



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES
Fifty-second Session

**PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES
PROPOSED FOR EVALUATION BY JECFA**

REPORT OF IN SESSION WG CHAIR ON THE JECFA PRIORITY LIST

(CX/FA 21/52/2 Add.1; CX/FA 21/52/12; 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 21/52/7 Add.1; CX/FA 21/52/12 Add.1; CRD2)

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 of substances proposed for evaluation by JECFA* (hereafter referred to as the "Priority List"), as shown in 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

In preparation of this report, the Priority List was circulated for comment as part of CL 2021/61-FA. Comments received by Members and Observers are compiled in CX/FA 21/52/12 Add.1.

Regarding CX/FA 21/52/7 Add.1 and CRD2, questions to JECFA on a revised exposure assessment approach to certain colourings and sweeteners, developed by the ICBA, were forwarded to the working group on JECFA Priorities.

Discussion of comments received and recommendations

Titanium dioxide (INS 171): In response to a reassessment of the safety of titanium dioxide by the European Food Safety Authority (EFSA)³, the JECFA Secretariat anticipates issuing a call-for-data for purposes of conducting its own re-evaluation. Comments provided to CL 2021/61-FA were very supportive of placing the highest priority on this re-evaluation exercise. One Member noted that although new specifications for titanium dioxide were established in 2012, the last toxicological assessment was conducted in 1969. Further, it was noted that titanium dioxide is a widely used additive and so the expected revocation of the use of titanium dioxide as a food additive in the European Union presents a significant potential for a disruption in trade.

One Member requested clarification from the JECFA Secretariat on the proposed timelines for the call for data and the subsequent re-evaluation. Clarification has been sought from the JECFA Secretariat, and it has been indicated 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). Accordingly, the scope of the request has been amended with this additional information, as presented in Table 1 of Annex 1. The request for this substance is subject to Recommendation 5, below.

Aspartame (INS 951), Acesulfame (INS 950), Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), Annatto extracts, norbixin based (INS 160b(ii)): Regarding the discussion of recommendation in CRD2, the Committee agreed to forward questions to JECFA on the suitability of a refined exposure assessment method provided by the ICBA, and that a re-evaluation of exposure be conducted for INS 950, 954(i)-(iv), 123, and 160b(ii). Accordingly, the "basis for request" for aspartame has been modified with the addition of the comment "The re-evaluation of this substance is subject to the advice from JECFA on sweeteners and

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>.

³ <https://www.efsa.europa.eu/en/efsajournal/pub/6585>.

colours, as described for INS 954(i)-(iv), 123, and 160b(ii).” These modifications are found in item No. 2 of Table 1 to Annex 1, below. The request for these substances is subject to Recommendation 5, below.

Lead specifications for diatomaceous earth, charcoal (activated carbon) and bentonite: As part of CX/FA 21/52/2 Add. 1, the CCFA noted the request by the CCCF to request that JECFA review the lead specifications for diatomaceous earth and activated carbon, and establish lead specifications for bentonite. Because diatomaceous earth is recognized as a filtration aid, activated carbon is recognized as an adsorbent and decolourizing agent, these substances have been included in Table 2 of Annex 1 (processing aids). Bentonite (INS 558) does have recognized use as an anti-caking agent and has therefore been included in Table 1 of Annex 1. One Member offered support for the proposal, but further suggested that the scope of the request should include examination of the use of the substances in water purification processes.

Recommendation 1

Add the substances subject to the request from CCCF set out in 21/52/2 Add. 1 to the draft JECFA Priority List (Tables 1 and 2 of Annex 1).

THAUMATIN II: One Member, one Member Organization, and two Observers provided comments in reply to the questions posed in paragraph 7 of CL 2021/61-FA. There was no clear agreement that the definition for thaumatin (INS 957) and thus the specifications could be expanded to include THAUMATIN II, or if—because of the distinct method of production and starting materials—that new specifications and INS designation should be developed. The comment from the Member suggested that the JECFA should determine whether or not the previous safety assessment for thaumatin is adequate to address the safety of THAUMATIN II.

In light of the comments received, the working group chair has consulted with the JECFA Secretariat. The JECFA Secretariat indicated that it will be for the JECFA to determine whether the specifications and the safety evaluation needs to be updated. Therefore, the request has been included on the JECFA Priority List in Table 1 to Annex 1 with the “Type of request” described as “Safety evaluation”. The request for this substance is subject to Recommendation 5, below.

Rosemary extract (INS 392): One Member expressed concern that the JECFA ADI will be withdrawn if data are not provided by December 2021. The Member expressed that it is important to establish the ADI for rosemary extract with as much evidence as possible, and thus proposes more time for the collection of information. Also, the Member considers that the temporary ADI is suitably precautionous given the application of robust uncertainty factors. One Observer confirmed that data would be available by 2022. The working group chair has consulted with the JECFA Secretariat to the possibility of applying a stay on the confirmation of a data provider until CCFA53 or later. The JECFA Secretariat has indicated that the JECFA would consider extensions of the ADI based on the reasonable commitment to provide data, but that it is at its discretion to withdraw (temporary) ADIs. As a result of this clarification, INS 392 has been retained on the JECFA Priority List (Table 1 of Annex 1). The request for this substance is subject to Recommendation 5, below.

Substances without confirmation of the provision of data: There are 16 requests⁴ on the JECFA Priority List for which Members have offered support, but there has not been information provided regarding who would be able to provide data for JECFA’s consideration. Without a confirmed commitment to provide data within a given calendar year, the JECFA cannot reasonably be expected to include the substance in their annual call-for-data, for evaluation by their subsequent meeting. Further, in order to manage the increasingly expanding JECFA Priority List, substances should not be included in the list if there is no urgency to support their evaluation. The usual approach at an in-session working group on JECFA priorities would be to remove requests from the list, and encourage their re-addition to the list once it is known that data will be available. That said, given (1) the complexity of the approach to managing the JECFA Priority List this year, via a circular letter, and (2) that it could be unreasonably drastic to remove 16 requests from the List, many of whose inclusions are supported by Members, it is proposed for this year to retain these requests on the JECFA Priority List, with an expected confirmation of data by CCFA53. There should be an understanding

⁴ Anionic methacrylate copolymer (AMC) [INS 1207]; Neutral methacrylate copolymer (NMC) [INS 1206]; Azodicarbonamide [INS 927a]; Black carrot extract [INS 163(vi)]; L-cysteine hydrochloride [INS 920]; Dioctyl sodium sulfosuccinate [INS 480]; Fulvic acid (carbohydrate derived); Fungal amylase from *Aspergillus niger*; ORTHO-PHENYLPHENOLS [INS 231 and 232]; Polyglycerol esters of fatty acids [INS 475]; POLYSORBATES [INS 432, 433, 434, 435, 436]; Proteolytic enzyme from *Bacillus subtilis*; SORBITAN ESTERS OF FATTY ACIDS [INS 491, 492, 493, 494, 495]; Rosemary extract [INS 392]; Sucroglycerides [INS 474]; Tannins (oenological tannins).

that without the confirmation of data availability, the substances will likely not be subject to JECFA's upcoming call-for-data.

It should be noted that one Member Organization has specifically requested that azodicarbonamide (INS 927a), should there be no commitment to provide data, be removed from the GSFA and Codex commodity standards. This is because of the revocation of the permission to use INS 927a in certain jurisdictions due to safety concerns, and because the previous JECFA assessment was conducted in 1965; therefore, a re-evaluation is necessary to retain provisions in the GSFA. The working group chair proposes that, as described in the previous paragraph, confirmation of the provision of data should be deferred to CCFA53. That said, the CCFA should be mindful that this request has a high priority ranking (priority "1"), and as such, the CCFA53 should carefully consider appropriate risk-mitigation actions (including removal of the request from the JECFA Priority List, an examination of the uses of the additives) should a confirmation of the provision of data not be available by CCFA53.

Recommendation 2:

- (i) For all substances for which at least one Member or Member Organization has supported the request, but for which no confirmation of the provision of data has been made, retain the requests on the JECFA Priority List, with a new date for the confirmation of data availability at CCFA53.
- (ii) For CCFA52 to note that during the development of the JECFA Priority List at CCFA53, the absence of a commitment to provide data suggests that the request is not urgent and that it should be removed from the JECFA Priority List.
- (iii) For CCFA52 to note that the removal of requests from the JECFA Priority List may require the Committee to consider subsequent risk-management options for provisions in the GSFA or in the Step process, including an examination if the additives are in use.

Carob bean gum (INS 410): One Member Organization remarked on recent findings of the presence of ethylene oxide in preparations of carob bean gum. The working group chair suggests that public health concerns should be further substantiated, and that if the Member Organization would like for JECFA to consider the matter further that the Member Organization should be listed as a data provider. The JECFA Secretariat does not support that JECFA conducts an extensive literature review on its own. Accordingly, the request for INS 410 in Table 1 of Annex 1 has not been revised. The request for this substance is subject to Recommendation 5, below.

Pentasodium triphosphate (INS 451(i)): A duplicate listing for this substance was included in Table 1 of Annex 1. The 2nd entry better reflects the information provided by CEFIC in CX/FA 21/52/12 and is proposed to be retained, while the other entry is proposed to be deleted (see Recommendation 5).

Benzoic acid and its salts (INS 210-212): One Member raised the concern that benzoic acid and its salts have been removed from the JECFA Priority List, but that this is a high-priority request and should be retained on the list. As a matter of clarification, JECFA has completed its evaluation at its 92nd meeting; and the outcome is set out in the *Summary report of the ninety-second meeting of JECFA*.⁵

Ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232): One Member Organization remarked that there this ongoing discussion on the classification of these substances as food additives (as per matter of interest arising from the JECFA87). Further, the current request is at the behest of the JECFA, in order to complete a safety re-evaluation. It would therefore seem inappropriate to remove the request from the JECFA Priority List, based on a potential concern related to their classification.

Recommendation 3:

- (i) Retain INS 231 and 232 on the JECFA Priority List.
- (ii) For the CCFA52 to note that any discussions on the classification of these substances as food additives should occur as a separate matter outside of the working group on JECFA Priorities.

Alpha-amylase: In CL 2021/61-FA, the working group chair asked for clarification if the call-for-data for alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus* would include the similar source *Bacillus stearothermophilus* expressed in *Bacillus licheniformis*. One supporting Member Organization confirmed that the principal enzyme substances are different and that the former substance (modified alpha-amylase) should be retained in Table 2 of the JECFA Priority List. Therefore, no changes have been made to the list in Annex 1.

⁵ Summary and Conclusions of the 92nd JECFA meeting: <http://www.fao.org/3/cb5597en/cb5597en.pdf>.

Glutaminase from *Aspergillus niger*: One Member Organization raised concerns about the use of glutaminase to produce L-glutamate-rich yeast extracts and protein hydrolysates, and such ingredients could in turn be used to bypass regulatory rules applicable to the use of L-glutamate (and its salts).

The working group chair does not share the Member Organization's concerns due to a number of considerations, including:

- Glutamates (INS 620-625) are already permitted in a variety of foods at GMP;
- The use of an ingredient enriched in L-glutamate would presumably also be used at GMP, consistent with glutamates;
- Consumers sensitive to glutamates should be aware of and avoid the many foods that are natural sources of glutamates in food, including cheese, seafood and fish and oyster sauces; nuts; processed meats; bread, whole-wheat flour, tomatoes, yeast extracts and protein hydrolysates, etc.;
- The working group chair is of the opinion that the addition of glutamate and ingredients rich in glutamates to processed foods should be subject to clear labelling legislation and consumer education.

In considering the factors above, the request for glutaminase from *A. niger* on the JECFA Priority List as set out in Table 2 of Annex 1 has not been amended.

Prioritization ranking of certain additives: Some Members commented on the priority ranking on certain requests set out in the JECFA Priority List. As a matter clarification, CCFA50 established that a Priority 1 request is relevant to the re-evaluation of an additive based on an identified safety concern. Priority 2 is relevant to the evaluation of additives for the purpose of populating the GSFA. In consideration of this, no changes to the priority rankings are proposed. Furthermore, many of the noted requests are subject to on-going JECFA evaluation, meaning that the priority ranking was relevant to the request when the substance was added to the JECFA Priority List, but is no longer relevant. The JECFA will continue with their evaluations once it receives the pending data.

Spirulina extract (INS 134): One Member requested that spirulina extract be added back to the JECFA Priority List given that data will be available by December 2021. The JECFA had placed this substance on its call-for-data for its 92nd meeting⁶, which would normally result in the removal of the request from the Priority List. However, due to resource and travel restrictions, several substances originally scheduled for discussion were not considered (CX/FA 21/52/3). In order to ensure that the request is maintained, it has been reintroduced onto the JECFA Priority List (Table 1 of Annex 1), and is subject to Recommendation 5, below.

Natamycin (INS 235) and Nisin (INS 234): The JECFA Secretariat clarified that there are ongoing discussions on data to be provided for INS 235 and 234. Although the request has been subject to the call-for-data for its 89th meeting, these substances have yet to be evaluated. In order to ensure that the request is maintained, it has been reintroduced onto the JECFA Priority List (Table 1 of Annex 1), and is subject to Recommendation 5, below.

Chymosin from *Camelus dromedaries* expressed in *Aspergillus niger*: Comments received correctly noted that this request was put forward by the European Union and not Japan, as indicated in CL 2021/61-FA. Table 2 of Annex 1 has been amended, accordingly, and is subject to Recommendation 5, below.

Lycopenes (synthetic, INS 160d(i)); and from *Blakeslea trispora*, INS 160d(iii): In reply to CL 2021/61-FA, Member support for this request was not provided. The working group chair consulted with the requester, who has clarified that the United Kingdom is in a position to offer Member support. The working group chair has tentatively revised the request in Table 1 of Annex 1.

Recommendation 4:

Confirm with the United Kingdom that they are willing to provide Member support for this request.

Endorsement of the JECFA Priority List

Recommendation 5:

It is recommended that CCFA52 consider including the substances identified in the tables attached to this report (Annex 1) on the Priority List of Food Additives Proposed for Evaluation by JECFA.

⁶ Call for Data – JECFA 92 meeting: <https://www.who.int/news-room/articles-detail/call-for-data-jecfa-92-meeting>.

New work on a discussion paper to map food categories of the GSFA to the FoodEx2 database

With respect to the requests for Sucrose esters of fatty acids (INS 473) and Sucrose oligoesters, type I and type II (INS 473a), the JECFA, as described in the outcomes of its 89th meeting⁷, requested additional information in order to complete an exposure assessment, noting that the information should be as specific as possible, and the foods should be classified according to the FoodEx2 classification system, or another appropriate system. The 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.

In reply to CL 2021/61-FA, Japan is of the understanding that the mapping exercise is not only for INS 473 and 473a but also for other food additives used in a number of food categories.

The working group chair is of the opinion that Japan should only be responsible for providing information in support of the request for INS 473 and 473a. Further, to develop a complete mapping of the GSFA food categories to the FoodEx2 database should require greater involvement and scrutiny by the CCFA.

However, the working group chair recognizes the comments from the JECFA Secretariat that such an exercise is valuable to ensure that mapping is consistent for all meetings.

Considering the above, the working group chair proposed Recommendation 6.

Recommendation 6:

- (i) That the CCFA52 endorse new work to develop a discussion paper with the purpose of developing a complete mapping exercise between the food categories of the GSFA and the FoodEx2 database.
- (ii) That the Committee establish the authors of the discussion paper.
- (iii) That the discussion paper be presented at the meeting held prior to December 2023, in order to align with the timeline proposed by the JECFA for INS 473 and 473a.

⁷ Summary and Conclusions of the 89th JECFA meeting: <http://www.fao.org/3/ca9918en/ca9918en.pdf>

**ANNEX 1 - PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA
(Recommended by the WG on priorities for evaluation by JECFA for consideration by the 52nd CCFA)**

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</p> <p>Intertek Scientific & Regulatory Consultancy Danika Martyn, Ph.D. Danika.martyn@intertek.com</p> <p><i>Systematic Assessment of Mechanistic Data in context of overall carcinogenicity assessment</i> ToxStrategies, Inc.</p>	<p>Basis for request: The request for re-evaluation is supported by the following:</p> <ul 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*
	Acesulfame (INS 950), Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), Annatto extracts, norbixin based (INS 160b(ii))	<p>Daniele Wikoff, Ph.D. dwikoff@toxstrategies.com</p> <p>Type of request: Re-evaluation of exposure Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: Not applicable Data provider: Not applicable</p>	<p>Basis for request: Based on CRD2, Recommendation 27, the JECFA has been asked the following questions:</p> <p>The WG 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 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</p>	

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>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 level for Saccharins (INS 954(i)-(iv)) to 230 mg/kg 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>	
2.	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
3.	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. 	3
4.	Black carrot extract (INS 163(vi))	<p>Type of request: Data pending – characterization and toxicological information 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 prepared tentative specifications for black carrot extract as the powder form, at its 87th meeting. However, JECFA could not conclude on its safety or establish specifications. Additional characterization and toxicological data are required, namely:</p> <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 	2

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>ii. at least a 90-day toxicological study on a well-characterized extract representative of the material in commerce.</p> <p>Possible issues for trade: currently unidentified</p>	
5.	Butterfly Pea Flower Extract	<p>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</p> <p>Sensient Colors LLC Sue Ann McAvoy Sueann.macavoy@sensient.com</p>	<p>Basis for request: Safety assessment and establishment of specifications for use as a colour.</p> <p>Possible issues for trade: currently unidentified</p>	2
6.	Carob bean gum (INS 410)	<p>Type of request: Data pending – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas Proposed by: JECFA Year requested: 2016 (CCFA48) Data availability: ongoing discussion with JECFA Data provider: ongoing discussion with JECFA</p>	<p>Basis for request: Although no confirmation was provided for carob bean gum (INS 410), JECFA indicated that there was ongoing discussion with industry and that the deadline for the submission of data could be extended and therefore carob bean gum was retained on the JECFA priority list subject to confirmation of provision of data by CCFA50.</p> <p>Possible issues for trade: currently unidentified</p>	1
7.	L-cysteine hydrochloride (INS 920)	<p>Type of request: safety evaluation and establishment of specifications Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: to be confirmed at CCFA53 Data provider: to be confirmed at CCFA53</p>	<p>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.</p>	3

No.	Substance(s)	General information	Comments about the request	Priority*
			Possible issues for trade: currently unidentified	
8.	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
9.	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; • (-)-carvone: data on the oral exposure from all sources and toxicological data. Possible issues for trade: currently unidentified	
	Flavouring agents:(Ethyl 2-methyl pentanoate (No.214), cis-3-Hexen-1-ol (No.315), Menthol (No.427), l-Menthyl l-	Type of request: revise the JECFA specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: April 2019	Basis for request: (see CX/FA 19/51/4 add.2) Requests reconsideration of the specifications for 16 flavouring agents that were considered at the 86th JECFA meeting (listed in either Annex 1 or	

No.	Substance(s)	General information	Comments about the request	Priority*
	lactate (No.433), Myrcene (No.1327), Maltol (No.1480), 2-pentylfuran (No.1491), 3-(2-Furyl)acrolein (No.1497), 3-(5-Methyl-2-furyl)-butanal (No.1500), 2-Furyl methyl ketone (No.1503), 3-Acetyl-2,5-dimethylfuran (No.1506), (2-Furyl)-2-propanone (No.1508), 4-(2-furyl)-3-buten-2-one (No.1511), and Furfuryl methyl ether (No.1520))	Data provider: Japan and IOFI codex@mext.go.jp Sean V. Taylor, Ph.D. staylor@vertosolutions.net	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.	
10.	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: 2021 (CCFA52) Data availability: To be confirmed at CCFA53 Data provider: To be confirmed at CCFA53	Basis for request: The 89 th 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: <ol style="list-style-type: none"> 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:	2

No.	Substance(s)	General information	Comments about the request	Priority*
			i. Data on manufacturing processes; and, ii. Chemical characterization of the article(s) of commerce. Possible issues for trade: currently unidentified	
11.	Fungal amylase from <i>Aspergillus niger</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
12.	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: December 2021 Data provider: EU Specialty Food Ingredients	Basis for request: JECFA developed tentative specifications and ADI at its 87 th 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: <ol 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. Possible issues for trade: currently unidentified	3
13.	Lycopene (synthetic, INS 160d(i)); and from <i>Blakeslea trispora</i> , INS 160d(iii))	Type of request: Revision of JECFA specifications with regard to the parameter “solubility” Proposed by: EU Specialty Food Ingredients Supported by: United Kingdom Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider:	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.	3

No.	Substance(s)	General information	Comments about the request	Priority*
		BASF SE Nicola Leinwetter Nicola.leinwetter@basf.com DSM Dirk Cremer dirk.cremer@dsm.com	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". Possible issues for trade: currently unidentified	
14.	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 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. Possible issues for trade: currently unidentified	1
	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 re-evaluated, due to to emerging data on nisin role in: (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora. It is suggested that previous evaluations were specific to chemical toxicology and did not	

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>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>	
15.	ortho-Phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232)	<p>Type of request: Re-evaluation of ADI</p> <p>Proposed by: JECFA</p> <p>Year requested: 2019 (CCFA51)</p> <p>Data availability: To be confirmed at CCFA53</p> <p>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
16.	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</p> <p>Proposed by: CEFIC</p> <p>Supported by: Colombia; European Union</p> <p>Year Requested: 2021 (CCFA52)</p> <p>Data availability: December 2021</p> <p>Data provider: Frederic Martens Prayon S.A. rue Joseph Wauters 144 4480 Engis Belgique</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 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</p>	3

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>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>	
17.	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
18.	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
19.	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)	<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> <p>Possible issues for trade: currently unidentified</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
20.	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
21.	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
22.	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
23.	Spirulina extract (INS 134)	Type of request: Data pending – analytical data Proposed by: JECFA Supported by: N/A Year requested: 2019 (CCFA51) Data availability: December 2019 Data provider: IACM	Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3) JECFA86 received limited analytical data on spirulina extract. To remove the tentative designation from the specifications, the following	2

No.	Substance(s)	General information	Comments about the request	Priority*
		scodrea@vertosolutions.net	<p>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>	
24.	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 that “no safety issues exist for steviol glycosides produced by any one of these methods</p>	2

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>resulting in products with $\geq 95\%$ 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>	
25.	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
26.	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 according to the FoodEx2 classification system,</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>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>	
27.	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>	
28.	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
29.	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 thaumatins 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 thaumatins, 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 Ray DeVirgiliis, MPH rdevirgiliis@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</p>	

No.	Substance(s)	General information	Comments about the request	Priority*
			<p>review by JECFA of NOMAD's specification and safety determination, so that other regulatory jurisdictions can rely on this assessment</p> <p>Possible issues for trade: currently unidentified.</p>	
30.	Titanium dioxide (INS 171)	<p>Type of request: Re-evaluation of safety, and revision of specifications if necessary</p> <p>Proposed by: JECFA</p> <p>Year requested: 2021 (CCFA52)</p> <p>Data availability: Not applicable</p> <p>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</p>	1

No.	Substance(s)	General information	Comments about the request	Priority*
			measures to be taken. This revocation presents significant potential for trade disruption.	

* CCFA50⁸ 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	cis-9-Dodecenal	I
Submitted at CCFA52	4918		68820-38-2	Tridec-5-enal	I
Submitted at CCFA52	4886		126745-61-7	cis-6-Dodecenal	I
Submitted at CCFA52	4904		115018-39-8	trans-Tetradec-4-enal	I
Submitted at CCFA52	4905		2119671-25-7	2,6-Dimethylheptenyl formate	I
Submitted at CCFA52	4885		68820-34-8	trans-5-Dodecenal	I
Submitted at CCFA52	4898		41547-29-9	trans-5-Octenal	I
Submitted at CCFA52	4891		2088117-65-9	(E)-3-Methyl-4-dodecenoic acid	I
Submitted at CCFA52	4917		22032-47-9	(Z)-9-Dodecenoic acid	I
Submitted at CCFA52	4926		65398-36-9	(Z)-8-Pentadecenal	I
Submitted at CCFA52	4841		16676-96-3	cis-5-Dodecenyl 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

⁸ REP 18/FA, para 156.

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
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
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	cis-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> -Menthoxo)-2-butanone	II
Submitted at CCFA52	4844		118026-67-8	(2 <i>E</i> ,4 <i>E</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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
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
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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA51	4817		38634-59-2	S-[(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-2H-thiopyran-3-carboxaldehyde	II
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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
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
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	(<i>E</i>)-2-hexenal diethyl acetal	2004 (Session 63)	The specification requires clarity. 92% 2 <i>E</i> -isomer and 3-5% 2 <i>Z</i> -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-(<i>L</i> -Menthoxo)-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	<i>p</i> -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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
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 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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
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 stearothermophilus</i> expressed in <i>Bacillus 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 is used for the hydrolysis of starch during the processing of starch-containing foods. Possible issues for trade: currently unidentified</p>
6.	Alpha-amylase from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2015 (CCFA47) Data availability: December 2018 Data provider: Novozymes A/S Tine Vitved Jensen (tvit@novozymes.com)</p>	<p>Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods. Possible issues for trade: currently unidentified</p>
7.	Amyloglucosidase 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: 2016 (CCFA48) Data availability: December 2018 Data provider: Novozymes A/S Mr. Peter Hvass (phva@novozymes.com)</p>	<p>Basis for request: The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods. Possible issues for trade: currently unidentified</p>
8.	Asparaginase from <i>Aspergillus niger</i> expressing a modified gene from <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2014 (CCFA46) Data availability: December 2018 Data provider: DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)</p>	<p>Basis for request: The enzyme is used in cereal- and potato-based products to convert asparagine to aspartic acid, to reduce acrylamide formation during processing. Possible issues for trade: currently unidentified</p>
9.	Asparaginase from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2015 (CCFA47) Data availability: December 2018</p>	<p>Basis for request: The enzyme is indicated as a thermotolerant enzyme used to convert asparagine to aspartic acid to reduce acrylamide formation in the course of baking processes, cereal-based processes, fruit and vegetable processing, and coffee and cocoa processing.</p>

		Data provider: Novozymes A/S Tine Vitved Jensen tvit@novozymes.com	Possible issues for trade: currently unidentified
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.	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
12.	Diatomaceous earth	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
13.	Endo-1,4- β -xylanase from <i>Bacillus subtilis</i> produced by <i>B. subtilis</i> LMG S-28356	Type of request: Safety assessment and establishment of specifications Proposed by: European Union	Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified

		<p>Year requested: 2016 (CCFA48) Data availability: December 2018 Data provider: Puratos NV Mr. Olivier Maigret (omaigret@puratos.com)</p>	
14.	Endo-1,4- β -xylanase from <i>Pseudoalteromonas haloplanktis</i> produced by <i>B. subtilis</i> , strain LMG S-24584	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. 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. Possible issues for trade: currently unidentified</p>
15.	Endo-1,4- β -xylanase from <i>Thermotoga maritima</i> produced by <i>B. subtilis</i> , strain LMG S-27588	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. 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. Possible issues for trade: currently unidentified</p>
16.	Glucose oxidase from <i>Penicillium chrysogenum</i> expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2014 (CCFA46) Data availability: December 2018 Data provider: DSM Food Specialties Dr. Jack Reuvers (jack.reuvers@dsm.com)</p>	<p>Basis for request: The enzyme is used in baking, as it forms inter-protein bonds in dough, strengthening the dough and increasing its gas-retaining capacity and improving its handling properties. Possible issues for trade: currently unidentified</p>
17.	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:</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>

		Intertek Shahrzad Tafazoli, MSc (Eng.), MSc, PhD +1 905 542-2900 ext. 0268	
18.	Inulinase from <i>Aspergillus ficuum</i> produced by <i>Aspergillus oryzae</i> , 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 Mr. Olivier Maigret (omaigret@puratos.com)	Basis for request: The enzyme catalyzes the hydrolysis of inulin to produce fructo-oligosaccharides, theoretically from all food materials that naturally contain inulin. Possible issues for trade: currently unidentified
19.	Lactase from <i>Bifidobacterium bifidum</i> expressed in <i>Bacillus licheniformis</i>	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)	Basis for request: The lactase enzyme preparation is used as a processing aid during food manufacture for hydrolysis of lactose during processing of milk and other lactose containing dairy products, e.g. in order to obtain lactose-reduced milk products for lactose-intolerant individuals as well as dairy products with better consistency and increased sweetness due hydrolysis of lactose to form glucose and galactose. Possible issues for trade: currently unidentified
20.	Lipase from <i>Aspergillus oryzae</i> expressing a modified gene from <i>Thermomyces lanuginosus</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 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
21.	Phosphodiesterase from <i>Penicillium citrinum</i>	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Amano Enzyme Inc. Mr. Tomonari Ogawa (tomonari_ogawa@amano-enzyme.com)	Basis for request: The enzyme is used in processing yeast products by hydrolysing RNA, thereby increasing ribonucleotide levels and improving umami flavour. Possible issues for trade: currently unidentified

22.	Phospholipase A2 from pig pancreas expressed in <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2014 (CCFA46) Data availability: December 2018 Data provider: DSM Food Specialties Dr. Mariella Kuilman (mariella.kuilman@dsm.com)</p>	<p>Basis for request: The enzyme hydrolyzes natural phospholipids present in foodstuffs resulting in the formation of lyso-phospholipids that have emulsifying properties. This may be of benefit in baking and in egg processing for superior emulsifying properties (e.g. useful in dressings, spreads, sauces). In addition, the enzyme preparation is used during degumming of vegetable oils, where phospholipids can be separated more effectively from the oil. Possible issues for trade: currently unidentified</p>
23.	Protease Aqualysin 1 from <i>Thermus aquaticus</i> produced by <i>B. subtilis</i> , strain LMGS 25520	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. Olivier Maignret (omaignret@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: - 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 Possible issues for trade: currently unidentified</p>
24.	Transglucosidase/alpha-glucosidase from <i>Trichoderma reesei</i> expressing an Alpha-glucosidase gene from <i>Aspergillus niger</i>	<p>Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2016 (CCFA48) Data availability: December 2018 Data provider: Danisco US Inc Dr. Vincent J. Sewalt (vincent.sewalt@dupont.com)</p>	<p>Basis for request: The food enzyme catalyzes both hydrolytic and transfer reactions on incubation with α-D-gluco-oligosaccharides. In molasses, non-fermentable sugars including raffinose and stachyose are converted to sucrose, galactose, glucose and fructose, which can then be fermented into alcohol. The enzyme preparation is intended for use in the production of isomalto-oligosaccharides and in the manufacture of potable alcohol, lysine, lactic acid and MSG. Possible issues for trade: currently unidentified</p>
25.	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</p>	<p>Basis for request: The enzyme catalyzes the endo-hydrolysis of 1,4-beta-D-xylosidic linkages in xylans, including arabinoxylans in various plant materials including the cell walls and endosperm of cereals, such as wheat, barley, oats and malt. It is used in baking processes and other cereal based processes where it improves characteristics and handling of the dough.</p>

		Tine Vitved Jensen (tvit@novozymes.com)	Possible issues for trade: currently unidentified
26.	Xylanase 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: 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