Appendix XI

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

PART A: LIST OF SUBSTANCES USED AS FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA

No.	Substance(s)	General information	Comments about the request	Priority*
1	ADIPATES	Type of request: Exposure assessment Proposed by: JECFA Supported by: CCFA53 Year requested: 2023 (CCFA53) Data availability: December 2024 Data provider: N/A	Basis for request : Provisions for ADIPATES in the step process of the GSFA were circulated for comment by the electronic working group (EWG) on the GSFA and discussed by the GSFA PWG at CCFA48. During that discussion it was noted that the JECFA risk assessment for Adipates was conducted in 1966 and no exposure assessment was conducted by JECFA at that time (see FA/48 CRD2). As a result, CCFA48 requested the Codex Secretariat issue a circular letter (CL 2016/9-FA) requesting information on use level in specific food categories be provided to the JECFA Secretariat for the purpose of exposure assessment (REP 16/FA para 59). Replies to CL 2016/9-FA were compiled in CX/FA 17/49/8, FA/49 CRD12 and FA/49 CRD19. Possible issues for trade: currently unidentified	1
2	Ascorbyl palmitate (INS 304)	Type of request: Safety evaluation. Safety assessment, including addressing consumption for infants under 12 weeks of age. Proposed by: CCNFSDU Year requested: 2023 (CCFA53) Data availability: December 2024 Data provider: ISDI, secretariat@isdi.org	 Basis for request: CCNFSDU43 agreed that the use of ascorbyl palmitate (INS 304) as an antioxidant at 1 mg/100 mL in all types of formula covered by CXS 72-1981 was technologically justified. However, the additive has no adequate risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for infants under the age of 12 weeks. Prior to endorsement, an adequate safety evaluation in this sub-population is necessary. CCFA54 agreed to expand the request to include full safety evaluation in particular for infants below 12 weeks. Possible issues for trade: currently unidentified 	1
3	Acesulfame (INS 950), Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), Annatto extracts, norbixin based (INS 160b(ii))	Type of request: Re-evaluation of exposure Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: Not applicable Data provider: Not applicable	 Basis for request: Based on CRD2 of CCFA52, Recommendation 27, the JECFA has been asked the following questions: 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: Part 1: CCFA requests JECFA to comment on and discuss the following questions regarding the refined Budget Method and tiered-intake assessment approach proposed by ICBA: 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)? 	1

			 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? c. Are there any limitations, uncertainties, and applicability of the approach proposed by ICBA that CCFA should be made aware of? 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? 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? Part 2: CCFA requests that JECFA perform a dietary exposure estimate for Accesulfame 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 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. 	
4	Bentonite (INS 558)	Type of request: Establishment of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2024 Data provider: USP	 Basis for request: In view of the Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004), the CCCF14 recommended that the JECFA: i. review the lead specifications for diatomaceous earth and activated carbon and evaluate available data to support development of a lead specification for 	3
5	Beta-apo-8'-carotenal (INS 160e) and	Type of request: Exposure assessment Proposed by: JECFA Year requested: 2023 (CCFA53)	 bentonite. Basis for request: considering Recommendation 6 of CRD 2 to CCFA53. It was proposed by the JECFA Secretariat to consider a re-evaluation of Exposure, in particular due to the discrepancies in information on use 	1

	beta-carotenes (INS 160a(i), 160a(ii), 160a(iii), 160a(iv))	Data availability: December 2025 Data provider: NATCOL secretariat@natcol.org	levels in food categories of the GSFA and use levels provided to JECFA in previous assessments. The CCFA is seeking clear information on exposure for beta-apo-8'- carotenal and also BETA-CAROTENES separately, to be able to apply appropriate risk management strategies. The JECFA Secretariat indicated a willingness to consider the needs of the CCFA in the course of re-evaluating the exposure of these substances. Possible issues for trade: currently unidentified	
6	Black carrot extract (INS 163(vi))	Type of request: Data pending – characterization and toxicological information Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2027 Data provider: NATCOL secretariat@natcol.org	 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: i. data regarding full characterization of the protein, carbohydrate, lipid, fibre, mineral and non-anthocyanin polyphenol components in five lots each of the liquid and powder forms of black carrot extract; and ii. at least a 90-day toxicological study on a well-characterized extract representative of the material in commerce. 	2
7	Carob bean gum (INS 410)	Type of request: Data pending – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas Proposed by: JECFA Year requested: 2016 (CCFA48) Data availability: December 2024 Data provider: ISDI secretariat@isdi.org	Basis for request : Although no confirmation was provided for carob bean gum (INS 410), JECFA indicated that there was ongoing discussion with industry and that the deadline for the submission of data could be extended and therefore carob bean gum was retained on the JECFA priority list subject to confirmation of provision of data by CCFA50. Possible issues for trade: currently unidentified	1
8	Dioctyl sodium sulfosuccinate (INS 480)	Type of request: Exposure assessment Proposed by: CCFA51 Year requested: 2019 (CCFA51) Data availability: December 2024 Data provider: ICBA	Basic for request: The Physical Working Group on GSFA discussed exposure to this food additive, some members noted that exposure of a small child could exceed the ADI. One observer noted that they had performed a budget calculation and that the calculation could be made available upon request. The WG agreed to request JECFA review the calculation, to be submitted by the observer, as well as other exposure information that maybe available.	1
9	Flavouring substances (6 newly proposed and 105 previously submitted for safety evaluation, and 10 for	Type of request : Safety assessment and establishment of specifications Proposed by : International Organization of the Flavour Industry (IOFI) Supported by: United States of America	Basis for request:Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable <i>Refer to tables of flavourings in <u>Annex 2</u></i> Possible issues for trade:currently unidentified	Not applicable

revised specification; see Annex 2)	Year requested: 2019 to 2023 (CCFA51 to CCFA53) Data availability: December 2021 Data provider: IOFI, Sean V. Taylor, Ph.D. (staylor@vertosolutions.net)		
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: (+)-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 	Not applicable
Flavouring agents: (Ethyl 2-methyl pentanoate (No.214), cis-3-Hexen-1-ol (No.315), Menthol (No.427), I-Menthyl I-lactate (No.433), Myrcene (No.1327), Maltol (No.1480), 2-pentylfuran (No.1491), 3-(2-Furyl)acrolein (No.1497), 3-(5-Methyl-2-furyl)- butanal (No.1500), 2-Furyl methyl ketone (No.1503), 3-Acetyl-2,5- dimethylfuran (No.1506), (2-Furyl)-2-propanone (No.1508), 4-(2-furyl)-3-buten-2- one (No.1511), and	Type of request: revise the JECFA specifications Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: April 2019 Data provider: Japan and IOFI codex@mext.go.jp Sean V. Taylor, Ph.D. (staylor@vertosolutions.net)	Basis for request : (see CX/FA 19/51/4 add.2) Requests reconsideration of the specifications for 16 flavouring agents that were considered at the 86th JECFA meeting (listed in either Annex 1 or Annex 2 of CX/FA 19/51/4) due to introduced gaps between the JECFA specification (some items therein) and the commercially available products for each compound.	Not applicable

	Furfuryl methyl ether (No.1520))			
10	Gardenia blue (INS 165)	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2023 (CCFA53) Data availability: December 2024 Data provider: Gardenia Blue Interest Group (GBIG) San-Ei Gen F.F.I., Inc. (Representative organizer) Minoru Iniwa E-mail: minoru-iniwa@saneigenffi.co.jp Phone: +81-6-6333-0521 Masayuki Nishino E-mail: mnisino@saneigenffi.co.jp Phone: +81-6-6333-0521 Riken Vitamin Co., Ltd. (Organizer) Nobuo Dotsu Glico Nutrition Co., Ltd. (Organizer) Teruhisa Okabe	Basis for request : Gardenia blue is a colour intended to add or restore colour to food. In doing so it will impart blue, green, purple, or brown colours to foods, thus improving the organoleptic properties of those foods, which are otherwise uncoloured or the colour of which has been affected by processing and requires restoration. The proposed maximum use levels are based on the amount of colouring technologically required to achieve the desired effect in the different foods and are set out in detail in the reply to CL 2021/81-FA. Possible issues for trade: currently unidentified	2
11	Gellan gum, low-acyl clarified	Type of request: Establishment of specifications Proposed by: CCNFSDU Year requested: 2023 (CCFA53) Data availability: December 2024 Data provider: EU Specialty Food Ingredients (EUSFI) Avenue de Tervuren 13, 1040 Bruxelles,Belgium info@specialtyfoodingredients.eu and Biopolymer International secretariat@biopolymer-international.com (EU Specialty Food Ingredients member)	 Basis for request: CCNFSDU43 agreed that the proposed use of low-acyl clarified gellan gum as a thickener and stabilizer in formulas for special medical purposes intended for infants at 5 mg/100 mL limited to hydrolysed protein and/or amino acid-based liquid formula is technologically justified. CCNFSDU43 also agreed to request that CCFA consider including the food additive in the GSFA food category 13.1.3 "Formulae for special medical purposes for infants" once the specifications for the food additive had been assigned as "full", noting the on-going CCFA work on alignment of the food additive provisions in CXS 72-1981 with the GSFA as well as the "tentative" specification status for this food additive. CCNFSDU43 (CX/FA 23/53/2) requested to CCFA53 specification setting for this low-acyl clarified gellan gum. Possible issues for trade: currently unidentified 	1
12	Glycolipids	Type of request: Safety assessment and establishment of specifications Proposed by: IFAC Supported by: USA Year requested: 2023 (CCFA53) Data availability: December 2024	Basis for request: Glycolipids enhance the quality of beverages and help ensure product safety through antimicrobial preservation. Glycolipids can prevent the deterioration of beverages caused by spoilage microorganisms, thus extending shelf-life and reducing food waste. Possible issues for trade: Countries which refer to JECFA/Codex for national food additive provisions, including countries in Africa, the Asia-	2

		Data provider: Berit Dockter Senior Manager, Scientific & Regulatory Affairs International Food Additives Council bdockter@foodingredientfacts.org Robert Rankin Executive Director International Food Additives Council rrankin@foodingredientfacts.org Andrea Bosse Senior Regulatory Affairs Manager Lanxess Corporation Andrea.Bosse@lanxess.com	Pacific region, the Gulf Cooperation Council, and Latin and South America do not permit products containing glycolipids at present.	
13	 Phosphates Sodium dihydrogen phosphate (INS 339(i)) Disodium hydrogen phosphate (INS 339(ii)) Trisodium phosphate (INS 339(iii)) Potassium dihydrogen phosphate (INS 340(i)) Dipotassium hydrogen phosphate (INS 340 (iii)) Tripotassium phosphate (INS 340 (iii)) 	Type of request: Safety evaluation. Safety assessment, including addressing consumption for infants under 12 weeks of age. Proposed by: CCNFSDU Year requested: 2023 (CCFA53) Data availability: December 2025 Data provider: ISDI Secretariat@isdi.org	 Basis for request: CCNFSDU43 agreed that the use of phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)) as acidity regulators at 45 mg/100 mL as phosphorus singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) of CXS 72-1981 in all types of formula was technologically justified. However, the additives have no adequate risk assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for infants under the age of 12 weeks. Prior to endorsement, an adequate safety evaluation in this sub-population is necessary. Possible issues for trade: currently unidentified 	1
14	Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)	Type of request Re-evaluation of safety Proposed by: FoodDrinkEurope Supported by: Colombia; European Union Year requested: 2021 (CCFA52) Data availability: December 2024	Basis for request : In 2017, the European Food Safety Authority (EFSA) has re-evaluated polyglycerol polyricinoleate (E 476) as a food additive, and considered that the available dataset give reason to revise the ADI of 7.5 mg/kg bw per day allocated by Scientific Committee for Foods (SCF) in 1978, to a new ADI of 25 mg/kg bw per day. Possible issues for trade: currently unidentified	1

		Data provider: FoodDrinkEurope		
15	Polyoxyethylene (20) sorbitan monolaurate (INS 432), Polyoxyethylene (20) sorbitan monooleate (INS 433), Polyoxyethylene (20) sorbitan monopalmitate (INS 434), Polyoxyethylene (20) sorbitan monostearate (INS 435), Polyoxyethylene (20) sorbitan tristearate (INS 436)	Type of request: Re-evaluation of safety Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2024 Data provider: EU Specialty Food Ingredients (EUSFI) Avenue de Tervuren 13, 1040 Bruxelles,Belgium info@specialtyfoodingredients.eu and EFEMA info@efema.org	Basis for request: JECFA noted during its 89 th meeting that five polyoxyethylene sorbitan esters polysorbates) were evaluated by JECFA at its 17th meeting, and specifications were established. JECFA recommends that a new call for data be issued for their full evaluation. Possible issues for trade : currently unidentified	1
16	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 2024 Data providers: 1. EU Specialty Food Ingredients (EUSFI) Avenue de Tervuren 13, 1040 Bruxelles,Belgium info@specialtyfoodingredients.eu severin.mueller@givaudan.com or 2. Intertek barbara.nikiel@intertek.com	Basis for request: Additional studies on developmental toxicity and on noted effects on rodent pup thyroid hormone levels are required to complete the evaluation. JECFA requests a deadline of data submission by December 2021 for the additional data, or its ADI will be withdrawn. Possible issues for trade: currently unidentified	1
17	Silicon Dioxide, Amorphous (INS 551)	Type of request: Safety re-evaluation of Silicon Dioxide, Amorphous (INS 551), including toxicological evaluation, exposure assessment, and specifications Proposed by: IFAC Supported by: USA Year requested: 2023 (CCFA53) Data availability: December 2024	 Basis for request: Silicon dioxide (INS 551) is permitted in a variety of Food Categories as an anticaking agent, antifoaming agent, and carrier. INS 551 provides anti-caking properties to prevent lumping of powdery foodstuffs. INS 551 also serves as a carrier to assist in the handling and applications of for use in food additives, food enzymes, flavorings, and nutrients. Possible issues for trade: Questions regarding the particle size of silicon dioxide have affected the evaluation of the available toxicity data. Similar 	1

		Data provider: IFAC Association of Synthetic Amorphous Silica Producers (ASASP), a Cefic Sector Group Caroline Andersson, <u>CAN@cefic.be</u> Synthetic Amorphous Silica and Silicate Industry Association (SASSI) Joel F. Carpenter joel.f.carpenter@gmail.com Berit Dockter Senior Manager, Scientific & Regulatory Affairs International Food Additives Council <u>bdockter@foodingredientfacts.org</u> Robert Rankin Executive Director International Food Additives Council rrankin@foodingredientfacts.org	questions for titanium dioxide led to the withdrawal of its food additive approvals in several jurisdictions. The resulting trade disruptions are cited as significant basis for JECFA's current prioritization of its safety re- evaluation of titanium dioxide (see Replies to CL 2021/61-FA at the 52nd Session of the Codex Committee on Food Additives).	
18	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: December 2024 Data provider: EU Specialty Food Ingredients (EUSFI) Avenue de Tervuren 13, 1040 Bruxelles,Belgium info@specialtyfoodingredients.eu and EFEMA info@efema.org	 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
19	Steviol glycosides	Type of request: Safety evaluation Proposed by: ISC Supported by: USA Year requested: 2023 (CCFA53) Data availability: December 2024 Data provider: Brendan Naulty, Chief Commercial Officer, ManusBio Inc.1762 Lovers Lane Augusta, GA. 30901 The manufacturer is represented by: Maria Teresa Scardigli, Executive Director International Stevia Council	Basis for request : Enzyme modified steviol glycosides (typically termed bioconversion) were evaluated at the JECFA 87th meeting (2019). The specifications generated included several methods of manufacture in Appendix3. The specification outlined the acceptable enzyme production organism and the gene source. A similar method of manufacture has been developed to produce enzyme modified steviol glycosides using 1. Alternative sources for the genes to modify the E coli to manufacture the enzymes that transform a stevia extract product to Rebaudiside M and 2. An additional enzyme. The additional manufacturing method is requested for evaluation. The novel enzyme modification production process results in an identical specification and as a result, no changes to the steviol glycoside specifications are requested or to the food categories or use levels.	3

		Global Office-Avenue de Tervuren 188A- 1150 Brussels Belgium	Possible issues for trade: currently unidentified.	
20	Sucroglycerides (INS 474)	Type of request: exposure assessment Proposed by: CCFA 51 Year requested: 2019 (CCFA51) Data availability: December 2027 Data provider: ICBA	Basis for request : During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment.	1
21	Sucrose esters of fatty acids (INS 473)	Type of request: Data pending - exposure assessment Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2027 Data provider: Japan codex@mext.go.jp	 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. At the 89th JECFA meeting, JECFA considered that more refined dietary exposures should be provided. Specifically, JECFA recommends that sponsors provide information on: i. typical or mean and high use levels for foods in which the food additives are used; and ii. foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used. 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. <u>Given the extent of the request for information</u>. Possible issues for trade: currently unidentified 	1
22	Sucrose oligoesters type I and type II (INS 473a)	Type of request: Data pending - exposure assessment Proposed by: JECFA Year requested: 2021 (CCFA52) Data availability: December 2027 Data provider: Japan codex@mext.go.jp	 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. At the 89th JECFA meeting, JECFA considered that more refined dietary exposures should be provided. Specifically, JECFA recommends that sponsors provide information on: i. typical or mean and high use levels for foods in which the food additives are used; and ii. foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used. The information should be as specific as possible, and the foods should be classified according to the FoodEx2 classification system, or another 	1

			appropriate system. JECFA recommends that the data should be presented in tabular format by mapping the foods recorded in both the FoodEx2 to the GSFA food categories. This exercise can improve mapping consistency for all meetings. Given the extent of the request for information, the JECFA proposes that the data be available 2 years after the date of confirmation. Possible issues for trade : currently unidentified	
23	Tocopherol concentrate, mixed (INS307b)	Type of request: Safety evaluation. Safety assessment, including addressing consumption for infants under 12 weeks of age. Proposed by: CCNFSDU Year requested: 2023 (CCFA53) Data availability: December 2025 Data provider: ISDI	 Basis for request: CCNFSDU43 agreed that the use of tocopherol concentrate, mixed (INS 307b) as an antioxidant at 1 mg/100 mL in all types of infant formula covered by CXS 72-1981 was technologically justified. However, the additive has no adequate risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for infants under the age of 12 weeks. Prior to endorsement, an adequate safety evaluation in this sub-population is necessary. Possible issues for trade: currently unidentified 	1
24	THAUMATIN II	Type of request: Safety evaluation Proposed by: CCC Supported by: Colombia; United States of America Year requested: 2021 (CCFA52) Data availability: December 2024 Data provider: Karima Kendall Senior Director, Scientific & Nutrition Affairs Calorie Control Council kkendall@caloriecontrol.org Robert Rankin President Calorie Control Council rrankin@caloriecontrol.org Yuri Gleba CEO Nomad Bioscience GmbH gleba@nomadbioscience.com	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 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 Nicotiana benthamiana; all of which can be cultivated sustainably and in large scale. NOMAD's production process yields THAUMATIN II with the identical amino acid sequence as the thaumatin II (also referred to as thaumatin 2 or thaumatin B in the literature) in commercial products. NOMAD's process yields a highly pure product that meets the existing specifications and includes some trace impurities that have been demonstrated to be safe at the levels present. NOMAD requests an opinion from JEFCA with respect to the possibility of modifying the definition and expanding the specification of THAUMATIN II. Although thaumatin II (thaumatin 2) is a component of thaumatin mixtures approved for marketing in the EU and is encompassed by the specification of E957, the process used by NOMAD for manufacturing THAUMATIN II	2

			recombinantly is different than the process employed to produce E957, albeit the thaumatin 2/THAUMATIN II proteins responsible for functionality are identical. The different processes yield thaumatin 2/II with different impurity profiles. NOMAD's product (THAUMATIN II and its associated impurities) has received GRAS classification by US FDA and is considered safe for use in all food classes defined for E957 and at the same rates of application (GRN 738). Thaumatin produced recombinantly has not been evaluated by EFSA. As such, it is NOMAD Bioscience's intent to seek review by JECFA of NOMAD's specification and safety determination, so that other regulatory jurisdictions can rely on this assessment Possible issues for trade : currently unidentified.	
25	PROPYLENE GLYCOL (INS 1520)	Type of request: Safety evaluation Proposed by: CCFA54 Year requested: 2024 (CCFA54) Data availability: To be confirmed in CCFA55 Data provider:	 Basis of request: Propylene glycol has the functions of carrier, emulsifier, glazing agent and humectant in food products. The committee requests for safety re-evaluation for use of propylene glycol as a carrier in foods in general and specifically its use as carrier for flavour in FC 14.1.4 Due to a possible exposure concern related to the proposed maximum use level of 3000mg/l in the food category 14.1.4, one member organization requested that JECFA assessment also takes into account the use level of 1000mg/l to compare the impact of these use levels on the overall assessment. Possible issues for trade: currently unidentified 	1

* Priority ranking in accordance with REP18/FA, paragraph 156.

PART B: LIST OF SUBSTANCES USED AS PROCESSING AIDS PROPOSED FOR EVALUATION BY JECFA

No	Substance(s)	General information	Comments about the request
1.	Activated carbon (activated charcoal)	Type of request: Revision of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2024 Data provider: USP	 Basis for request: In view of the Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004), the CCCF14 recommended that the JECFA: i. review the lead specifications for diatomaceous earth and activated carbon and ii. evaluate available data to support development of a lead specification for bentonite. Possible issues for trade: currently unidentified
2.	Diatomaceous earth	Type of request: Revision of specifications (lead) Proposed by: CCFA52 Year requested: 2021 (CCFA52) Data availability: December 2024 Data provider: USP	Basis for request: In view of the Code of Practice for the Prevention and Reduction of Lead Contamination in foods (CXC 56-2004), the CCCF14 recommended that the JECFA: i. review the lead specifications for diatomaceous earth and activated carbon and

			 ii. evaluate available data to support development of a lead specification for bentonite. Possible issues for trade: currently unidentified
3.	Alpha-Amylase (JECFA95-1) from Geobacillus stearothermophilus expressed in Bacillus licheniformis	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider:	 Basis for request: The 95th JECFA established a temporary ADI "not specified" for α-amylase (JECFA95-1) from G. stearothermophilus expressed in B. licheniformis, when used in the applications specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications. The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: validated method of analysis to determine α-amylase activity, including the validation report; unit definition for α-amylase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products. Note the JECFA request for technical information by the end of 2023, to complete the safety assessment.
4.	Alpha-Amylase (JECFA95-2) from <i>Geobacillus</i> <i>stearothermophilus</i> expressed in <i>Bacillus</i> <i>licheniformis</i>	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider:	 Basis for request: The 95th JECFA established a temporary ADI "not specified" for α-amylase (JECFA95-2) from G. stearothermophilus expressed in B. licheniformis, when used in the applications specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications. The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: validated method of analysis to determine α-amylase activity, including the validation report; unit definition for α-amylase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products. Note the JECFA request for technical information by the end of 2023, to complete the safety assessment.

5.	Alpha-amylase (JECFA95-3) from <i>Rhizomucor</i> pusillus expressed in <i>Aspergillus niger</i>	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider:	 Basis for request: The 95th JECFA established a temporary ADI "not specified" for α-amylase (JECFA95-3) from R. pusillus expressed in A. niger, when used in the applications specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications. The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: validated method of analysis to determine α-amylase activity, including the validation report; unit definition for α-amylase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products. Note the JECFA request for technical information by the end of 2023, to complete the safety assessment.
6.	Amyloglucosidase (JECFA95-4) from <i>Rasamsonia</i> <i>emersonii</i> expressed in <i>Aspergillus niger</i>	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider:	 Basis for request: The 95th JECFA established a temporary ADI "not specified" for α-amylase (JECFA95-3) from R. pusillus expressed in A. niger, when used in the applications specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications. The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: digestibility data in order to complete the allergenicity assessment; validated method of analysis to determine amyloglucosidase activity, including the validation report; unit definition for amyloglucsosidase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products. Note the JECFA request for technical information by the end of 2023, to complete the safety assessment.
7.	Asparaginase (JECFA-95-5) from <i>Pyrococcus furiosus</i>	Type of request : Data pending to complete evaluation – Evaluation by JECFA95 Proposed by : JECFA	Basis for request: The 95th JECFA established a temporary ADI "not specified" for α -amylase (JECFA95-3) from R. pusillus expressed in A. niger, when used in the applications

	expressed in <i>Bacillus</i> subtilis	Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider:	 specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications. The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: validated method of analysis to determine alpha-amylase activity, including the validation report; unit definition for alpha-amylase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products. Note the JECFA request for technical information by the end of 2023, to complete the safety assessment.
8.	Beta-Amylase (JECFA95-6) from Bacillus flexus expressed in Bacillus licheniformis	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider:	 Basis for request: The 95th JECFA established a temporary ADI "not specified" for beta-amylase (JECFA95-6) from B. flexus expressed in B. licheniformis, when used in the applications specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications. The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: validated method of analysis to determine beta-amylase activity, including the validation report; unit definition for beta-amylase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products. Note the JECFA request for technical information by the end of 2023, to complete the safety assessment.
9.	Protease from <i>Bacillus</i> <i>amyloliquefaciens</i>	Type of request:Safety evaluation when used as processing aid and establishment of specificationsProposed by:JapanYear requested:2023 (CCFA53)Data availability:December 2024Data provider:Atsushi Kawahara (Quality Assurance Dept. General Manager)E-mail:akawahara@hbi-enzymes.com	Basis for request: Neutral Protease may be of benefit in the processing of all foods raw materials which naturally contain proteins. By decomposing the protein contained in the raw material, it is effective in the production of bread, infant formula, beer, malt beverages, and spirits with an alcohol content of 15% or more. It is also used to add flavor to soups and broths, sauces and like products and ready-to-eat savouries with protein digests such as yeast extract. Possible issues for trade: currently unidentified

		Tel: +81-790-64-1201; Fax: +81-790-64-1202	
10.	Chymosin from <i>Camelus</i> dromedaries expressed in Aspergillus niger	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
11.	Endo-1,4-ß-xylanase from <i>Pseudoalteromonas</i> <i>haloplanktis</i> produced by <i>B.</i> <i>subtilis</i> , strain LMG S-24584	Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV, Mr. Olivier Maigret (omaigret@puratos.com)	 Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified
12.	Endo-1,4-ß-xylanase from <i>Thermotoga maritima</i> produced by <i>B. subtilis</i> , strain LMG S- 27588	Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV, Mr. Olivier Maigret (omaigret@puratos.com)	 Basis for request: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. Possible issues for trade: currently unidentified
13.	Glutaminase from Aspergillus niger	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2021 (CCFA52) Data availability: December 2024 Data provider: Nobuo Okado, Shin Nihon Chemical Co., Ltd. c/o: Intertek, Shahrzad Tafazoli, MASc (Eng.), MSc, PhD +1 905 542-2900 ext. 0268	Basis for request : The enzyme catalyzes the conversion L- glutamine to L-glutamate, and is used in the manufacture of glutamic acid-rich yeast extracts and glutamic acid-rich protein hydrolysates. These, in turn, are added to other foods, including beverages, to impart savoury or umami taste. Possible issues for trade: currently unidentified

14.	Inulinase from <i>Aspergillus</i> <i>ficuum</i> produced by <i>Aspergillus</i> <i>oryzae</i> , strain MUCL 44346 Lactase from <i>Bifidobacterium</i> <i>bifidum</i> expressed in <i>Bacillus</i> <i>licheniformis</i>	Type of request: Safety assessment and establishment of specificationsProposed by: European Union Year requested: 2017 (CCFA49)Data availability: December 2018 Data provider: Puratos NV, Mr. Olivier Maigret (omaigret@puratos.com)Type of request: Safety assessment and establishment of specifications Proposed by: European Union	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 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
		Year requested: 2017 (CCFA49) Data availability: December 2024 Data provider: Novozymes A/S , Mr. Peter Hvass (phva@novozymes.com)	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
16.	Phospholipase A2 (PLA2) from porcine pancreas expressed in Aspergillus niger	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: December 2024 Data provider: DSM	 Basis for request: Because of the late submission of highly relevant toxicological data, other missing information and time constraints, the 95th JECFA was unable to complete this evaluation. The 95th JECFA recommended that the evaluation of this enzyme preparation is completed at a future meeting. The 95th JECFA requested the JECFA Secretariat to urge the sponsor and Codex Members to ensure that the following additional information is available for evaluation prior to requesting inclusion of this enzyme preparation in the CCFA JECFA Priority List: additional data to clarify the genotoxic potential of the PLA2 enzyme concentrate; digestibility data for enzyme preparations containing both glucoamylase and PLA2; results from five different batches of all types of PLA2 enzyme preparations using the assay to determine PLA2 activity provided in the dossier; validation information of the alternative method of analysis used to determine PLA2 activity (this should include the method description in English); unit definition for the PLA2 activity based on the alternative method of assay; and analytical data using the alternative validated method for at least five different batches of all commercially available products.

			Note the JECFA request for the JECFA Secretariat to urge the sponsor and Codex Members to ensure that the additional data requested by JECFA is available for evaluation prior to requesting inclusion of this enzyme preparation in the CCFA JECFA Priority List. Possible issues for trade: currently unidentified
17.	Protease Aqualysin 1 from <i>Thermus aquaticus</i> produced by <i>B. subtilis</i> , strain LMGS 25520	Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2017 (CCFA49) Data availability: December 2018 Data provider: Puratos NV Mr. Olivier Maigret (omaigret@puratos.com)	Basis for request: The enzyme preparation is used as a processing aid during production of bakery products. The food enzyme catalyses hydrolyzes of the peptide bonds. The addition of enzyme provides several benefits during the production of bakery products: - Faster dough development upon mixing; - Better dough machinability; - Reduced dough rigidness; - Improved dough's structure and extensibility during the shaping or moulding step; - Uniform shape of the bakery product; - Regular batter viscosity, and - Improved short-bite of certain products like hamburger breads
18.	Ribonuclease from Penicillium citrinum RP-4	Type of request:Safety evaluation and establishment of specification-Evaluation by JECFA92Proposed by:JECFAYear requested:2023 (CCFA53)Data availability:March 2025Data provider:Amano Enzyme Inc.Mr. Hiromichi Yoshida (hiromichi_yoshida@ amano-enzyme.com)	Basis for request : During its recent evaluation of Ribonuclease P, the 92nd JECFA noted that ribonuclease P can also be produced by P. citrinum RP-4, but insufficient information was available on the enzyme concentrate produced from this strain. To evaluate the safety of ribonuclease P from <i>P. citrinum</i> RP-4, toxicological studies with well-characterized enzyme concentrate are required. Possible issues for trade: currently unidentified
19.	Xylanase from Bacillus licheniformis expressed in Bacillus licheniformis	Type of request: Data pending to complete evaluation – Evaluation by JECFA95 Proposed by: JECFA Year requested: 2023 (CCFA53) Data availability: To be confirmed at CCFA55 Data provider: To be confirmed at CCFA55	 Basis for request: The 95th JECFA requested the following information, by the end of 2023, to complete the safety assessment: validated method of analysis to determine xylanase activity, including the validation report; unit definition for α-amylase activity based on the method of assay; and analytical data using the validated method for at least five different batches of commercially available products.

20.	Acylglycerol lipase from Penicillium crustosum expressed in Penicillium crustosum	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2024 (CCFA54) Data availability: December 2024 Data provider: Amano Enzyme Inc. Yasuhiro Nomura (yasuhiro nomura@amano- enzyme.com)	 Note the JECFA request for technical information by the end of 2023, to complete the safety assessment. Possible issues for trade: currently unidentified Basis for request: The enzyme is used in milk processing to hydrolyze ester bond between fatty acid and glycerol in monoglycerides and diglycerides to release fatty acids and glycerol. This results to enzyme modified cheese (EMC), enzyme modified dairy products (EMD) and enhanced flavour. The enzyme is also used in fats and oil processing to hence improve the relative purity of triglyceride in oil. Possible issues for trade: currently unidentified
21.	Triacylglycerol lipase from Limtongozyma cylindracea	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2024 (CCFA54) Data availability: December 2024 Data provider: Amano Enzyme Inc. Yasuhiro Nomura (<u>yasuhiro_nomura@amano- enzyme.com</u>)	Basis for request : The enzyme catalyzes hydrolysis of lipids into fatty acids and mono-, di-glycerides or glycerol. It's used in milk processing to produce enzyme modified cheese (EMC), enzyme modified dairy products (EMD), improvement of the flavor by the increment of free fatty acids. Fats and oils processing to produce unsaturated fatty acids such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) as well as production of free fatty acid and in baking to produce monoglycerides which act as emulsifiers and improve the stability and elasticity of the dough. Possible issues for trade: currently unidentified
22.	Transglutaminase (EC 2.3.2.13) derived from Streptomyces mobaraensis strain M2020197	Type of request: Safety assessment and establishment of specifications Proposed by: China Year requested: 2024 (CCFA54) Data availability: December 2024 Data provider: Marco Marcucci, R&D Director Dongsheng Biotech (Taixing) Co., Ltd. No. 91-92 Junmin Road, Huangqiao, Taixing, Taizhou, Jiangsu, China Shahrzad Tafazoli, Ph.D. Intertek Health Sciences Inc. 2233 Argentia Road, Suite 201 Mississauga, Ontario Canada,L5N 2X7	 Basis for request: The enzyme used in food and beverage processing to catalyze the formation of cross-linking of bonds between glutamine and lysine residues within and between proteins in food. These cross-linkages increase the size and structure of food proteins, thus modifying the physical properties of the food such as breaking strength, texture, and moisture retention. Possible issues for trade: currently unidentified

PART C: flavourings for inclusion on the JECFA Priority List to be considered at the 54th session of the Codex Committee on Food Additives

C.1- Six (6) flavourings newly proposed for inclusion on the JECFA Priority List

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS

New 54 th	3038	126-14-7	Sucrose octaacetate	III
New 54 th	3811	20702-77-6	Neohesperidin dihydrochalcone	III
New 54 th	4825	2277-20-5	(E)-6-Nonenal	I
New 54 th	4943	111-20-6	Decanedioic acid	I
New 54 th	4944	6402-36-4	trans-2-Dodecenedioic acid	I
New 54 th	4945	174155-46-5	cis-8-Decenal	I

C.2- One hundred and five (105) flavourings previously submitted to the Codex Committee on Food Additives for inclusion on the JECFA Priority List

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
Submitted at the 51st CCFA	3557 (JECFA 973)	2111-75-3	p-Mentha-1,8-dien-7-al (Perillaldehyde)	
Submitted at the 43rd CCFA	4074	6321-45-5	Allyl valerate	``
Submitted at the 43rd CCFA	4072	20474-93-5	Allyl crotonate	I
Submitted at the 45th CCFA	4685	7370-92-5	(±)-6-Octahyltetrahydro-2 <i>H</i> -pyran-2-one	I
Submitted at the 45th CCFA	4673	7370-44-7	delta-Hexadecalactone	I
Submitted at the 45th CCFA	4682	23333-91-7	Octahydro-4,8a-dimethyl-4a(2H)-naphthol	I
Submitted at the 45th CCFA	4742	917750-72-2	1-(2-Hydroxy-4-methylcyclohexyl)ethanone	
Submitted at the 45th CCFA	4687	544409-58-7	(±)-3-Hydroxy-3-methyl-2,4-nonanedione	II
Submitted at the 51st CCFA	4836	137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol	
Submitted at the 51st CCFA	4842	911212-28-7	2,4,5-Trithiaoctane	
Submitted at the 51st CCFA	4817	38634-59-2	S-[(Methylthio)methyl]thioacetate	I
Submitted at the 51st CCFA	4870	17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane	II
Submitted at the 51st CCFA	4828	729602-98-6	1,1-Propanedithioacetate	
Submitted at the 51st CCFA	4824	1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate	
Submitted at the 51st CCFA	4843	1838169-65-5	3-(Allyldithio) butan-2-one	
Submitted at the 51st CCFA	4822	61407-00-9	2,6-Dipropyl-5,6-dihydro-2H-thiopyran-3-carboxaldehyde	
Submitted at the 51st CCFA	4823	33368-82-0	1-Propenyl 2-propenyl disulfide	
Submitted at the 51st CCFA	4782	1679-06-7; 1633- 90-5	2(3)-Hexanethiol	I
Submitted at the 51st CCFA	4779	1416051-88-1	(±)-2-Mercapto-5-methylheptan-4-one	I
Submitted at the 51st CCFA	4792	548740-99-4	(±)-3-Mercapto-1-pentanol	I
Submitted at the 51st CCFA	4791	22236-44-8	3-(Acetylthio)hexanal	
Submitted at the 51st CCFA	4769	851768-51-9	5-Mercapto-5-methyl-3-hexanone	
Submitted at the 51st CCFA	4730	1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate	III
Submitted at the 51st CCFA	4734	1256932-15-6	3-(Methylthio)-decanal	

Submitted at the 51st CCFA	4733	1006684-20-3	(±)-2-Mercaptoheptan-4-ol	
Submitted at the 51st CCFA	4761	75631-91-3	Prenyl thioisovalerate	I
Submitted at the 51st CCFA	4760	53626-94-1	Prenyl thioisobutyrate	I
Submitted at the 45th CCFA	4700	614-60-8	o-trans-Coumaric acid	
Submitted at the 43rd CCFA	4622	61683-99-6	Piperonal propyleneglycol acetal	
Submitted at the 43rd CCFA	4627	6414-32-0	Anisaldehyde propyleneglycol acetal	
Submitted at the 43rd CCFA	4618	23495-12-7	2-Phenoxyethyl propinate	
Submitted at the 43rd CCFA	4625	6314-97-2	Phenylacetaldehyde diethyl acetal	I
Submitted at the 43rd CCFA	4629	5468-05-3	Phenylacetaldehyde propyleneglycol acetal	
Submitted at the 43rd CCFA	4620	122-99-6	2-Phenoxyethanol	
Submitted at the 43rd CCFA	4619	92729-55-0	Propyl 4-tert-butylphenylacetate	I
Submitted at the 43rd CCFA	4314	61810-55-7	Phenethyl decanoate	
Submitted at the 43rd CCFA	2860	94-47-3	Phenethyl benzoate	
Submitted at the 43rd CCFA	4438	591-11-7	beta-Angelicalactone	I
Submitted at the 43rd CCFA	4195	87-41-2	Phthalide	
Submitted at the 45th CCFA	4768	67936-13-4	2,6,10-Trimethyl-9-undecenal	I
Submitted at the 45th CCFA	4612	645-62-5	2-Ethyl-2-hexenal	II
Submitted at the 45th CCFA	4616	13019-16-4	2-Hexylidenehexanal	II
Submitted at the 45th CCFA	4486	5694-82-6	Citral glyceryl acetal	I
Submitted at the 52 nd CCFA	4902	22122-36-7	3-Methyl-2(5H)-furanone	III
Submitted at the 52 nd CCFA	4915	2142634-65-7	(5Z)-3,4-Dimethyl-5-propylidene-2(5H)-furanone	III
Submitted at the 52 nd CCFA	4784	57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	
Submitted at the 52 nd CCFA	4939	2180135-09-3	S-Methyl 5-(1-ethoxyethoxy)decanethioate	
Submitted at the 52 nd CCFA	4894	116229-37-9	2-Mercapto-3-methyl-1-butanol	
Submitted at the 52 nd CCFA	4883	556-27-4	S-Allyl-L-cysteine sulfoxide	II
Submitted at the 52 nd CCFA	4935	98139-71-0	3-Methylbutane-1,3-dithiol	III
Submitted at the 52 nd CCFA	4916	124831-34-1	2-Methyl-3-butene-2-thiol	
Submitted at the 52 nd CCFA	4938	2180135-08-2	S-Methyl 5-(1-ethoxyethoxy)tetradecanethioate	
Submitted at the 52 nd CCFA	4901	2097608-89-2	O-Ethyl S-(3-methylbut-2-en-1-yl)thiocarbonate	
Submitted at the 52 nd CCFA	4900	64580-54-7	Hexyl propyl disulfide	
Submitted at the 52 nd CCFA	4914	24963-39-1	bis-(3-Methyl-2-butenyl)disulfide	III
Submitted at the 52 nd CCFA	4889	3877-15-4	Methyl propyl sulfide	
Submitted at the 52 nd CCFA	4930	159017-89-7	4-Isopropoxycinnamaldehyde	
			Mixture of 5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-	
Submitted at the 52 nd CCFA	4888	1945993-01-0;	methylchroman-2-	Ш
Submitted at the 52 ^m CCFA	4000	828265-08-3	one and 7-hydroxy-4-(4´-hydroxy-3´-methoxyphenyl)-5-	111
			methylchroman-2-one	
Submitted at the 52 nd CCFA	4879	21145-77-7	1-(3,5,5,6,8,8-Hexamethyl-5,6,7,8-tetrahydronaphthalen-2-	II
			yl)ethanone	
Submitted at the 52 nd CCFA	4892	4707-61-3	cis-2-Hexylcyclopropaneacetic acid	II

Submitted at the 52 nd CCFA	4890	27841-22-1	3- <i>p</i> -Menthen-7-al	
Submitted at the 52 nd CCFA	4928	554-14-3	2-Methylthiophene	II
Submitted at the 52 nd CCFA	4839	163460-99-9 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	II
Submitted at the 52 nd CCFA	4813	1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	II
Submitted at the 52 nd CCFA	4884	1569-60-4	6-Methyl-5-hepten-2-ol	
Submitted at the 52 nd CCFA	4827	6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	
Submitted at the 52 nd CCFA	4869	886449-15-6	4-(<i>I</i> -Menthoxy)-2-butanone	
Submitted at the 52 nd CCFA	4844	118026-67-8	(2E,4E)-2,4-Decadien-1-ol acetate	
Submitted at the 52 nd CCFA	4747	91212-78-1	(±)-2,5-Undecadien-1-ol	
Submitted at the 52 nd CCFA	4913	18478-46-1	3,7-Dimethyl-2-methyleneoct-6-en-1-ol	
Submitted at the 52 nd CCFA	4785	25234-33-7	2-Octyl-2-dodecenal	
Submitted at the 52 nd CCFA	4786	13893-39-5	2-Hexyl-2-decenal	I
Submitted at the 52 nd CCFA	4929	60857-05-8	4-Methylidene-2-(2-methylprop-1-enyl)oxane	
Submitted at the 52 nd CCFA	4920	220462-51-9	1-Ethyl-2-(1-pyrrolylmethyl)pyrrole	
Submitted at the 52 nd CCFA	4832	108715-62-4	2-(3-Benzyloxypropyl)pyridine	
Submitted at the 52 nd CCFA	4829	616-45-5	2-Pyrrolidone	
Submitted at the 52 nd CCFA	4818	1370711-06-0	trans-1-ethyl-2-methylpropyl 2-2-butenoate	
Submitted at the 52 nd CCFA	4867	18374-76-0	(3S,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 the 52 nd CCFA	4840	38427-80-4	Tetrahydronootkatone	II
Submitted at the 52 nd CCFA	4807	1078-95-1	Pinocarvyl acetate	II
Submitted at the 52 nd CCFA	4906	36687-82-8	L-Carnitine tartrate	
Submitted at the 52 nd CCFA	4868	61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5H)-furanone	
Submitted at the 52 nd CCFA	4896	2186611-08-3	N-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5- dimethylcyclohexane-1-carboxamide	III
Submitted at the 52 nd CCFA	4882	1857330-83-9	N-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5- dimethylcyclohexanecarboxamide	III
Submitted at the 52 nd CCFA	4899	1622458-34-7; 2079034-28-7	N-(1-((4-amino-2,2-dioxido-1 <i>H</i> -benzo[c][1,2,6]thiadiazin-5- yl)oxy)-2-methylpropan-2-yl)-2,6-dimethylisonicotinamide	III
Submitted at the 52 nd CCFA	4880	2015168-50-8	2-(4-Ethylphenoxy)- <i>N</i> -(1 <i>H</i> -pyrazol-3-yl)- <i>N</i> -(thiophen-2- ylmethyl)acetamide	111
Submitted at the 52 nd CCFA	4881	1857331-84-0	<i>N</i> -(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5- dimethylcyclohexanecarboxamide	111
Submitted at the 52 nd CCFA	4877	76733-95-4	(<i>E</i>)-3-(3,4-Dimethoxyphenyl)- <i>N</i> -[2-(3- methoxyphenyl)- ethyl]-acrylamide	III
Submitted at the 52 nd CCFA	4835	877207-36-8	2,4-Dihydroxy-N-[(4-hydroxy-3- methoxyphenyl)methyl]benzamide	III
Submitted at the 53rd CCFA	4948	1129-69-7	2-Hexylpyridine	II
Submitted at the 53rd CCFA	4958	2308574-23-2	4-Formyl-2-methoxyphenyl <i>I</i> -menthyl glutarate	

Submitted at the 53 rd CCFA	4959	301310-73-6; 79894-05-6	9-Dodecen-12-olide	III
Submitted at the 53 rd CCFA	4960	13474-59-4	trans-alpha-Bergamotene	
Submitted at the 53 rd CCFA	4961	2369713-22-2	4-Methyltrideca-2E,4-dienal	
Submitted at the 53 rd CCFA	4965	1622458-32-5	N-(1-((4-Amino-2,2-dioxido-1 <i>H</i> - benzo[c][1,2,6]thiadiazin-5- yl)oxy)-2-methylpropan-2-yl)isonicotinamide	111
Submitted at the 53 rd CCFA	4966	6137-11-7	4-Methylheptan-3-one	II
Submitted at the 53 rd CCFA	4967	483-76-1	delta-Cadinene	
Submitted at the 53 rd CCFA	4970	2413115-68-9	2-Methyl-1-(2-(5-(p-tolyl)-1 <i>H</i> -imidazol-2-yl)piperidin-1- yl)butan-1-one	III
Submitted at the 53 rd CCFA	4971	18794-84-8	beta-Farnesene	
Submitted at the 53 rd CCFA	4972	23060-14-2	Diethyl mercaptosuccinate	
Submitted at the 53 rd CCFA	4973	2411762-60-0	3-Mercapto-3-methyl-1-pentyl acetate	
Submitted at the 53 rd CCFA	4974	23986-74-5	Germacrene D >85%	
Submitted at the 53 rd CCFA	4977	65210-18-6	10-Hydroxy-4,8-dimethyldec-4-enal	
Submitted at the 53rd CCFA	4979	142062-38-2	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	III
Submitted at the 53 rd CCFA	4980	2415657-73-5	Mixture of (8Z,11Z)-heptadeca-8,11-dienal and (Z)- heptadec-8-enal	I

C.3- Priority additions list of ten (10) compounds proposed for specifications modification by JECFA Priority List

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
Old	3415	461	505-10-2	(3-Methylthio)propanol	2001 (Session 57)	Full	The Specific Gravity, Solubility Description and possibly Purity does not reflect the material currently in commerce.
Old	3376	500	23550- 40-5	4-(Methylthio)-4-methyl-2- pentanone	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3897	510	75-33-2	2-Propanethiol	2001 (Session 57)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3475	543	828-26-2	Trithioacetone	2001 (Session 57)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	2911	896	120-57-0	Piperonal	2001 (Session 57)	Full	The Melting Point does not reflect the material currently in commerce.
Old	3557	973	2111-75- 3	<i>p</i> -Mentha-1,8-dien-7-al	2018 (Session 86)	Full	The Purity Specification, Acid Value and Specific Gravity do not reflect the material currently in commerce.
Old	2349	1093	622-45-7	Cyclohexyl acetate	2002 (Session 59)	Full	The Specific Gravity does not reflect the material currently in commerce.

Old	2467	1529	97-53-0	Eugenol	2005 (Session 65)		The Density Range does not reflect the material currently in commerce.
Old	4321	1763	116505- 60-3	Pyrrolidino-[1,2e]-4H-2,4- dimethyl1,3,5-dithiazine	2007 (Session 68)	Full	The melting point does not reflect the material in commerce.
Old	3507	49	2050-01- 3	Isoamyl isobutyrate	1997 (Session 49)	Full	The specific gravity and refractive index does not reflect the material in commerce.