comments about the request	Priority*
		Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	as flour treatment agent to the list.	
15.	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 bolarte@minsalud.gov.co	Basis for request: (see JECFA84 report) Additional biochemical and toxicological data. Information of characterization of food additive is needed on: Characterization of the low molecular weight components of the "blue polymer"; A validated method for the determination of dimers; and Data on concentrations of dimers from five batches of the commercial products Possible issues for trade: currently unidentified	2
16.	Gellan gum (INS 418)	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: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	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. The information must address: 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. Possible issues for trade: currently unidentified	3
17.	Lycopene (synthetic, INS 160d(i)); and from Blakeslea trispora, INS 160d(iii))	Type of request: Revision of JECFA specifications with regard to the parameter "solubility" Proposed by: EU Specialty Food Ingredients Supported by: To be determined at CCFA52	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,	3

	Substance(s)	General information	Comments about the request	Priority*
		Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: BASF SE Nicola Leinwetter Nicola.leinwetter@basf.com DSM	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	
		Dirk Cremer dirk.cremer@dsm.com	been determined as: "not to be used".	
			Possible issues for trade: currently unidentified	
18.	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	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	3
		Supported by: European Union Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider:	determination of magnesium content and should be replaced by the titration method reported in the Food Chemical Codex monograph or other pharmacopoeia monographs.	
		CEFIC -The European Chemical Industry Council Sofia Serafim (sse@cefic.be)	Possible issues for trade: currently unidentified	
19.	Natamycin (INS 235)	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 natamycin in the GSFA should be reevaluated, 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	1

	Substance(s)	General information	Comments about the request	Priority*
			ensuring food safety.	
			Possible issues for trade: currently unidentified	
	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.	
20.		Type of request: Revise JECFA specifications with	Possible issues for trade: currently unidentified Basis for request: (see CX/FA 21/12)	3
	(INS 451(i))	regard to assay for P ₂ O ₅ and the maximum value for pH Proposed by: CEFIC Supported by: To be confirmed at CCFA52 Year requested: 2021 (CCFA52) Data availability: 2021 Data provider: PAPA Sector Group Manager Miguel Angel Prieto Arranz map@cefic.be	The proposal to revise the maximum values for P_2O_5 and pH would bring the values in alignment with EU Commission Regulation No EU/231/2012. Possible issues for trade: currently unidentified	
21.	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)	Basis for request: (see Appendix 1 of CX/FA 19/51/2 Add. 1) Analysis of all group food additives in the GSFA:	1

	Substance(s)	General information	Comments about the request	Priority*
		Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	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	
22.	Pentasodium triphosphate (INS 451(i))	Type of request: Revision of specifications with regards to (1) revising the assay as P ₂ O ₅ to "not more than 59.0%"; and revising the maximum pH value to 10.2 Proposed by: CEFIC Supported by: To be confirmed at CCFA52 Year Requested: 2021 (CCFA52) Data availability: December 2021 Data provider: Frederic Martens Prayon S.A. rue Joseph Wauters 144 4480 Engis Belgique	i. Align the assay as P2O5 to "not more than 59.0%" 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 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 % P ₂ O ₅ as mentioned in the EU Commission Regulation No EU/231/20125.	3
			ii. Align the maximum pH value to 10.2 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. Possible issues for trade: currently unidentified	
23.	Polyglycerol esters of fatty acids (INS 475)	Type of request: The completeness of the information for safety assessment	Basis for request: The Physical Working Group on GSFA of CCFA	3

	Substance(s)	General information	Comments about the request	Priority*
		Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA52 Data provider: to be confirmed at CCFA52	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.	
24.	Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)	Type of request Re-evaluation of safety. Proposed by: FoodDrinkEurope Supported by: To be confirmed at CCFA52 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	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. Possible issues for trade: currently unidentified	1
25.	Polyoxyethylene (20) sorbitan monolaurate (INS 432), Polyoxyethylene (20) sorbitan monooleate (INS 433), Polyoxyethylene (20) sorbitan monopalmitate (INS 434), Polyoxyethylene (20) sorbitan monostearate (INS 435), Polyoxyethylene (20) sorbitan tristearate (INS 436)	Type of request: Re-evaluation of safety Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	Basis for request: JECFA noted during its 89 th 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. Possible issues for trade: currently unidentified	1
26.	Polyvinyl alcohol (INS 1203)	Type of request 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
27.	Proteolytic enzyme from Bacillus subtilis	Type of request: safety assessment and establishment of specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51)	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	2

	Substance(s)	General information	Comments about the request	Priority
		Data availability: To be confirmed at CCFA52	as flour treatment agent to the list.	
		Data provider: To be confirmed at CCFA52		
28.	Riboflavin from Ashbya	Type of request: Safety assessment and	Basis for request: Alternative source of	2
	gossypii	establishment of specifications	riboflavin for colouring purposes and as nutrient	
		Proposed by: EU Specialty Food Ingredients	source	
		Supported by: European Union		
		Year requested: 2019 (CCFA51)	Possible issues for trade: currently unidentified	
		Data availability: December 2019	, ,	
		Data provider:		
		BASF SE		
		Nicola Leinwetter		
		(nicola.leinwetter@basf.com)		
29.	Rosemary extract (INS 392)	Type of request Data pending – studies required for	Basis for request: Additional studies on	1
		(1) the developmental toxicity of rosemary extract;	developmental toxicity and on noted effects on	
		and (2) determining whether the effects noted on	rodent pup thyroid hormone levels are required to	
		rodent pup thyroid hormone levels can be replicated.	complete the evaluation. JECFA requests a	
		Proposed by: JECFA	deadline of data submission by December 2021	
		Year requested: 2021(CCFA52)	for the additional data, or its ADI will be	
		Data availability: December 2021 (to be confirmed	withdrawn.	
		at CCFA52)		
		Data provider: To be confirmed at CCFA52	Possible issues for trade: currently unidentified	
30.	Sorbitan monostearate (INS	Type of request: Revision of specifications with	Basis for request:	3
	491); Sorbitan tristearate (INS	regards to the congealing range identification	The congealing range identification method as	
	492); Sorbitan monopalmitate	method	reported in the JECFA monographs for INS 491,	
	(INS 495)	Proposed by: European Food Emulsifier	492 and 495 is obsolete, difficult to work with due	
		Manufacturers' Association (EFEMA)	to poor reproducibility, and irrelevant. This	
		Supported by: European Union	identification parameter should be replaced by	
		Year requested: 2019 (CCFA51)	the identification test "acid value, iodine value,	
		Data availability: Immediately	gas chromatography".	
		Data provider:		
		EFEMA	Possible issues for trade: currently unidentified	
		Caroline Rey		
		(efema@ecco-eu.com)		
31.	Sorbitan monostearate (INS	Type of request: Safety re-evaluation and revision	Basis for request:	1
	491); Sorbitan tristearate (INS	of specifications	Previously, a request was made to revise the	
	492); Sorbitan monolaurate	Proposed by: JECFA	specifications for INS 491, 492 and 495 to	
	(INS 493), Sorbitan	Year requested: 2021 (CCFA52)	replace the congealing range identification	
	monooleate (INS 494);	Data availability: To be confirmed at CCFA52	method as reported in the JECFA monographs	

	Substance(s)	General information	Comments about the request	Priority*	
	Sorbitan monopalmitate (INS 495)	Data provider: To be confirmed at CCFA52	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		
32.	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 scodrea@vertosolutions.net	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 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).	2	
			Possible issues for trade: currently unidentified		

	Substance(s)	General information	Comments about the request	Priority*
33.	Steviol glycosides	Type of request: Safety assessment Proposed by: ISC Supported by: To be confirmed at CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2021 (already provided to JECFA) Data provider: ISC Maria Teresa Scardigli (globaloffice@internationalsteviacouncil.org)	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 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. Possible issues for trade: currently unidentified.	2
34.	Sucroglycerides (INS 474)	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	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.	1

	Substance(s)	General information	Comments about the request	Priority'
35.	,	Type of request: exposure assessment	Basis for request: During the discussion on the	4
	(INS 473)	Proposed by: CCFA 51	use of this food additive in FC 05.1.4, one	
		Year requested: 2019 (CCFA51)	member country concern that the proposed use	
		Data availability: December 2019	would result in exposures which exceed the ADI,	
		Data provider: Japan	the physical Working Group on GSFA of CCFA51	
		codex@mext.go.jp	to request for exposure assessment.	
36.	Sucrose oligoesters ,type I	Type of request: exposure assessment	Basis for request: During the discussion on the	4
	and type⊞ (INS 473a)	Proposed by: CCFA 51	use of this food additive in FC 05.1.4, one	
	,	Year requested: 2019 (CCFA51)	member country concern that the proposed use	
		Data availability: December 2019	would result in exposures which exceed the ADI,	
		Data provider: Japan	the physical Working Group on GSFA of CCFA51	
		codex@mext.go.jp	to request for exposure assessment.	
37.	Sucrose esters of fatty acids	Type of request: Data pending - exposure	Basis for request: During the discussion on the	1
	(INS 473)	assessment	use of this food additive in FC 05.1.4, one	
		Proposed by: JECFA	member country concern that the proposed use	
		Year requested: 2021 (CCFA52)	would result in exposures which exceed the ADI,	
		Data availability: December 2023 (to be confirmed	the physical Working Group on GSFA of CCFA51	
		at CCFA52)	to request for exposure assessment.	
		Data provider : Japan (to be confirmed at CCFA52)		
		codex@mext.go.jp	At the 89 th JECFA meeting, JECFA considered	
			that more refined dietary exposures should be	
			provided. Specifically, JECFA recommends that	
			sponsors provide information on:	
			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.	
			·	
			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	

	Substance(s)	General information	Comments about the request	Priority*
			the request for information, the JECFA proposes that the data be available 2 years after the date of confirmation.	
38.	Sucrose oligoesters ,type I	Type of request: Data pending - exposure	Possible issues for trade: currently unidentified Basis for request: During the discussion on the	1
36.	and typeⅡ (INS 473a)	assessment Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2023 (to be confirmed at CCFA52) Data provider: Japan (to be confirmed at CCFA52) codex@mext.go.jp	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. At the 89th JECFA meeting, JECFA considered that more refined dietary exposures should be provided. Specifically, JECFA recommends that sponsors provide information on: 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.	1
			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 that the data be available 2 years after the date of confirmation. Possible issues for trade: currently unidentified	
39.	Tannins (oenological tannins)	Type of request: Data pending to complete evaluation – Evaluation by JECFA84	Basis for request: In order to complete its	2

General information	Comments about the request	Priority*
Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52	 evaluation, JECFA requires information on: The following information is required: 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. 	
	Possible issues for trade: currently unidentified	
Type of request: Safety assessment and establishment or revision of specifications, as the case may be Proposed by: CCC Supported by: To be confirmed at CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: NOMAD Bioscience GmbH Jurijus (Yuri) Gleba, Ph.D gleba@nomadbioscience.com Centre for regulatory Services Inc. Kristi O. Smedley, Ph.D. smedley@cfr-services.com DT/Consulting Group Daniel Tusé, Ph.D.	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 thaumatins are extracted from Thaumatococcus daniellii 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 thaumatins, especially as sweeteners. NOMAD's manufacturing process does not deplete natural resources and can be scaled to meet increasing demand for thaumatin. THAUMATIN II is NOMAD Bioscience's single thaumatin-family protein	2
	Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52 Data provider: To be confirmed at CCFA52 Type of request: Safety assessment and establishment or revision of specifications, as the case may be Proposed by: CCC Supported by: To be confirmed at CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: NOMAD Bioscience GmbH Jurijus (Yuri) Gleba, Ph.D gleba@nomadbioscience.com Centre for regulatory Services Inc. Kristi O. Smedley, Ph.D. smedley@cfr-services.com DT/Consulting Group	Proposed by: CCFA50 Year requested: 2018 (CCFA50) Data availability: To be confirmed at CCFA52 Data provider: Data provider: Safety assessment and establishment or revision of specifications, as the case may be Proposed by: CCC Supported by: To be confirmed at CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: NOMAD Bioscience GmbH Jurijus (Yurr) Gleba, Ph.D gleba@nomadbioscience.com DT/Consulting Group evaluation, JECFA requires information on: The following information is required: Composition of tannins derived from the full range of raw materials as well as the processes used in their manufacture; Validated analytical meethod(s) and relevant quality control data; Analytical data from five batches of each commercial product including information is required: Validated analytical meethod(s) and relevant quality control data; Analytical data from five batches of each commercial product including information is required: Validated analytical meethod(s) and relevant quality control data; Analytical data from five batches of each commercial product including information on: The following information is required: Composition of tannins derived from the full range of raw materials as well as the processes used in their manufacture; Validated analytical meethod(s) and relevant quality control data; Analytical

Substance(s)	General information	Comments about the request	Priority*
	Calorie Control Council Ray DeVirgiliis, MPH rdevirgiliis@caloriecontrol.org	benthamiana; 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. 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 safety determination, so that other regulatory jurisdictions can rely on this assessment	

S	Substance(s)	General information	Comments about the request	Priority*
41. T	itanium dioxide (INS 171)	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	 Basis for request: The EFSA has recently published a re-evaluation of titanium dioxide, with the key messages: 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. Given the above, and that the previous JECFA assessment is from 1969, JECFA will issue a call for data in the summer of 2021 for the purpose of its re-evaluation. This is an open call for data and details on the scope of the data requirements will be set out in the call for data. Possible issues for trade: currently unidentified. 	1

^{*} CCFA50⁴ 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.

⁴ <u>REP 18/FA</u>, para 156.

CL 2021/61-FA

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	FEMA	JECFA	CAS	Principle Name	Structural
History	No	No			class
Submitted at CCFA52	4902		22122-36-7	3-Methyl-2(5 <i>H</i>)-furanone	Ш
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	1
Submitted at CCFA52	4887		56219-03-5	cis-9-Dodecenal	1
Submitted at CCFA52	4918		68820-38-2	Tridec-5-enal	1
Submitted at CCFA52	4886		126745-61-7	cis-6-Dodecenal	1
Submitted at CCFA52	4904		115018-39-8	trans-Tetradec-4-enal	1
Submitted at CCFA52	4905		2119671-25-7	2,6-Dimethylheptenyl formate	1
Submitted at CCFA52	4885		68820-34-8	trans-5-Dodecenal	1
Submitted at CCFA52	4898		41547-29-9	trans-5-Octenal	1
Submitted at CCFA52	4891		2088117-65-9	(E)-3-Methyl-4-dodecenoic acid	1
Submitted at CCFA52	4917		22032-47-9	(Z)-9-Dodecenoic acid	1
Submitted at CCFA52	4926		65398-36-9	(Z)-8-Pentadecenal	1
Submitted at CCFA52	4841		16676-96-3	cis-5-Dodecenyl acetate	1
Submitted at CCFA52	4784		57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	1
Submitted at CCFA52	4939		2180135-09-3	S-Methyl 5-(1-ethoxyethoxy)decanethioate	1
Submitted at CCFA52	4894		116229-37-9	2-Mercapto-3-methyl-1-butanol	1
Submitted at CCFA52	4883		556-27-4	S-Allyl- <i>L</i> -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	1
Submitted at CCFA52	4938		2180135-08-2	S-Methyl 5-(1-ethoxyethoxy)tetradecanethioate	1
Submitted at CCFA52	4901		2097608-89-2	O-Ethyl S-(3-methylbut-2-en-1-yl)thiocarbonate	1
Submitted at CCFA52	4900		64580-54-7	Hexyl propyl disulphide	1
Submitted at CCFA52	4914		24963-39-1	bis-(3-Methyl-2-butenyl)disulphide	III
Submitted at CCFA52	4889		3877-15-4	Methyl propyl sulphide	1
Submitted at CCFA52	4903		26516-27-8	Ethyl 3-methyl-2-oxopentanoate	1
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	1
Submitted at CCFA52	4888		1945993-01-0;	Mixture of 5-hydroxy-4-(4'-hydroxy3'-methoxyphenyl)-7-methylchroman-2-	Ш
			828265-08-3	one and 7-hydroxy-4-(4'-hydroxy3'-methoxyphenyl)-5-methylchroman-2-one	
Submitted at CCFA52	4879		21145-77-7	1-(3,5,5,6,8,8-Hexamethyl-5,6,7,8- tetrahydronaphthalen-2- yl)ethanone	П
Submitted at CCFA52	4893		4912-58-7	2-Ethoxy-4-(hydroxymethyl)phenol	1
Submitted at CCFA52	4892		4707-61-3	cis-2-Hexylcyclopropaneacetic acid	П
Submitted at CCFA52	4890		27841-22-1	3-p-Menthen-7-al	1
Submitted at CCFA52	4928		554-14-3	2-Methylthiophene	П

CCFA Listing	FEMA	JECFA	CAS	Principle Name	Structural
History	No	No			class
Submitted at CCFA52	4839		163460-99-9; 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	
Submitted at CCFA52	4813		1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	П
Submitted at CCFA52	4884		1569-60-4	6-Methyl-5-hepten-2-ol	1
Submitted at CCFA52	4827		6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	1
Submitted at CCFA52	4869		886449-15-6	4-(<i>L</i> -Menthoxy)-2-butanone	II
Submitted at CCFA52	4844		118026-67-8	(2E,4E)-2,4-Decadien-1-ol acetate	1
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-Benzyloxypropyl)pyridine	III
Submitted at CCFA52	4829		616-45-5	2-Pyrrolidone	
Submitted at CCFA52	4818		1370711-06-0	trans-1-ethyl-2-methylpropyl 2-2-butenoate	1
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	Ш
Submitted at CCFA52	4807		1078-95-1	Pinocarvyl acetate	II
Submitted at CCFA52	4906		36687-82-8	L -Carnitine tartrate	III
Submitted at CCFA52	4868		61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5H)-furanone	III
Submitted at CCFA52	4896		2186611-08-3	<i>N</i> -(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	Ш
Submitted at CCFA52	4882		1857330-83-9	N-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at CCFA52	4899		1622458-34-7; 2079034-28-7	N-(1-((4-amino-2,2-dioxido-1 <i>H</i> -benzo[c][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	N-(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at CCFA52	4877		76733-95-4	(E)-3-(3,4-Dimethoxyphenyl)-N-[2-(3-methoxyphenyl)-ethyl]-acrylamide	III
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	FEMA	JECFA	CAS	Principle Name	Structural
History	No	No			class
Submitted at CCFA43	4074		6321-45-5	Allyl valerate	II
Submitted at CCFA43	4072		20474-93-5	Allyl crotonate	
Submitted at CCFA45	4688		105-82-8	1,1-Dipropoxyethane	
Submitted at CCFA43	4432		25334-93-4	(±) Acetaldehyde ethyl isopropyl acetal	
Submitted at CCFA43	4528		6986-51-2	Acetaldehyde ethyl isobutyl acetal	
Submitted at CCFA43	4527		5669-09-0	Acetaldehyde di-isobutylacetal	
Submitted at CCFA43	4335		10486-19-8	Tridecanal	
Submitted at CCFA43	4334		1002-84-2	Pentadecanoic acid	
Submitted at CCFA43	4336		638-53-9	Tridecanoic acid	
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	
Submitted at CCFA45	4673		7370-44-7	delta-Hexadecalactone	
Submitted at CCFA45	4749		35852-42-7	4-Methylpentyl4-methylvalerate	
Submitted at CCFA45	4346		180348-60-1	5-Methylhexyl acetate	
Submitted at CCFA45	4347		850309-45-4	4-Methylpentyl isovalerate	
Submitted at CCFA45	4343		25415-67-2	Ethyl 4-methylpentanoate	
Submitted at CCFA45	4344		2983-38-2	Ethyl 2-ethylbutyrate	
Submitted at CCFA45	4345		2983-37-1	Ethyl 2-ethylhexanoate	
Submitted at CCFA45	4735		13552-95-9	(4Z, 7Z)-Trideca-4,7-dienal	
Submitted at CCFA45	4682		23333-91-7	Octahydro-4,8a-dimethyl-4a(2 <i>H</i>)-naphthol	
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	S-[(methylthio)methyl]thioacetate	
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
Submitted at CCFA51	4823		33368-82-0	1-Propenyl 2-propenyl disulfide	ll l
Submitted at CCFA51	4782		1679-06-7;	2/2) Havanathial	
			1633-90- 5	2(3)-Hexanethiol	
Submitted at CCFA51	4779		1416051-8-1	(±)-2-Mercapto-5-methylheptan-4-one	
Submitted at CCFA51	4792		548740-99-4	(±)-3-Mercapto-1-pentanol	
Submitted at CCFA51	4791		22236-44-8	3-(Acetylthio)hexanal	III
Submitted at CCFA51	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone	

CCFA Listing	FEMA	JECFA	CAS	Principle Name	Structural
History	No	No			class
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	cis-3-Hexenyl salicylate	I
Submitted at CCFA45	4700		614-60-8	o-trans-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-tert-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	beta-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
Submitted at CCFA45	4486		5694-82-6	Citral glyceryl acetal	

Priority list of 29 flavours proposed for inclusion on the JECFA Priority List to be considered for <u>revision of specifications</u> 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 Lisomer but the substance is a mixture of D and Lisomers, 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-(<i>L</i> -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	<i>p</i> -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
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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
						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 be142-19-8
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 (cis and trans 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	trans-3-Heptenyl acetate	1997 (Session 49)	The CAS number for the trans-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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	SIMPLE ALIPHATIC AND AROMATIC SULFIDES AND THIOLS		J20	TRS 896 TRS 922 TRS 947 TRS 960 TRS 974		
Old	4730		1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate		
Old	4733		1006684-20-3	(±)-2-Mercaptoheptan-4-ol		
Old	4734		1256932-15-6	3-(Methylthio)-decanal		
Old	4760		53626-94-1	Prenyl thioisobutyrate		
Old	4761		75631-91-3	Prenyl thioisovalerate		
Old	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone		
Old	4779		1416051-88-1	(±)-2-Mercapto-5-methylheptan-4-one		
Old	4782		1679-06-7; 1633-90-5	2(3)-Hexanethiol		
Old	4791		22236-44-8	3-(Acetylthio)hexanal		
Old	4792		548740-99-4	(±)-3-Mercapto-1-pentanol		
Old	4817		38634-59-2	S-[(methylthio)methyl]thioacetate		
Old	4822		61407-00-9	2,6-Dipropyl-5,6-dihydro-2H-thiopyran-3-carboxaldehyde		
Old	4823		33368-82-0	1-Propenyl 2-propenyl disulfide		
Old	4824		1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate		
Old	4828		729602-98-6	1,1-Propanedithioacetate		
Old	4836		137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol		
Old	4842		911212-28-7	2,4,5-Trithiaoctane		
Old	4843		1838169-65-5	3-(Allyldithio) butan-2-one		
Old	4870		17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane		
	PHENC	L AND PH	ENOL DERIVATIV	/ES	J2 4	TRS 901 TRS 960 TRS 974
Old	4228		4 62631-45-4	(-)-Homoeriodictyol, sodium salt		
Old	4797		480-41-1	(±)-Naringenin		
Old	4799		1449417-52-0	(2R)-3',5-Dihydroxy-4'-methoxyflavanone		
Old	4830		38183-03-8	7,8-Dihydroxyflavone		
Old	4833		87733-81-1	(2S)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan		
Old	4834		1796034-68-2	(R)-5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one		
Old	4872		35400-60-3	3-(3-Hydroxy-4-methoxy-phenyl)-1-(2,4,6-trihydroxyphenyl)propan-1- one		
	HYDRO	XY- AND	ALKOXY-SUBSTI	TUTED BENZYL DERIVATIVES	J29	TRS 909

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	110	110			110	TRS 952
Old	4430		99-50-3	3,4-Dihydroxybenzoic acid		
Old	4431		99-06-9	3-Hydroxybenzoic acid		
Old	4435		673-22-3	2-Hydroxy-4-methoxybenzaldehyde		
Old	4606		930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate		
Old	4622		61683-99-6	Piperonal propyleneglycol acetal		
Old	4627		6414-32-0	Anisaldehyde propyleneglycol acetal		
Old	4700		614-60-8	o-trans-Coumaric acid		
Old	4750		65405-77-8	cis-3-Hexenyl salicylate		
Old	4810		60563-13-5	Ethyl-2-(4-hydroxy-3-methoxy-phenyl)acetate		
Old	4826		10525-99-8	3-Phenylpropyl 2-(4-hydroxy-3-methoxy-phenyl)acetate		
Old	4871		1962956-83-7	2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate		
	ALICY	CLIC KETO	NES, SECONDAF	RY ALCOHOLS AND RELATED ESTERS	J36	TRS 913 TRS 960
Submitted at CCFA51	4724		21862-63-5	trans-4-tert-Butyleyclohexanol		
Submitted at CCFA51	4780		38284-26-3	Caryophylla-3(4),8-dien-5-ol		
	AMINO	ACIDS AN	ID RELATED SUB		J49	TRS 928 TRS 974
Old	4223		107-43-7	Betaine		
Old	4738		16869-42-4	Glutamyl-2-aminobutyric acid		
Old	4739		38837-71-7	Glutamyl-norvalyl-glycine		
Old	4740		71133-09-0	Glutamyl-norvaline		
Old	4752		1188-37-0	N-Acetyl glutamate		
Old	4781		18598-63-5	L-Cysteine methyl ester hydrochloride		

CCFA Listing	FEMA	JECFA	CAS	Principle Name	Group	TRS
History	No	No			No	No
	ALICYCLIC PRIMARY ALCOHOLS, ALDEHYDES, ACIDS AND RELATED ESTERS (RE-EVALUATION)				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 rd -JECFA	Full	Secondary components
Old	4085	1575	1139-30-6	beta-Caryophyllene oxide	65 th JECFA	Full	Updated isomeric composition
Old	4249	1604	99583-29-6	2-Acetylpyrroline	65 th JECFA	Full	Updated assay value, CAS number and secondary components
Old	4668	2077	504-48-3; 25394-57-4	(2E,6E/Z,8E)-N-(2-Methylpropyl)- 2,6,8-decatrienamide	76 th JECFA	Full	Updated isomeric mixture
Old	3352	1125	2497-21-4	4-Hexen-3-one	59 th JECFA	Full	Updated assay value and isomeric composition
Old	2249	380.1	2244-16-8	d-Carvone	86 th JECFA	Tentative	Updated refractive index
Old	3317	1491	3777-69-3	2-Pentylfuran	86 th JECFA	Full	Updated specific gravity range and assay value
Old	2494	1497	623-30-3	3-(2-Furyl)acrolein	86 th JECFA	Full	Updated melting point range
Old	3586	1502	65545-81-5	2-Phenyl-3-(2-furyl)prop-2-enal	86 th JECFA	Full	UpddatedAssay value and physical and odor descriptions
Old	3609	1504	1193-79-9	2-Acetyl-5-methylfuran	86 th JECFA	Full	Updated Physical appearance description; specific gravity
Old	3391	1506	10599-70-9	3-Acetyl-2,5-dimethylfuran	86 th JECFA	Full	Updated Specific gravity range
Old	2495	1511	623-15-4	4-(2-Furyl)-3-buten-2-one	86 th JECFA	Full	Updated Physical appearance and melting point range
Old	2435	1513	10031-90-0	Ethyl 3-(2-furyl)propanoate	86 th JECFA	Full	Updated Physical form, refractive index and specific gravity
Old	2865	1517	7149-32-8	Phenethyl 2-furoate	86 th JECFA	Full	Updated Refractive index and specific gravity ranges; physical appearance

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

No	Substance(s)	General information	Comments about the request
	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
	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
	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 oryzacis 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
	D-Allulose 3-epimerase from Arthrobacter 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
	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	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
	Alpha-amylase from Bacillus stearothermophilus expressed in Bacillus licheniformis	(lisa.jensen@dupont.com) 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
	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
	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
	Asparaginase from Aspergillus niger expressing	Type of request: Safety assessment and establishment of specifications Proposed by: European Union	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.

No	Substance(s)	General information	Comments about the request
	a modified gene from	Year requested: 2014 (CCFA46)	Possible issues for trade: currently unidentified
	Aspergillus niger	Data availability: December 2018	
		Data provider:	
		DSM Food Specialties	
		Dr. Mariella Kuilman	
		(mariella.kuilman@dsm.com)	
	Asparaginase from	Type of request: Safety assessment and	Basis for request: The enzyme is indicated as a
	Pyrococcus furiosus	establishment of specifications	thermotolerant enzyme used to convert asparagine to
	expressed in Bacillus subtilis	Proposed by: European Union	aspartic acid to reduce acrylamide formation in the course of
	expressed in Dacinus subtins	Year requested: 2015 (CCFA47)	baking processes, cereal-based processes, fruit and
		Data availability: December 2018	vegetable processing, and coffee and cocoa processing.
		Data provider:	Possible issues for trade: currently unidentified
		Novozymes A/S	
		Tine Vitved Jensen	
		(tvit@novozymes.com)	
	Beta-amylase from Bacillus	Type of request: Safety assessment and	Basis for request: The enzyme is used for the hydrolysis of
	flexus expressed in Bacillus	establishment of specifications	starch during the processing of starch-containing foods.
	licheniformis	Proposed by: European Union	Possible issues for trade: currently unidentified
	lichermonnis	Year requested: 2016 (CCFA48)	
		Data availability: December 2018	
		Data provider:	
		Novozymes A/S	
		Mr. Peter Hvass	
		(phva@novozymes.com)	
	Beta-glucanase from	Type of request: Safety assessment and	Basis for request: The enzyme is used in the production of
	Streptomyces violaceoruber	establishment of specifications	yeast extract products. It is indicated that by disrupting cell
	expressed in S.	Proposed by: Japan	walls, an increased yield of yeast extract can be obtained,
	violaceoruber	Year requested: 2016 (CCFA48)	and bacterial contamination during manufacturing is reduced.
	Troide de l'abor	Data availability: December 2018	Possible issues for trade: currently unidentified
		Data provider:	
		Nagase ChemteX Corporation	
		Mr. Kensaku Uzura	
		(kensaku.uzura@ncx.nagase.co.jp)	Paris famous word Thank at the first transfer of
	Chysomis from Camelus	Type of request: Safety assessment and	Basis for request: The chymosin catalyze the hydrolysis, at
	dromedaries expressed in	establishment of specifications	a very particular site in the amino acid chain, of κ-casein - the
	Aspergillus niger	Proposed by: Japan	main protein in milk. This is the absolute first key step in all
		Year requested: 2021 (CCFA52)	cheese-making, through which the liquid milk is coagulated
		Data availability: December 2021	(precipitated) and converted to a semi-solid form by the
		Data provider:	catalytic action of coagulants, such as chymosin. Therefore,

No	Substance(s)	General information	Comments about the request
		Chr-Hansen A/S Christina Westphal Christensen dkchwe@chr-hansen.com	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
	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@nex.nagase.co.ip)	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
	Endo-1,4-ß-xylanase from Bacillus subtilis produced by B. subtilis 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
	Endo-1,4-ß-xylanase from Pseudoalteromonas haloplanktis produced by B. subtilis, 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

No	Substance(s)	General information	Comments about the request
	Endo-1,4-ß-xylanase from Thermotoga maritima produced by <i>B. 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	Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified
	Glucose oxidase from Penicillium chrysogenum expressed in Aspergillus niger	(bverhagen@puratos.com) 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	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
	Glutaminase from Aspergillus niger	(jack.reuvers@dsm.com) 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	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
	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

No	Substance(s)	General information	Comments about the request
	Lactase from Bifidobacterium	Type of request: Safety assessment and	Basis for request: The lactase enzyme preparation is used
		establishment of specifications	as a processing aid during food manufacture for hydrolysis of
	bifidum expressed in Bacillus licheniformis	Proposed by: European Union	lactose during processing of milk and other lactose
	licheniionnis	Year requested: 2017 (CCFA49)	containing dairy products, e.g. in order to obtain lactose-
		Data availability: December 2018	reduced milk products for lactose-intolerant individuals as
		Data provider:	well as dairy products with better consistency and increased
		Puratos NV	sweetness due hydrolysis of lactose to form glucose and
		Bas Verhagen	galactose.
		(bverhagen@puratos.com)	Possible issues for trade: currently unidentified
		Type of request: Safety assessment and	Basis for request: The enzyme is used as a processing aid
	Lipase from Aspergillus	establishment of specifications	during food manufacture for hydrolysis of lipids during
	oryzae expressing a modified	Proposed by: European Union	processing of lipid-containing foods, e.g., in order to improve
	gene from Thermomyces	Year requested: 2016 (CCFA48)	dough strength and stability in baking and other cereal based
	lanuginosus	Data availability: December 2018	processes.
		Data provider:	Possible issues for trade: currently unidentified
		Puratos NV	Tools locate for trader carrottily armacritimed
		Bas Verhagen	
		(bverhagen@puratos.com)	
		Type of request: Safety assessment and	Basis for request: The enzyme catalyzes the hydrolysis of
	Lipase from <i>Mucor javanicus</i>	establishment of specifications	mono-, di- and triglycerides containing short-, medium-, and
		Proposed by: Japan	long-chain fatty acid moieties, providing various sensory
		Year requested: 2017 (CCFA49)	benefits in processed dairy products, processed baking
		Data availability: December 2018	products, and processed egg products.
		Data provider:	Possible issues for trade: currently unidentified
		Amano Enzyme Inc.	Tools locate for trader carrottily armacritimed
		Mr. Tomonari Ogawa	
		(tomonari_ogawa@amano-enzyme.com)	
		Type of request: Safety assessment and	Basis for request: The enzyme hydrolyzes
	Phosphatidyl inositol-specific	establishment of specifications	phosphatidylinositol present in vegetable oil, thereby
	phospholipase C from a	Proposed by: European Union	reducing its concentration. PI negatively impacts taste,
	genetically modified strain of	Year requested: 2016 (CCFA48)	colour, and stability of vegetable oil, while the hydrolytic
	Pseudomonas fluorescens	Data availability: December 2018	products do not.
		Data provider:	Possible issues for trade: currently unidentified
		DSM Food Specialties	Todalate located for trade, buttering aniacritimed
		Dr. Mariella Kuilman	
		(mariella.kuilman@dsm.com)	
		Type of request: Safety assessment and	Basis for request: The enzyme is used in processing yeast
	Phosphodiesterase from	establishment of specifications	products by hydrolysing RNA, thereby increasing
	Penicillium citrinum		
	Penicillium citrinum	Proposed by: Japan	ribonucleotide levels and improving umami flavour

No	Substance(s)	General information	Comments about the request
-		Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari ogawa@amano-enzyme.com)	Possible issues for trade: currently unidentified
	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
	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
	Protease Aqualysin 1 from Thermus aquaticus produced by B. subtilis, 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

No	Substance(s)	General information	Comments about the request
	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, 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.
	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)	Possible issues for trade: currently unidentified 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
	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