



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-third Session

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2021/81-FA)

(Japan, Peru, FIA, IFAC, Intertek, IOFI and ISC)

Part A: Replies to CL 2021/81-FA, Annex 2 - Form for the submission of substances to be evaluated by JECFA

Japan

I. Gardenia (genipin) blue

Name of Substance(s):	Gardenia (genipin) blue
Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	A safety assessment of the food colour used as a green or blue colour in Japan and other countries and authorization as a useful colour

1. **Proposal for inclusion submitted by:** Japan

2. **Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):**

Chemical name: Gardenia (genipin) blue
Synonyms, common names: Gardenia blue
CAS number: N/A
INS Number: 165

3. **Names and addresses of basic producers:**

San-Ei Gen F.F.I., Inc. 1-1-11, Sanwa-cyo, Toyonaka, Osaka, 564-8588, Japan
Riken Vitamin Co., Ltd. 1-6-1, Yotsuya, Shinjuku-ku, Tokyo, 160-0004, Japan
Glico Nutrition Co., Ltd. 4-6-5, Utajima, Nishiyodogawa-ku, Osaka, 555-8502, Japan

4. **Identification of the manufacturer that will be providing data (Please indicate contact person):**

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

5. **Justification for use:** In line with the definitions set out in Class Names and the International Numbering System (INS) for Food Additives (CXG 36-1989) along with the requirements of Section 3.2 (c) of the General Standard for Food Additives (GSFA), Gardenia (genipin) 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 Section 6 below.

6. **Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):**

GSFA food category number	GSFA food category name	Proposed Food Use	Maximum use level mg/kg
01.1.4	Flavoured fluid milk drinks	Flavoured milk	500
01.7	Dairy-based desserts	Flavoured yoghurt	10,000
03.0	Edible ices, including sherbet and sorbet	Frozen desserts	1,000
		Ice-cream	10,000
04.1.2.5	Jam, jellies, marmalades	Jam, jellies and marmalades	500
05.2.1	Hard candy	Hard candy	500
05.2.2	Soft candy	Soft candy	10,000
05.2.3	Nougats and marzipans	Soft candy	10,000
05.3	Chewing gum	Chewing gum	10,000
05.4	Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces	Sugar coating	10,000
		Icing	5,000
		Syrup for shaved ice	1,000
06.3	Breakfast cereals, including rolled oats	Processed breakfast cereals	5,000
07.2.1	Cakes, cookies and pies	Sponge cake	5,000
11.4	Other sugars and syrups	Syrup for shaved ice	1,000
13.6	Food supplements	Chewable tablet	10,000
14.1.3	Fruit and vegetable nectars	Fruit nectars	250
14.1.4	Water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and "particulated" drinks	Flavoured enhanced water	500
		Fruit drinks/ades	500
		Sports drinks	500
		Carbonated drink	500
		Powdered beverage	500 *Note 127; On the served to the consumer basis
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	Ready-to-drink Tea	500
14.2.7	Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)	Other alcoholic drink e.g. cocktails, alcopops	500

7. **Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))**

Other than the general prohibition against the use of the colorant in fresh fish and seafood, meat, and vegetables, there are currently no food-specific standards for the use of Gardenia (genipin) blue in Japan, and the use of the technically necessary amount is permitted.

Gardenia (genipin) blue is also approved for use in foods in China, Korea, and Taiwan in a range of products. An application for authorisation has also been submitted in the USA and applications are planned to the EU and UK in the near future.

8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.

Codex Alimentarius Commission has assigned INS 165 to Gardenia (genipin) blue, but no safety evaluation has been conducted by JECFA. Once this has been completed a proposal for its inclusion in the General Standard for Food Additives, in line with the proposed uses and use levels described in Section 6 above will be submitted to the CCFA.

9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.

Gardenia (genipin) blue is currently being evaluated by the US FDA and applications for approval in the EU and UK will be submitted shortly (with these requiring risk assessments by EFSA and the UK Food Standards Agency, respectively).

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries

Not applicable

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

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

	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y <i>Toxicokinetic (ADME) data are available from rodent studies conducted in line with OECD Test Guidelines. In addition studies examining the fate of the additive under simulated gastric conditions have been conducted.</i>
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y <i>Genotoxicity: Bacterial reverse mutation assay, In vitro chromosome aberration studies, and In vitro and in vivo micronucleus studies Sub-chronic: Data are available from two sub-chronic (90 day) studies in rats Chronic / Carcinogenicity: Data are available from a two year, chronic / carcinogenicity study in rats as well as a 6 month rasH2 mice carcinogenicity study Reproductive and developmental toxicity: Data are available from an Extended One Generation reproductive and developmental study in rats as well as a 12M in-utero exposure toxicity study in rats.</i>
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N/A
(iv) Other data (please specify)	<i>Potential allergenicity of Gardenia (genipin) blue has been reviewed The potential toxicity of the two main residual impurities (Genipin/Geniposide) has been reviewed</i>
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
Dietary exposure assessment data	
(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used	Y
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y
Other information: (please specify)	

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

The data supporting this request are available for submission immediately

II. Protease From *Bacillus amyloliquefaciens*

Name of Substance(s):	Protease From <i>Bacillus amyloliquefaciens</i>
Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	Safety evaluation when used as processing aid and establishment of specifications.

1. **Proposal for inclusion submitted by:** Japan

2. Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):

Name of substance: Neutral Protease

Trade name: ORIENTASE 90N, ORIENTASE 10NL

Chemical name: Bacillolysin, Neutral Protease (CAS-No.76774-43-1)

3. Names and addresses of basic producers:

HBI Enzymes Inc.

650-1, Kamihiji, Yamasaki-cho, Shiso-City, HYOGO 671-2558, JAPAN

4. Identification of the manufacturer that will be providing data (Please indicate contact person):

Atsushi Kawahara (Quality Assurance Dept. General Manager)

E-mail: akawahara@hbi-enzymes.com

Tel: +81-790-64-1201; Fax: +81-790-64-1202

5. Justification for use:

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.

6. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

FoodCatNo	FoodCategory	MaxLevel
07.0	Bakery wares	70 TOS in mg/kg food
12.5	Soups and broths	120 TOS in mg/kg food
12.6	Sauces and like products	120 TOS in mg/kg food
13.1.1	Infant formulae	70 TOS in mg/kg food
14.2.1	Beer and malt beverages	10 TOS in mg/kg food

14.2.6	Distilled spirituous beverages containing more than 15% alcohol	10 TOS in mg/kg food
15.	Ready-to-eat savouries	120 TOS in mg/kg food

7. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

Below, a non-exhaustive list of existing authorizations and evaluations is presented:

Non-exhaustive list of authorisations of Bacillolysin produced by <i>Bacillus subtilis</i> / <i>Bacillus amyloliquefaciens</i>		
Authority	Description	Reference
Japan	Protease <i>Bacillus amyloliquefaciens</i>	<u>Japan's Specifications and Standards for Food Additives (JSFA)</u>
Australia/ New Zealand	Metalloproteinase from <i>B. amyloliquefaciens</i> / <i>B. subtilis</i>	<u>Standarbasiaad 1.3.3 processing aids</u>
Canada	Protease from <i>Bacillus amyloliquefaciens</i> var./ <i>Bacillus subtilis</i> var	<u>B.16.100, Table V Food Additives That May Be Used as Food Enzymes List of Permitted Food Enzymes (Lists of Permitted Food Additives)</u>
France	Protéases (métallo-) de <i>B. subtilis</i> Protéases de <i>B. subtilis</i> Protéase issue d'une souche non génétiquement modifiée de <i>B. amyloliquefaciens</i> (NB).	<u>Arrêté du 19 Octobre 2006</u>
JECFA	Mixed microbial carbohydrase and protease from <i>B. subtilis</i> var.	<u>FAS 1/NMRS 50A-JECFA 15/9</u>
Korea	Protease from <i>Bacillus amyloliquefaciens</i> and its variety	<u>Food Additives Code(#2020-59, 2020.07.10.)</u>
Thailand	Microbial metalloproteinases (<i>Bacillus amyloliquefaciens</i>)	<u>ประกาศกระทรวงสาธารณสุข (ฉบับที่ 409) พ.ศ. 2562 ออกตามความในพระราชบัญญัติอาหาร พ.ศ. 2522 เรื่อง เอนไซม์ส าหรับใช้ในการผลิตอาหาร</u>

8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.

N/A

9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment. .

Due to the positive list, it is currently under review (risk assessment). (EU Regulation No. 1331/2008 and Regulation No. 1332/2008)

Organization :EFSA (<https://www.efsa.europa.eu/en>)

Situation In progress

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries

N/A

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

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

	Data available? (Y / N)
Toxicological data	
(v) Metabolic and pharmacokinetic studies (please specify)	N
(vi) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify) <ul style="list-style-type: none"> • 3-Month repeated dose oral toxicity study in rats • Reverse mutation test with bacteria • Chromosomal aberration test with cultured mammalian cells All tests were conducted in compliance with Principles of Good Laboratory Practice (GLP). In these reports, the production strain is described as <i>Bacillus subtilis</i> . The former name of the production organism was <i>Bacillus subtilis</i> ; the current name is <i>Bacillus amyloliquefaciens</i> .	Y <i>Signed original report: Japanese</i> <i>(English version available)</i>
(vii) Epidemiological and/or clinical studies and special considerations (please specify)	N
(viii) Other data (please specify)	N
Technological data	
(iii) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y
(iv) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
Dietary exposure assessment data	
(iii) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used	Y
(iv) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y
Other information: (please specify) <ul style="list-style-type: none"> • Cytotoxicity test data of production strain supporting QPS status Qualified presumption of safety (QPS) https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps	Y

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

When requested by JECFA, we will immediately submit the above data.

IFAC (International Food Additives Council)

IFAC is a global association representing manufacturers and end-users of food additives. IFAC has NGO Observer status before Codex Alimentarius and appreciates the opportunity to provide the following information.

IFAC is requesting that CCFA add glycolipids and silicon dioxide, amorphous, to the JECFA priority list. Glycolipids would be a new JECFA evaluation and silicon dioxide, amorphous, will be a re-evaluation.

I. Glycolipids

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

1. Proposal for inclusion submitted by:

International Food Additives Council (IFAC), 529 14th St NW, Suite 1280, Washington, DC 20045, USA.

2. Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S Number (as applicable):

Glycolipids, Nagardo®, Glycolipids from Sweet Osmanthus Ear (Dacryopinax spathularia), 2205009-17-0.

3. Names and addresses of basic producers:

Lanxess Deutschland GmbH, Kennedyplatz 1, D- 50569 Cologne, Germany.

4. Identification of the manufacturer that will be providing data (Please indicate contact person):

Lanxess Deutschland GmbH, Kennedyplatz 1, D- 50569 Cologne, Germany

Dr. Andrea Bosse, Senior Regulatory Affairs Manager (andrea.bosse@lanxess.com)

5. Justification for use:

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. Glycolipids do not present a human health risk based on a very favourable safety profile and low use levels.

6. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

Glycolipids would be a new GSFA entry, but it would be intended that they would be used in products within Food Categories 14.1.2 (Fruit and vegetable juices), 14.1.3 (Fruit and vegetable nectars, 14.1.4 (Water based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks), and 14.1.5 (Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa).

7. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies)).

Glycolipids are approved as a preservative in beverages in the European Union ([E 246](#)), Australia and New Zealand ([A1180](#)), and Canada ([NOM/ADM-0184](#)). In the United States, glycolipids are generally recognized as safe when used as an antimicrobial agent in select non-alcoholic beverages ([GRN 740](#)).

8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.

Countries which refer to JECFA/Codex for national food additive provisions, including countries in Africa, the Asia-Pacific region, the Gulf Cooperation Council, and Latin and South America do not permit products containing glycolipids at present.

9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.

- Health Canada completed a risk assessment as part of its premarket safety assessment published in June 2022 ([NOM/ADM-0184](#))
- The European Food Safety Authority (EFSA) adopted a scientific opinion regarding its safety evaluation of long-chain glycolipids from Dacryopinax spathularia in May 2021 (<https://www.efsa.europa.eu/en/efsajournal/pub/6609>).
- Food Standards Australia New Zealand (FSANZ) completed a risk assessment as part of its evaluation of glycolipids which was published in December 2020 ([A1180](#)).
- The U.S. Food and Drug Administration (FDA) completed a risk assessment as part of its review of GRAS Notice 740 ([GRN 740](#)), which was published in May 2018.
- The Federal Commission for Protection Against Health Risks in Mexico (COFEPRIS) completed a risk assessment as part of its premarket safety assessment of glycolipids and amended [Annex I](#), Additives with different Functional Classes, and established ADIs.

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries.

Nagardo is a preservative with a favorable safety profile, which protects beverages for *the* deterioration caused by spoilage microorganisms and hence ensure the safety of the final consumer. Nagardo may be used as an alternative to conventional preservatives such as benzoate and sorbate. This is especially of relevance in regions who do not have an established chilled chain in place. Further Nagardo is as a powder stable up to 40 ° C and may be added to the production process easily via a stock solution, which does not need sophisticated equipment even under simple conditions.

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

	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y (ADME)
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y (see attachment)
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N
(iv) Other data (please specify)	Y (see attachment)
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
Dietary exposure assessment data	
(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used	Y
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y for US, EU and AUS/NZ
Other information: (please specify)	

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

All data are available and can be submitted in response to a JECFA call for data as soon as it is published.

II. Silicon Dioxide, Amorphous

Name of Substance(s):	Silicon Dioxide, Amorphous
Questions to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	Request for a safety re-evaluation of Silicon Dioxide, Amorphous (INS 551), including toxicological evaluation, exposure assessment, and specifications. JECFA last conducted a safety assessment of Silicon Dioxide, Amorphous (INS 551) in 1985, resulting in an assigned acceptable daily intake (ADI) of "not specified" for silicon dioxide and certain silicates. Evaluations in 2015 and 2017 were considered for specification only. Extensive physical, chemical, and toxicological data have been developed since the last safety assessment and, in consideration of the global use of silicon dioxide as a food additive and advances in risk assessment of particles, a timely safety re-evaluation would provide international assurance for the substance's continued use.

1. **Proposal for inclusion submitted by:** International Food Additives Council (IFAC)
529 14th Street NW, Suite 1280 Washington, DC 20045 USA

2. Name of the substance; trade name(s); chemical names(s), IUPAC name, C.A.S number (as applicable):

Name of the substance:	Silicon Dioxide, Amorphous
Synonyms:	Silica; INS No. 551; Synthetic Amorphous Silica (SAS); Silicon dioxide
Trade names:	AEROSIL [®] , CAB-O-SIL [®] , DARACLAR [®] , FLO-GARD [™] , GASIL [®] , HDK [®] , IBERSIL [®] , NEOSYL [®] , PERKASIL [®] , RxCIPIENTS [®] , SILCRON [®] , SILICA VP, SIPERNAT [®] , SYLOBLANC [®] , SYLODENT [®] , SYLOID [®] , Tixosil [®] , TRISYL [®] , Zeofree [®] , Zeothix [®] (list not exhaustive)
Chemical name(s):	Silicon dioxide, chemically prepared
IUPAC name:	Dioxosilane
CAS Number:	7631-86-9 112945-52-5 (pyrogenic silica) 112696-00-8 (hydrated silica)

3. Names and addresses of basic producers

Cabot Performance Materials Belgium/Cabot Corporation, Boston, USA

Evonik Resource Efficiency GmbH, Hanau-Wolfgang, Germany

GRACE GmbH, Worms, Germany/W.R. Grace & Co., Columbia, Maryland, USA

IQESIL S.A., Zaragoza Spain

PPG, Pittsburgh, Pennsylvania, USA/ PPG Industries Chemicals B.V., Delfzijl, The Netherlands

PQ LLC, US/PQ Silicas UK Ltd, Warrington, UK

Solvay S.A., Bruxelles, Belgium

Wacker Chemie AG, Munich, Germany

4. Identification of the manufacturer that will be providing data (Please indicate contact person):

The basic producers identified in item 3 above will be providing data through their representative trade associations, as follows:

Association of Synthetic Amorphous Silica Producers (ASASP), a Cefic Sector Group

Contact: Caroline Andersson, CAN@cefic.be

Synthetic Amorphous Silica and Silicate Industry Association (SASSI)

Contact: Joel F. Carpenter, joel.f.carpenter@gmail.com

5. Justification for use:

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.

6. Food products and food categories within GSFA in which the substance is used as a food additive or an ingredient, including use level(s):

Silicon dioxide, amorphous is listed in Table 3 of the General Standard for Food Additives (GSFA), as an additive permitted for use in food in general in accordance with good Manufacturing Practice (GMP). It is also listed in the following GSFA food categories.

Category No.	Category	Use Level
1.6.1	Unripened cheese	GMP
1.6.2.1	Ripened cheese, includes rind	GMP
1.8.2	Dried whey and whey products, excluding whey cheeses	10,000 mg/kg
11.1.2	Powdered sugar, powdered dextrose	15,000 mg/kg
12.1.1	Salt	GMP
12.1.2	Salt substitutes	GMP
12.2.1	Herbs and spices	GMP
13.2	Complementary foods for infants and young children	2000 mg/kg
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	GMP

7. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country (ies))

Silicon dioxide, amorphous is used in all countries that legally permit use of GSFA-listed food additives.

Silicon dioxide, amorphous, is also explicitly approved under the food additive laws and regulations in many jurisdictions, including Australia, Canada, China, European Union, Japan, United Kingdom, and the US.

8. Are you aware of any current impediments in international trade due to lack of JECFA evaluation and/or Codex standard? If so, please provide details.

As indicated in item 9 below, global regulatory authorities continue to evaluate the safety of silicon dioxide for use as a human and animal food additive, in response to specific industry petition or as part of on-going safety re-evaluations. In some instances, questions regarding the particle size of silicon dioxide have affected the evaluation of the available toxicity data. Similar 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 reevaluation of titanium dioxide (see [Replies to CL 2021/61-FA at the 52nd Session of the Codex Committee on Food Additives](#)). Significant efficiency is presented by leveraging already planned safety assessment of titanium dioxide and concurrently reviewing amorphous silicon dioxide, given the similarities presented between the substances and their uses.

9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.

The European Food Safety Authority (EFSA, Via Carlo Magno 1A, 43126 Parma, Italy) is currently re-evaluating INS 551 as part of the ongoing food additive re-evaluation process in Europe.

The US Food and Drug Administration (FDA, Center for Veterinary Medicine, 12225 Wilkins Avenue, Rockville, Maryland 20852, USA) evaluated silicon dioxide in 2019 (Food Additive Petition (FAP) 2308) for use as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal food components, for example, ingredients, intermediate premixes, premixes, supplements, or concentrates at an amount not to exceed 2% by weight of complete animal food. This evaluation included both human and target animal safety assessments.

In 2021-2022, FDA (Center for Food Safety & Applied Nutrition, 5001 Campus Drive, College Park, Maryland, 20740) evaluated an industry notification ([GRN No. 996](#)) regarding the generally recognized safety of synthetic amorphous silica (SAS) for use as a carrier to deliver and improve the perception of sweetness of white sugar at levels up to 0.30 g/100 g.

10. Please provide details if this food additive is of particular relevance to the livelihood and the food safety in developing countries

INS 551 is globally relevant to food safety. For developing countries, INS 551 is critical in ensuring the safety of spices originating from such countries as well as powdered infant formulae that are available in such countries.

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

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

	Data available? (Y/N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y (Metabolic studies)
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y (Studies and summaries on these toxicological endpoints are available and can be provided)
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	Y (Epidemiological studies evaluating inhalation route)
(iv) Other data (please specify)	N
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y (JECFA Monograph for Silicon Dioxide, Amorphous (2017) Physical (IR) or Chemical identification)

	test)
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y (Description of the manufacturing process, efficacy)
Dietary exposure assessment data	
(i) Levels of the listed substance used in food or expected to be used in food based on the technological function and the range	Y (Food legislation, food categories and allowed max. concentrations)
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used	Y (EFSA Scientific Opinion Re-evaluation of Silicon dioxide (2017), section 3.4.4 EU Consumption database)
Other information: (please specify)	

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

All information and data identified in response to Item 11 is currently available and can be submitted upon publication of a JECFA call for data.

ISC (International Stevia Council)

Name of Substance(s):	Steviol Glycosides
Question(s) to be answered by JECFA <i>(Provide a brief justification of the request in case of re-evaluations)</i>	Enzyme modified steviol glycosides (typically termed bioconversion) were evaluated at the JECFA 87 th meeting (2019). The specifications generated included several methods of manufacture in Appendix 3. 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 <i>E coli</i> to manufacture the enzymes that transform a stevia extract product to Rebaudioside 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.

- Proposal for inclusion submitted by:** International Stevia Council (ISC)
- Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):**
Steviol Glycosides
- Names and addresses of basic producers:** Manus Bio Inc. 1762 Lovers Lane, Augusta, GA, 30901, USA.
- Identification of the manufacturer that will be providing data (Please indicate contact person):**

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
Global Office-Avenue de Tervuren 188A-1150 Brussels Belgium

- Justification for use:** Sweetener. The benefits to the consumer of the enzyme modified steviol glycosides would mirror those of other steviol glycosides manufactured using the same technology that are currently permitted internationally. Steviol glycosides produced through enzyme modification would be used in foods and beverages to replace sugar, which will benefit consumers seeking products that have reduced caloric content. In addition, this would also include consumers with specific medical conditions that require reduced sugar intake, such as those with diabetes, as the consumption of steviol glycosides does not interfere with glucose homeostasis. The enzyme modified technology is capable of selecting those minor glycosides that have more favorable sensory characteristics than the major glycosides, present within the leaf, prompting

development of the enzyme modification technology to modify glycosides to improve the sensory profile of the articles of commerce (JECFA 87th report).

6. **Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):** Details can be found within the GSFA reference for steviol glycosides at link: <http://www.fao.org/gsaonline/groups/details.html?id=309>

7. **Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))** The specific steviol glycosides manufactured via enzyme modification is approved in the United States only. Enzyme modified steviol glycosides are approved in Australia/New Zealand, Canada, Ecuador, Columbia, Peru, Europe (EFSA positive safety opinion), Mexico and the United States

8. **Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.** A JECFA evaluation and Codex standard is internationally recognized and is adopted by many countries around the world who currently do not have the recognized capability for scientific evaluation. Therefore, a Codex standard supports the global acceptance of those glycosides offering improved sensory quality, produced by enzyme modification, providing additional opportunities and a broader freedom to operate in a wider international marketplace.

9. **Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.** A risk assessment for steviol glycosides meeting $\geq 95\%$ purity has been conducted at the 69th JECFA and other major international Regulatory Authorities, including EFSA, FSANZ, Health Canada and the FDA. In 2017, JECFA reassessed steviol glycosides for stevia rebaudiana Bertoni due to expansion of the SG specification. A risk assessment for the various new technologies including enzyme modification, has also been conducted by International Regulatory authorities.

10. **Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries** *Not applicable.*

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

	Data available? (Y/N)
Toxicological data	A full safety data package is available for steviol glycosides
(i) Metabolic and pharmacokinetic studies (please specify)	
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	
(iv) Other data (please specify)	
Technological data	All technology data have previously been provided
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	

Dietary exposure assessment data	Data previously provided
(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used	
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	
Other information: (please specify)	1.Data on the origins of the sequences used to modify E.coli, 2. Allergenicity screens 3. Toxicity screens

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

The data is available to be submitted immediately.

IOFI (International Organization of the Flavor Industry)

IOFI respectfully requests the addition of 16 new flavorings to the JECFA Priority list on Appendix IIa. IOFI also provides within this package Appendix IIb, which is a list of 88 flavourings that were previously submitted to CCFA for inclusion on the priority list, some of which were noted in Annex 3 of CL 2020/37-FA. Finally, Appendix IIc of this package includes 17 flavourings for which updated specifications data have become available.

We would like to note that, in particular, since IOFI proposed *p*-Mentha-1,8-dien-7-al (JECFA 973) for re-evaluation at the CCFA 51st Meeting, significant new data have been published.

The required information for the flavours as requested in Annex II of CL 2021/81-FA are attached as Appendix IIa_2023CCFA53, Appendix IIb_2023CCFA53, and Appendix IIc_2023CCFA53. If there are any questions or concerns, please do not hesitate to contact me at staylor@iofi.org.

<i>Name of Substance(s):</i>	See Appendix IIa_2023CCFA53, Appendix IIb_2023CCFA53 for substances to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents. See Appendix IIc_2023CCFA53 for substances that have updates to the online edition of "Specifications for Flavourings"
<i>Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)</i>	1. Are the substances in Appendix IIa and IIb of no safety concern at the current levels of exposure? 2. Do the published specifications for the flavouring agents as listed in Appendix IIc represent what is in global commerce?

1. **Proposal for inclusion submitted by:**

International Organization of the Flavor Industry

2. **Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):**

See Appendix IIa_2023CCFA53 and Appendix IIb_2023CCFA53 for substances to be evaluated by the Revised Procedure for the Safety Evaluation of Flavouring Agents.

3. **Names and addresses of basic producers:**

International Organization of the Flavor Industry (IOFI).

Flavor producers are members of the International Organization of the Flavor Industry (IOFI). All contacts can be made through IOFI.

4. **Identification of the manufacturer that will be providing data (Please indicate contact person):**

Sean V. Taylor, Ph.D., Scientific Director, IOFI (staylor@vertosolutions.net)

5. **Justification for use:**

The listed flavouring ingredients are used to improve the quality and enjoyment of food for human consumption.

6. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

Food Categories and Use Levels will be submitted for all new flavouring agents and candidates.

7. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

Yes (United States, European Union, Latin America and Japan)

8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.

We are currently unaware of any impediments to international trade due to a lack of JECFA evaluation and/or Codex standard for the ingredients listed.

9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.

We are currently unaware of ongoing risk assessments at a national or regional level for these flavourings. For the flavouring *p*-Mentha-1,8-dien-7-al (JECFA 973), JECFA concluded at its eighty-sixth (86th) Meeting that there were concerns for the genotoxic potential, and thus the re-evaluation was not completed. At the 51st CCFA Meeting IOFI requested that this flavouring be added to the JECFA priority list for an updated re-evaluation. Since the 51st Meeting, additional helpful genotoxicity information are available in the peer-reviewed literature that should be helpful to finalize the JECFA evaluation.

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries

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

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

	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N
(iv) Other data (please specify)	N
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
Dietary exposure assessment data	
(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used	Y
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y
Other information: (please specify)	

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

The earliest date that the data can be made available to JECFA is December 15, 2023.

Appendix IIa. Sixteen (16) flavourings newly proposed for inclusion on the JECFA Priority List to be considered at the 53rd session of the Codex Committee on Food Additives

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
New 53 rd	4948	1129-69-7	2-Hexylpyridine	II
New 53 rd	4958	2308574-23-2	4-Formyl-2-methoxyphenyl <i>l</i> -menthyl glutarate	I
New 53 rd	4959	301310-73-6; 79894-05-	9-Dodecen-12-olide	III
New 53 rd	4960	13474-59-4	<i>trans-alpha</i> -Bergamotene	I
New 53 rd	4961	2369713-22-2	4-Methyltrideca-2 <i>E</i> ,4-dienal	I
New 53 rd	4965	1622458-32-5	<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)isonicotinamide	III
New 53 rd	4966	6137-11-7	4-Methylheptan-3-one	II
New 53 rd	4967	483-76-1	<i>delta</i> -Cadinene	I
New 53 rd	4970	2413115-68-9	2-Methyl-1-(2-(5-(<i>p</i> -tolyl)-1 <i>H</i> -imidazol-2-yl)piperidin-1-yl)butan-1-one	III
New 53 rd	4971	18794-84-8	<i>beta</i> -Farnesene	I
New 53 rd	4972	23060-14-2	Diethyl mercaptosuccinate	I
New 53 rd	4973	2411762-60-0	3-Mercapto-3-methyl-1-pentyl acetate	I
New 53 rd	4974	23986-74-5	Germacrene D ≥85%	I
New 53 rd	4977	65210-18-6	10-Hydroxy-4,8-dimethyldec-4-enal	I
New 53 rd	4979	142062-38-2	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	III
New 53 rd	4980	2415657-73-5	Mixture of (8 <i>Z</i> ,11 <i>Z</i>)-heptadeca-8,11-dienal and (<i>Z</i>)-heptadec-8-enal	I

Appendix IIb. Eighty-eight (88) 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	<i>p</i> -Mentha-1,8-dien-7-al (Perillaldehyde)	
Submitted at the 43rd CCFA	4074	6321-45-5	Allyl valerate	II
Submitted at the 43rd CCFA	4072	20474-93-5	Allyl crotonate	II
Submitted at the 45th CCFA	4685	7370-92-5	(±)-6-Octahyltetrahydro-2H-pyran-2-one	I
Submitted at the 45th CCFA	4673	7370-44-7	<i>delta</i> -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	III
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	III
Submitted at the 51st CCFA	4842	911212-28-7	2,4,5-Trithiaoctane	III
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	III
Submitted at the 51st CCFA	4824	1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate	III
Submitted at the 51st CCFA	4843	1838169-65-5	3-(Allyldithio) butan-2-one	III
Submitted at the 51st CCFA	4822	61407-00-9	2,6-Dipropyl-5,6-dihydro-2H-thiopyran-3-carboxaldehyde	II
Submitted at the 51st CCFA	4823	33368-82-0	1-Propenyl 2-propenyl disulfide	II
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	III
Submitted at the 51st CCFA	4769	851768-51-9	5-Mercapto-5-methyl-3-hexanone	I
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	I
Submitted at the 51st CCFA	4733	1006684-20-3	(±)-2-Mercaptoheptan-4-ol	III
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	<i>o</i> -trans-Coumaric acid	III

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
Submitted at the 43rd CCFA	4622	61683-99-6	Piperonal propyleneglycol acetal	III
Submitted at the 43rd CCFA	4627	6414-32-0	Anisaldehyde propyleneglycol acetal	III
Submitted at the 43rd CCFA	4618	23495-12-7	2-Phenoxyethyl propinate	III
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	III
Submitted at the 43rd CCFA	4620	122-99-6	2-Phenoxyethanol	III
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	I
Submitted at the 43rd CCFA	2860	94-47-3	Phenethyl benzoate	I
Submitted at the 43rd CCFA	4438	591-11-7	<i>beta</i> -Angelicalactone	I
Submitted at the 43rd CCFA	4195	87-41-2	Phthalide	III
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 43rd CCFA	4486	5694-82-6	Citral glyceryl acetal	I
Submitted at the 52 nd CCFA	4902	22122-36-7	3-Methyl-2(5 <i>H</i>)-furanone	III
Submitted at the 52 nd CCFA	4915	2142634-65-7	(5 <i>Z</i>)-3,4-Dimethyl-5-propylidene-2(5 <i>H</i>)-furanone	III
Submitted at the 52 nd CCFA	4784	57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	I
Submitted at the 52 nd CCFA	4939	2180135-09-3	S-Methyl 5-(1-ethoxyethoxy)decanethioate	I
Submitted at the 52 nd CCFA	4894	116229-37-9	2-Mercapto-3-methyl-1-butanol	I
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	I
Submitted at the 52 nd CCFA	4938	2180135-08-2	S-Methyl 5-(1-ethoxyethoxy)tetradecanethioate	I
Submitted at the 52 nd CCFA	4901	2097608-89-2	O-Ethyl S-(3-methylbut-2-en-1-yl)thiocarbonate	I
Submitted at the 52 nd CCFA	4900	64580-54-7	Hexyl propyl disulfide	I
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	I
Submitted at the 52 nd CCFA	4930	159017-89-7	4-Isopropoxycinnamaldehyde	I
Submitted at the	4888	1945993-01-	Mixture of 5-hydroxy-4-(4'-	III

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
52 nd CCFA		0; 828265-08-3	hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one and 7-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-5-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-yl)ethanone	II
Submitted at the 52 nd CCFA	4892	4707-61-3	<i>cis</i> -2-Hexylcyclopropaneacetic acid	II
Submitted at the 52 nd CCFA	4890	27841-22-1	3- <i>p</i> -Menthen-7-al	I
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	I
Submitted at the 52 nd CCFA	4827	6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	I
Submitted at the 52 nd CCFA	4869	886449-15-6	4-(<i>I</i> -Menthoxo)-2-butanone	II
Submitted at the 52 nd CCFA	4844	118026-67-8	(2 <i>E</i> ,4 <i>E</i>)-2,4-Decadien-1-ol acetate	I
Submitted at the 52 nd CCFA	4747	91212-78-1	(±)-2,5-Undecadien-1-ol	II
Submitted at the 52 nd CCFA	4913	18478-46-1	3,7-Dimethyl-2-methyleneoct-6-en-1-ol	II
Submitted at the 52 nd CCFA	4785	25234-33-7	2-Octyl-2-dodecenal	II
Submitted at the 52 nd CCFA	4786	13893-39-5	2-Hexyl-2-decenal	II
Submitted at the 52 nd CCFA	4929	60857-05-8	4-Methylidene-2-(2-methylprop-1-enyl)oxane	III
Submitted at the 52 nd CCFA	4920	220462-51-9	1-Ethyl-2-(1-pyrrolylmethyl)pyrrole	III
Submitted at the 52 nd CCFA	4832	108715-62-4	2-(3-Benzyloxypropyl)pyridine	III
Submitted at the 52 nd CCFA	4829	616-45-5	2-Pyrrolidone	I
Submitted at the 52 nd CCFA	4818	1370711-06-0	<i>trans</i> -1-ethyl-2-methylpropyl 2-2-butenolate	I
Submitted at the 52 nd CCFA	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 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	<i>L</i> -Carnitine tartrate	III
Submitted at the 52 nd CCFA	4868	61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5 <i>H</i>)-furanone	III
Submitted at the 52 nd CCFA	4896	2186611-08-3	<i>N</i> -(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-	III

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
			carboxamide	
Submitted at the 52 nd CCFA	4882	1857330-83-9	<i>N</i> -(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at the 52 nd CCFA	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 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	III
Submitted at the 52 nd CCFA	4881	1857331-84-0	<i>N</i> -(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
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- <i>N</i> -[(4-hydroxy-3-methoxyphenyl)methyl]benzamide	III

Appendix IIc - Priority additions list of seventeen (17) compounds proposed for specifications modification by JECFA Priority List to be considered at the 53rd session of the Codex Committee on Food Additives

History	FEMA No.	JECFA No.	CAS No.	Principal 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	3876	482	1534-08-3	S-Methyl thioacetate	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce.
Old	3864	487	23747-45-7	S-Methyl methylbutanethioate ³⁻	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce
Old	3266	498	1003-04-9	4,5-Dihydro-3(2H) thiophenone	2000 (Session 55)	Full	The Specific Gravity does not reflect the material currently in commerce
Old	3512	499	13679-85-1	2-Methyltetrahydrothiophen-3-one	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do 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	3478	511	109-79-5	1-Butanethiol	1999 (Session 53)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3240	528	137-06-4	o-Toluenethiol	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3878	533	1618-26-4	bis(Methylthio)methane	2000 (Session 55)	Full	The Specific Gravity does 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	3851	554	136954-20-6	3-Mercaptohexyl acetate	1999 (Session 53)	Full	The Purity Specification requires clarity. The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3852	555	136954-21-7	3-Mercaptohexyl butyrate	1999 (Session 53)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3300	560	67633-97-0	3-Mercapto-2-pentanone	2000 (Session 55)	Full	The Refractive Index does 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	p-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.

History	FEMA No.	JECFA No.	CAS No.	Principal Name	Most Recent Specification Evaluation	Status	Update
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)	Full	The Density Range does not reflect the material currently in commerce

Part B: Replies to CL 2021/81-FA, Annex 3 -- Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up**Peru****COMMENTS ON SUBSTANCES ALREADY INCLUDED IN THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA**

In 2019 and 2020 circular letters were issued to compile additional proposals on the Priority List of Substances Proposed for Evaluation by JECFA (called PRIORITY LIST), to be considered at the CCFA meeting that was postponed; Canada, which has generally chaired the in-session Working Group meeting on this matter, has developed from the available documents an updated Priority List and has also taken into account the request for data for the 92nd meeting of the JECFA

In 2021, circular letter CL 2021/61-FA with the request for comments on the updated Priority List was received and a response was sent; at the 52nd Session of the CCFA, Canada, as Chair of the Working Group, introduced the document with proposals for additions and changes to the Priority List of Substances Proposed for evaluation by JECFA (Responses to CL 2019/61-FA and CL 2020/37-FA) which includes 6 recommendations and agreed to forward to the CCFA44 the updated List for approval and request the Codex Secretariat to issue a circular letter requesting information and comments on the Priority List of Substances Proposed for Evaluation by JECFA.

Then, in 2022 the Codex Secretariat forwarded this Circular Letter requesting for comments on the substances already included in the Priority List of Substances Proposed for Evaluation by JECFA.

No.	Substance (information)	Position/proposal for changes and/or additions	Technical Base/Comments
1	<u>Anionic methacrylate copolymer (AMC) (INS 1207)</u> Type of request: Data pending to finalize safety evaluation Proposed by: JECFA	Position Peru supports the proposed priority (Priority 1).	The priority is based on consumer protection from the point of view of health, JECFA's terms of reference, the quality, quantity and adequacy and availability of relevant data to complete an evaluation, consistent with the considerations of the Codex Procedural Manual.
2	<u>Aspartame (INS 951)</u> Type of request: Re-evaluation of safety Proposed by: ICBA International Council of Beverage Associations with the support of Colombia, Costa Rica and the USA		
3	<u>Acesulfame potassium (INS 950), Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), Annatto extracts, norbixin based (INS 160b(ii))</u> Type of request: Re-evaluation of exposure Proposed by: CCFA52		
4	<u>Azodicarbonamide (INS 927a)</u> Type of request: Safety assessment and establishment of specifications Proposed by: CCFA51		

No.	Substance (information)	Position/proposal for changes and/or additions	Technical Base/Comments
5	<u>Carob bean gum (INS 410)</u> 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		
6	<u>Diocetyl sodium sulfosuccinate (INS 480)</u> Type of request: Exposure assessment Proposed by: CCFA51		
7	<u>Fungal amylase from <i>Aspergillus niger</i></u> Type of request: Safety assessment and establishment of specifications Proposed by: CCFA51		
8	<u>Natamycin (235)</u> Type of request: Re-evaluation of safety and revision of specifications Proposed by: Russian Federation		
9	<u>NISIN (SIN 234)</u> Type of request: Re-evaluation of safety and revision of specifications Proposed by: Russian Federation		
10	<u>ortho-Phenylphenol (INS 231) and sodium orthophenylphenol (INS 232)</u> Type of request: Re-evaluation of ADI Proposed by: JECFA		
11	<u>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)</u> Type of request: Re-evaluation of safety Proposed by: JECFA		
12	<u>Rosemary extract (INS 392)</u> 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		
13	<u>Sorbitan monostearate (INS 491); Sorbitan tristearate (INS 492); Sorbitan monolaurate (INS 493), Sorbitan monooleate (INS 494); Sorbitan monopalmitate (INS 495)</u>		

No.	Substance (information)	Position/proposal for changes and/or additions	Technical Base/Comments		
	Type of request: Re-evaluation of safety and revision of specifications Proposed by: JECFA				
14	<u>Sucroglycerides (INS 474)</u> Type of request: Exposure assessment Proposed by: CCFA51				
15	<u>Sucrose esters of fatty acids (INS 473)</u> Type of request: Data pending - exposure assessment Proposed by: JECFA				
16	<u>Sucrose oligoesters, type I and type II (INS 473a)</u> Type of request: Data pending - exposure assessment Proposed by: JECFA	Position Peru supports the proposed priority (Priority 1).	The priority is based on consumer protection from the point of view of health, JECFA's terms of reference, the quality, quantity, adequacy, and availability of data pertinent to performing an assessment, consistent with the considerations of the Codex Procedure Manual.		
17	<u>Thaumantin II</u> Type of request: Safety assessment Proposed by: CCC with the support of Colombia; United States of America				
18	<u>Titanium dioxide (INS 171)</u> Type of request: Re-evaluation of safety, and revision of specifications if necessary Proposed by: JECFA				

No.	Substance (information)	Position/proposal for changes and/or additions	Technical Base/Comments
1	Bentonite (INS 558) Type of request: Establishment of specifications (lead) Proposed by: CCFA52	Position Peru supports the proposed priority (Priority 2).	Priority is based on proposals from CCFA51, work already undertaken by JECFA and the diversity of national legislation, considered in the Codex Procedural Manual.
2	<u>Black carrot extract (INS 163(vi))</u> Type of request: Data pending – characterization and toxicological information Proposed by: JECFA		
3	<u>Fulvic acid (carbohydrate derived)</u> 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.		
4	<u>Proteolytic enzyme from <i>Bacillus subtilis</i></u> Type of request: safety assessment and establishment of specifications Proposed by: CCFA51		
5	<u>Spirulina extract (INS 134)</u> Type of request: Data pending: analytical data Proposed by: JECFA		
6	<u>Tannins (oenological tannins)</u> Type of request: Data pending to complete evaluation: evaluation by JECFA84 Proposed by: CCFA50.		

No.	Substance (information)	Position/proposal for changes and/or additions	Technical Base/Comments
1	<p><u>Lycopene (synthetic, INS 160d(i)); and from <i>Blakeslea trispora</i>, INS 160d(iii)</u> Type of request: Revision of JECFA specifications with regard to the parameter “solubility” Proposed by: EU Specialty Food Ingredients (Federation of European Specialty Food Ingredients Industries)</p>	<p>Position Peru supports the proposed priority (Priority 3).</p>	<p>Priority is based on work already undertaken by European Bodies requesting revision of specifications for test adjustments, CCFA requests for additional information and data, as well as JECFA pending data request, considered in the Codex Procedural Manual.</p>
2	<p><u>Pentasodium triphosphate (INS 451 (i))</u> Type of request: Revision of specifications with regards to (1) revising the assay as P2O5 to “not more than 59.0%”; and revising the maximum pH value to 10.2 Proposed by: CEFIC (European Chemical Industry Council).</p>		
3	<p><u>Polyglycerol esters of fatty acids (INS 475)</u> Type of request: The completeness of the information for safety assessment Proposed by: CCFA51.</p>		
4	<p><u>Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)</u> Type of request: Re-evaluation of safety Proposed by: FoodDrinkEurope Polyglycerol Esters of Interesterified Ricinoleic Acid(SIN 476)</p>		

- i) Peru will not submit information on new substances for inclusion in the priority list
ii) Peru has no previous requests to confirm.

FIA (Food Industry Asia)

Name of Substance(s):	General Information	Comments
Azodicarbonamide (INS 927a)	<p>Type of request: safety assessment and establishment of specifications</p> <p>Proposed by: CCFA 51</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: The Physical Working Group on Alignment noted the safety concern on this food additive and request the re-evaluation of this food additive</p>	<ul style="list-style-type: none"> • FIA is of support for the proposal to re-evaluate the safety assessment of Azodicarbonamide (ADA) and the priority proposal (Priority 1) for the re-evaluation of ADA. • ADA is an ingredient used in flour and bread. Due to safety concerns, authorities in some markets such as European Union (EU), Japan, Singapore, Hong Kong, Indonesia, Australia and New Zealand, have chosen to apply precautionary principle and thus ban ADA in food. • The European Commission has also decided to prohibit the use of ADA in food contact materials since 2005. • As ADA is permitted for use in other markets, FIA is of the opinion that it is timely to review the safety of ADA to ascertain its safety. • Furthermore, a harmonised approach for the authorisation of ADA will provide a level playing field for the industries, considering that flour and bread are staple products that are traded globally.

IOFI (International Organization of the Flavor Industry)

Priority list of 81 flavourings proposed for inclusion on the JECFA Priority List to be considered at the 53rd session of the Codex Committee on Food Additives submitted in reply to CL 2021/81-FA

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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA52	4893		4912-58-7	2-Ethoxy-4-(hydroxymethyl)phenol	I
Submitted at CCFA52	4892		4707-61-3	<i>cis</i> -2-Hexylcyclopropaneacetic acid	II
Submitted at CCFA52	4890		27841-22-1	3- <i>p</i> -Menthen-7-al	I
Submitted at CCFA52	4928		554-14-3	2-Methylthiophene	II
Submitted at CCFA52	4839		163460-99-9; 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	II
Submitted at CCFA52	4813		1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	II
Submitted at CCFA52	4884		1569-60-4	6-Methyl-5-hepten-2-ol	I
Submitted at CCFA52	4827		6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	I
Submitted at CCFA52	4869		886449-15-6	4-(<i>L</i> -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-butenate	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-1carboxamide	III
Submitted at CCFA52	4882		1857330-83-9	<i>N</i> -(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at CCFA52	4899		1622458-34-7; 2079034-28-7	<i>N</i> -(1-((4-amino-2,2-dioxido-1 <i>H</i> -benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2methylpropan-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-5,5dimethylcyclohexanecarboxamide	III
Submitted at CCFA52	4877		76733-95-4	(<i>E</i>)-3-(3,4-Dimethoxyphenyl)- <i>N</i> -[2-(3-methoxyphenyl)-ethyl]-acrylamide	III

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA52	4835		877207-36-8	2,4-Dihydroxy- <i>N</i> -[(4-hydroxy-3-methoxyphenyl)methyl]benzamide	III
Submitted at CCFA53	4943		111-20-6	Decanedioic acid	I
Submitted at CCFA53	4944		6402-36-4	trans-2-Dodecenedioic acid	I
Submitted at CCFA53	4945		174155-46-5	cis-8-Decenal	I
Submitted at CCFA53	4946		9012-76-4	2-Amino-2-deoxy-poly-D-glucosamine	I
Submitted at CCFA53	4948		1129-69-7	2-Hexylpyridine	II
Submitted at CCFA53	4958		2308574-23-2	4-Formyl-2-methoxyphenyl <i>l</i> -menthyl glutarate	I
Submitted at CCFA53	4959		301310-73-6; 79894-05-	9-Dodecen-12-olide	III
Submitted at CCFA53	4960		13474-59-4	trans-alpha-Bergamotene	I
Submitted at CCFA53	4961		2369713-22-2	4-Methyltrideca-2E,4-dienal	I
Submitted at CCFA53	4965		1622458-32-5	<i>N</i> -(1-((4-Amino-2,2-dioxido-1H-benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide	III
Submitted at CCFA53	4966		6137-11-7	4-Methylheptan-3-one	II
Submitted at CCFA53	4967		483-76-1	<i>delta</i> -Cadinene	I
Submitted at CCFA53	4970		2413115-68-9	2-Methyl-1-(2-(5-(<i>p</i> -tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one	III
Submitted at CCFA53	4971		18794-84-8	beta-Farnesene	I
Submitted at CCFA53	4972		23060-14-2	Diethyl mercaptosuccinate	I
Submitted at CCFA53	4973		2411762-60-0	3-Mercapto-3-methyl-1-pentyl acetate	I
Submitted at CCFA53	4974		23986-74-5	Germacrene D ≥85%	I
Submitted at CCFA53	4977		65210-18-6	10-Hydroxy-4,8-dimethyldec-4-enal	I
Submitted at CCFA53	4979		142062-38- 2	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	III
Submitted at CCFA53	4980		2415657-73-5	Mixture of (8 <i>Z</i> ,11 <i>Z</i>)-heptadeca-8,11-dienal and (<i>Z</i>)-heptadec-8-enal	I

Priority list of 68 flavours previously proposed for inclusion on the JECFA Priority List to be considered for safety evaluation at the 53rd session of the Codex Committee on Food Additives, identified in reply to CL 2021/81-FA

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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Structural class
Submitted at CCFA51	4792		548740-99-4	(±)-3-Mercapto-1-pentanol	I
Submitted at CCFA51	4791		22236-44-8	3-(Acetylthio)hexanal	III
Submitted at CCFA51	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone	I
Submitted at CCFA51	4730		1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate	III
Submitted at CCFA51	4734		1256932-15-6	3-(Methylthio)-decanal	I
Submitted at CCFA51	4733		1006684-20-3	(±)-2-Mercaptoheptan-4-ol	III
Submitted at CCFA51	4761		75631-91-3	Prenyl thioisovalerate	I
Submitted at CCFA51	4760		53626-94-1	Prenyl thioisobutyrate	I
Submitted at CCFA45	4745		62439-41-2	(±)-6-Methoxy-2,6-dimethylheptanal	I
Submitted at CCFA45	4765		1367348-37-5	Ethyl 5-formyloxydecanoate	III
Submitted at CCFA45	4719		110-15-6	Succinic acid	I
Submitted at CCFA51	4871		1962956-83-7	2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate	I
Submitted at CCFA51	4826		10525-99-8	3-Phenylpropyl 2-(4-hydroxy-3-methoxy-phenyl)acetate	I
Submitted at CCFA51	4810		60563-13-5	Ethyl-2-(4-hydroxy-3-methoxy-phenyl)acetate	I
Submitted at CCFA45	4750		65405-77-8	<i>cis</i> -3-Hexenyl salicylate	I
Submitted at CCFA45	4700		614-60-8	<i>o-trans</i> -Coumaric acid	III
Submitted at CCFA43	4622		61683-99-6	Piperonal propyleneglycol acetal	III
Submitted at CCFA43	4606		930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate	I
Submitted at CCFA43	4627		6414-32-0	Anisaldehyde propyleneglycol acetal	III
Submitted at CCFA43	4435		673-22-3	2-Hydroxy-4-methoxybenzaldehyde	I
Submitted at CCFA43	4430		99-50-3	3,4-Dihydroxybenzoic acid	I
Submitted at CCFA43	4431		99-06-9	3-Hydroxybenzoic acid	I
Submitted at CCFA43	4618		23495-12-7	2-Phenoxyethyl propionate	III
Submitted at CCFA43	4625		6314-97-2	Phenylacetaldehyde diethyl acetal	I
Submitted at CCFA43	4629		5468-05-3	Phenylacetaldehyde propyleneglycol acetal	III
Submitted at CCFA43	4620		122-99-6	2-Phenoxyethanol	III
Submitted at CCFA43	4619		92729-55-0	Propyl 4- <i>tert</i> -butylphenylacetate	I
Submitted at CCFA43	4314		61810-55-7	Phenethyl decanoate	I
Submitted at CCFA43	2860		94-47-3	Phenethyl benzoate	I
Submitted at CCFA43	4438		591-11-7	<i>beta</i> -Angelicalactone	I
Submitted at CCFA43	4195		87-41-2	Phthalide	III
Submitted at CCFA45	4768		67936-13-4	2,6,10-Trimethyl-9-undecenal	I
Submitted at CCFA45	4612		645-62-5	2-Ethyl-2-hexenal	II
Submitted at CCFA45	4616		13019-16-4	2-Hexylidenehexanal	II
Submitted at CCFA45	4486		5694-82-6	Citral glyceryl acetal	I

Priority list of 96 flavours proposed for inclusion on the JECFA Priority List to be considered for revision of specifications at the 53rd session of the Codex Committee on Food Additives submitted in reply to CL 2021/81-FA

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	3862	489		S-Methyl hexanethioate	2003 (session 61)	CAS number should be 2432-77-1; update the chemical formula and molecular weight
Old	4047	1383	67746-30-9	(E)-2-hexenal diethyl acetal	2004 (Session 63)	The specification requires clarity. 92% 2Eisomer and 3-5% 2Z-isomer
Old	3333	1170	551-08-6	3-Butylidenephthalide	2003 (Session 61)	The assay value is currently not reflective of the material in commerce
Old	2962	755		Isopulegol	2000 (Session 55)	The currently listed CAS number is for the Lisomer but the substance is a mixture of D and L-isomers, which are better represented by CAS 7786-67-6
Old	3658	1233	470-67-7	1,4-Cineole	2003 (Session 61)	The Specific Gravity and Refractive index do not reflect the material currently in commerce.
Old	3791	1166	4430-31-3	Octahydrocoumarin	2003 (Session 61)	Specific gravity in the database does not reflect the material currently in commerce
Old	3849	1411	195863-84-4	3-(L-Menthoxy)-2- methylpropane-1,2-diol	2004 (Session 63)	Specific gravity in the database does not reflect the material currently in commerce
Old	4053	1416	42822-86-6	p-Menthane-3,8-diol	2004 (Session 63)	Specific gravity in the database does not reflect the material currently in commerce.
Old	3927	808	645-13-6	p-Isopropylacetophenone	2001 (Session 57)	Clarity on the positional isomer description
Old	2005	810	100-06-1	Acetanisole	2001 (Session 57)	Clarity on the positional isomer description
Old	3839	1343	502-61-4	Farnesene (alpha and beta)	2004 (Session 63)	The CAS number 688330-26-9 better described the mixture of alpha and betafarnesene
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 9394060-4. 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

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	3865	571		Methyl 3-methyl-1-butenyl disulfide	2003 (Session 61)	The CAS number for this substance is 233666-09-6. There is currently not one listed in the database
Old	3752	933		Potassium 2-(1'-ethoxy)ethoxypropanoate	2001 (Session 57)	The CAS number for this substance is 100743-68-8. There is currently not one listed in the database
Old	3806	444	156329-82-2	(-)-Menthol 1- and 2-propylene glycol carbonate	1998 (Session 51)	The CAS number currently listed in the database has been deleted by the registry. The current CAS No. is 30304-82-6
Old	2611	930	598-82-3	Lactic acid	2001 (Session 57)	The CAS number currently listed in the database has been deleted by the registry. The CAS Nos. that represent this substance are 10326-41-7; 79-33-4; 50-21-5
Old	2044	9	7439-76-7	Allyl 10-undecenoate	1996 (Session 46)	There is a typographical error in the CAS number. It should be 7493-76-7
Old	2514	54	1005-86-2	Geranyl formate	2003 (Session 61)	There is a typographical error in the CAS number. It should be 105-86-2
Old	2031	4	142-91-8	Allyl heptanoate	1996 (Session 46)	There is a typographical error in the CAS number. It should be 142-19-8
Old	2040	1	2408-70-0	Allyl propionate	2000 (Session 55)	There is a typographical error in the CAS number. It should be 2408-20-0
Old	3353	1272	151824	3-Hexenyl formate (<i>cis</i> and <i>trans</i> mixture)	2003 (Session 61)	There is a data error in the CAS number field. The correct CAS number is 33467-73-1
Old	3493	135	34942-91-1	<i>trans</i> -3-Heptenyl acetate	1997 (Session 49)	The CAS number for the <i>trans</i> -isomer is 157677-8
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
Old	2875	1005	1303342	Phenylacetaldehyde 2,3-butylene glycol acetal	2002 (Session 59)	There is a typographical error in the CAS number. The correct CAS number is 5468-06-4
Old	2899	641	1297527	3-Phenylpropyl isovalerate	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 5452-07-3

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	2913	895	1300847	Piperonyl isobutyrate	2001 (Session 57)	There is a typographical error in the CAS number. The correct CAS number is 5461-08-5
Old	2939	661	2147784	Isopropyl cinnamate	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 7780-06-5
Old	2983	74	1338-23-8	Rhodinyl isobutyrate	2001 (Session 57)	There is a typographical error in the CAS number. The correct CAS number is 138-23-8.
Old	3164	1179	881395	(E,E)-2,4-Heptadienal	2003 (Session 61)	There is a typographical error in the CAS number. The correct CAS number is 4313-03-5
Old	3172	189	164183	Hexyl isobutyrate	1997 (Session 49)	There is a typographical error in the CAS number. The correct CAS number is 2349-07-7
Old	3212	1185	1771490	2,4-Nonadienal	2003 (Session 61)	There is a typographical error in the CAS number. The correct CAS numbers are 5910-87-2; 6750-03-4
Old	3365	1119	489673	5-Methyl-5-hexen-2-one	2002 (Session 59)	There is a typographical error in the CAS number. The correct CAS number is 3240-09-3
Old	3443	1337	997297	Valencene	2004 (Session 63)	There is a typographical error in the CAS number. The correct CAS numbers are 68773-84-2; 4630-07-3
Old	3445	1427	582174	DL-(3-Amino-3-carboxypropyl)dimethylsulfonium chloride	2004 (Session 63)	There is a typographical error in the CAS number. The correct CAS numbers are 1115-84-0; 3493-12-7
Old	3487	1481	1110651	Ethyl maltol	2007 (Session 68)	There is a typographical error in the CAS number. The correct CAS number is 4940-11-8
Old	3507	49	54791	Isoamyl isobutyrate	1997 (Session 49)	There is a typographical error in the CAS number. The correct CAS number is 2050-01-3
Old	3582	1836	198242	1-Octen-3-yl acetate	2008 (Session 69)	There is a typographical error in the CAS number. The correct CAS number is 2442-10-6
Old	3652	731	610841	4-(p-Acetoxyphenyl)-2-butanone	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 3572-06-3
Old	3677	553	1302615	Ethyl 3-mercaptopropionate	2002 (Session 59)	There is a typographical error in the CAS number. The correct CAS number is 5466-06-8
Old	3704	722	1730647	4-Methyl-2,6-dimethoxyphenol	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 6638-05-7
Old	3991	1269	1207311	Isoprenyl acetate	2003 (Session 61)	There is a typographical error in the CAS number. The correct CAS number is 5205-07-2
Old	4014	1563	130638	Phenethyl isothiocyanate	2005 (Session 65)	There is a typographical error in the CAS number. The correct CAS number is 2257-09-2

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	4099	1711	544550	2,4-Dimethyl-1,3-dioxolane	2007 (Session 68)	There is a typographical error in the CAS number. The correct CAS number is 3390-12-3
Old	4170	1550	299352	Methyl N-acetylanthranilate	2005 (Session 65)	There is a typographical error in the CAS number. The correct CAS number is 2719-08-6
Old	4203	2063	1207440	Prenyl benzoate	2010 (Session 73)	There is a typographical error in the CAS number. The correct CAS number is 5205-11-8
Old	4291	2138	1040030	Methyl hexyl ether	2012 (Session 76)	There is a typographical error in the CAS number. The correct CAS number is 4747-07-3
Old	4364	1744	1286359	Decanal propyleneglycol acetal	2007 (Session 68)	There is a typographical error in the CAS number. The correct CAS number is 5421-12-5
Old	4368	1739	895487	Heptanal propyleneglycol acetal	2007 (Session 68)	There is a typographical error in the CAS number. The correct CAS number is 4351-10-4
Old	4371	1730	709364	Isovaleraldehyde diethyl acetal	2007 (Session 68)	There is a typographical error in the CAS number. The correct CAS number is 3842-03-3
Old	4575	1930	55252	Diisoamyl disulfide	2010 (Session 73)	There is a typographical error in the CAS number. The correct CAS number is 2051-04-9
Old	2368	156	1298317	Decyl butyrate	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 5454-09-1
Old	2374	620	2065419	Diethyl malate	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 7554-12-3
Old	2400	235	148051	gamma-Dodecalactoe	1998 (Session 51)	There is a typographical error in the CAS number. The correct CAS number is 2305-05-7
Old	2031	4	142-91-8	Allyl heptanoate	1996 (Session 46)	There is a typographical error in the CAS number. The correct CAS number is 142-19-8.
Old	2040	1	2408-70-0	Allyl propionate	2000 (Session 55)	There is a typographical error in the CAS number. The correct CAS number is 2408-20-0
Old	2044	9	7493-76-7	Allyl 10-undecenoate	1996 (Session 46)	There is a typographical error in the CAS number. The correct CAS number is 7493-76-7
Old	2514	54	1005-86-2	Geranyl formate	2003 (Session 61)	There is a typographical error in the CAS number. The correct CAS number is 105-86-2
Old	2560	1353	6728-26-5	2-Hexenal	2004 (Session 63)	The general CAS number is 505-57-7
Old	3149	775	13925-07-0	2-Ethyl-3 (5 or 6)-dimethylpyrazine	2001 (Session 57)	The CAS number for 2-ethyl-3,6-dimethylpyrazine and mixture are 13360-65-1 and 27043-05-6

CCFA Listing History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation (Year (session No.))	Proposed Specification Update
Old	3196	1114	488-10-8	3-Methyl-2-(2-pentenyl)-2-cyclopenten-1-one	2016 (Session 82)	The CAS number for the trans isomer is 6261-18-3.
Old	3243	384	23726-92-3	beta-Damascone	2003 (Session 61)	The CAS numbers for the trans and general forms are 23726-91-2 and 35044-68-9.
Old	3264	326	30390-50-2	4-Decenal	2001 (Session 57)	The CAS number for the cis isomer is 21662-09-9. The specification requires clarity. Assay min 95% (90% cis isomer).
Old	3353	1272	151824	3-Hexenyl formate	2003 (Session 61)	The CAS numbers for the trans and general forms are 56922-80-6 and 2315-09-5
Old	3411	346	301-00-8	Methyl linoleate & Methyl linolenate (mixture)	2003 (Session 61)	The CAS numbers for methyl linoleate and mixture are 112-63-0 and 238757-19-2
Old	3478	511	61122-71-2	1-Butanethiol	1999 (Session 53)	The current CAS number in the database is for a different substance. The correct CAS number is 109-79-5.
Old	3486	1806	10544-63-5	Ethyl trans-2-butenate	2008 (Session 69)	The CAS number for the trans isomer is 623-70-1
Old	3493	135	34942-91-1	trans-3-Heptenyl acetate	1997 (Session 49)	The current CAS number in the database is for the general substance. The CAS number should be the trans isomer 34942-91-1
Old	3503	520		2, 3, or 10-Mercaptopinane	2000 (Session 55)	No CAS numbers previously provided. The CAS numbers should be 23832-18-0; 6588-78-9; 72361-41-2.
Old	3693	352	58625-95-9	Hexyl 2-methyl-3&4-pentenoate (mixture)	2001 (Session 57)	The CAS number for the 4-pentenoate (58031-03-1) is missing
Old	3752	933		Potassium 2-(1'-ethoxy)ethoxypropanoate	2001 (Session 57)	No CAS number previously provided. The CAS number should be 827024-53-3
Old	3773	1029	150436-68-3	Sodium 2-(4-methoxyphenoxy)propanoate	2019 (Session 87)	No free acid form CAS number previously provided. Free acid form CAS number is 13794-15-5.
Old	3790	493		Methylthio 2-(propionyloxy) propionate	2002 (Session 59)	No CAS number previously provided. The CAS number should be 827024-53-3
Old	3806	444	156329-82-2	(-)-Menthol 1- and 2-propylene glycol carbonate	1998 (Session 51)	The current CAS number has been deleted. The correct CAS number corresponding to a mixture of the 1- and 2-propylene glycol carbonates is 30304-82-6.
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
Old	3812	2014	24276-84-4	Sodium 3-methoxy-4-hydroxycinnamate	2010 (Session 73)	No free acid form (ferulic acid) CAS number previously provided. Free acid form CAS number is 1135-24-6

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 current CAS is for the alpha form. The CAS numbers should instead include the mixture (alpha and beta) and the general CAS which are 688330-26-9 and 125037-13-0, respectively.
Old	3862	489	20756-86-9	S-Methyl hexanethioate	2003 (Session 61)	The current CAS number in the database is for a different substance. The correct CAS number is 2432-77-1
Old	3865	571		Methyl 3-methyl-1-butenyl disulfide	2003 (Session 61)	No CAS number previously provided. The CAS number should be 233666-09-6
Old	3867	488		S-Methyl 4-methylpentanethioate	2003 (Session 61)	The CAS number should be 61122-71-2
Old	3881	501	51828-97-8	Sodium 4-(methylthio)-2-oxobutanoate	1999 (Session 53)	No free acid form CAS number previously provided. Free acid form CAS number is 583-92-6
Old	3886	1226		8-Ocimenyl acetate	2003 (Session 61)	No CAS number previously provided. The CAS number is 197098-61-6.
Old	4033	1716	62147-49-3	Dihydroxyacetone dimer	2007 (Session 68)	No CAS number for the monomer included. The CAS number for the monomer is 96-26-4.
Old	4513	2199	21368-68-3	dl-Camphor	2014 (Session 79)	The currently listed CAS number is incorrect. The CAS number is 76-22-2.
Old	4667	2116	54717-14-5	2-Ethyl-4,6-dimethyl-dihydro-1,3,5-dithiazine	2012 (Session 76)	Add CAS number of other isomer in mixture (54717-14-5) and change name to "2(4)-ethyl-4(2),6-dimethyldihydro-1,3,5-dithiazine (mixture of isomers)". Also under "Information Required" is says "FEMA number required"—remove.
Old	2700	418	80-71-7	Methylcyclo- pentenolone	2000 (Session 55)	Name should be "Methylcyclopentenolone" and the CAS number for the diketone of 765-70-8 should be added.
Old	3778	1382	33467-74-2	(Z)-3- & (E)-2-Hexenyl propionate	2004 (Session 63)	Add trans CAS number 53398-80-4
Old	3566	972	17916-91-5	1-p-Menthen-9-yl acetate	2002 (Session 59)	The currently listed CAS number is incorrect. The CAS number is 28839-13-6.
Old	3044	621	87-69-4	Tartaric acid (+)-, (-)-, (+/-)-, meso-	1999 (Session 53)	The racemic (133-37-9) and meso (147-73-9) CAS numbers are missing.
Old	2745	899	119-36-8	Methyl salicylate	2001 (Session 57)	Remove synonyms: "Synthetic sweet birch oil; Synthetic wintergreen oil; Synthetic teaberry oil"
Old	2306	218	77-92-9	Citric acid	2000 (Session 55)	Add FEMA number 2306 to specification entry.

ISC (International Stevia Council)

[The International Stevia Council \(ISC\)](#) has noticed that the 'Framework for the Safety Assessment and Adoption of Specifications for Steviol Glycosides Produced by Different Technologies' appears on the Priority List of substances proposed for evaluation by JECFA'. Considering such Framework has been adopted at the JECFA 91st and Codex Alimentarius Commission 44th meetings in 2021, and that the [Codex General Standard for Food Additives \(GSFA\)](#) has been updated accordingly, the ISC respectfully asks for the Framework to be deleted from the JECFA Priority List. We believe there was a clerical mistake in relation to the reasons why it has been kept into the Priority List, considering that the Framework has already been finalised and approved.

ISC wishes to thank you for taking this request into account and remains at your disposal should you require any additional information.

Part C: Replies to CL 2021/81-FA, Annex 4 – Confirmation of previous requests and data availability

Japan

I. Adenosine-5'-monophosphate deaminase from *Aspergillus oryzae*

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Adenosine-5'-monophosphate deaminase from <i>Aspergillus oryzae</i>
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, the data are available any time.
Change to data provider? (yes/no)	Yes The contact person of the representative has been changed: Shahrazad Tafazoli, Ph.D. Director, Safety & Regulatory Food & Nutrition Group Intertek Health Sciences Inc. Mobile +1 647 233 9561 Office +1 905 542-2900 ext. 0268 Intertek, 2233 Argentia Rd., Suite 201W, Mississauga, ON L5N 2X7

II. Glutaminase from *Aspergillus niger*

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Glutaminase from <i>Aspergillus niger</i>
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, the data are available any time.
Change to data provider? (yes/no)	Yes The contact person of the representative has been changed: Shahrazad Tafazoli, Ph.D. Director, Safety & Regulatory Food & Nutrition Group Intertek Health Sciences Inc. Mobile +1 647 233 9561 Office +1 905 542-2900 ext. 0268 Intertek, 2233 Argentia Rd., Suite 201W, Mississauga, ON L5N 2X7

Intertek

On behalf of Kalsec, Inc., Mane Kancor Ingredients Pvt. Ltd., Givaudan International SA, and Vitiva d.o.o., and in response to CL 2021/81-FA, please find attached a completed Form of Annex 4 (Confirmation of Previous Requests and Data Availability) of CL 2021/81-FA for rosemary extract (INS 392).

The outcomes of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at the Committee's 87th Meeting (4 to 13 June 2019) have not yet been considered by CCFA. The recommendation from JECFA in that meeting was as follows: "Studies on the developmental toxicity of rosemary extract and studies to elucidate whether the effects noted on pup thyroid hormone levels can be replicated were identified as research needs to complete the evaluation". The manufacturers of rosemary extract (Kalsec, Inc., Mane Kancor Ingredients Pvt. Ltd., Givaudan International SA, and Vitiva d.o.o.) would like to confirm that these additional studies have been conducted and final reports are expected to be available by Q3 2023.

Furthermore, the manufacturers of rosemary extract would like to propose an amendment to the intended uses and use levels for rosemary extract (an updated exposure assessment will be provided), and an amendment to the specification for residual acetone. These data will also be available by Q3 2023.

Based on the scheduled completion of the additionally requested studies by Q3 2023, we would appreciate prioritization of the evaluation of rosemary extract at the 2024 JECFA meeting.

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Rosemary extract (INS 392)
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, data available by Q3 2023.
Change to data provider? (yes / no)	No