



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-fourth Session

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES

PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2023/47-FA)

(Japan, Peru, AMFEP, CCC, DSM, EUSFI, FoodDrinkEurope, IACM, IFAC, IOFI and NATCOL)

Part A: Replies to CL 2023/47-FA, Annex 2 - Form for the submission of substances to be evaluated by JECFA

Japan

Name of Substance(s):	Acylglycerol lipase from <i>Penicillium crustosum</i> expressed in <i>Penicillium crustosum</i>
Question(s) to be answered by JECFA <i>(Provide a brief justification of the request in case of re-evaluations)</i>	<i>Safety evaluation when used as processing aid and establishment of specifications.</i>

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; Acylglycerol Lipase from *Penicillium crustosum* expressed in *Penicillium crustosum*
 Trade name; Lipase GS“Amano”250G (Main commercial name)
 Chemical name; Acylglycerol lipase (accepted IUBMB name)
 EC (IUBMB) number; 3.1.1.23
 CAS RN; 9040-75-9
3. Names and addresses of basic producers:
 Amano Enzyme Inc.
 2-7, 1-Chome, Nishiki, Naka-ku, Nagoya, Aichi, 460-8630, Japan
 Tel: +81 (0)52-211-3032
 Fax: +81 (0)52-211-3054
4. Identification of the manufacturer that will be providing data (Please indicate contact person):
 Yasuhiro Nomura
 Managing Director, Quality assurance division
 Amano Enzyme Inc.
 2-7, 1-chome, Nishiki, Naka-ku, Nagoya, Aichi 460-8630 Japan
 TEL: +81(0)52-211-3032 FAX: +81(0)52-211-3054
 E-mail: yasuhiro_nomura@amano-enzyme.com
 Hiromichi Yoshida
 RA Specialist

Amano Enzyme Inc.

27, Hanno, Kunotsubo, Kitanagoya, Aichi 481-8533 Japan

Tel: +81(0)568-21-4044 FAX: +81(0)568-26-6160

E-mail: hiromichi_yoshida@amano-enzyme.com

5. Justification for use:

Acylglycerol lipase catalyses the hydrolysis of ester bond between fatty acid and glycerol in monoglycerides and diglycerides and releases fatty acids and glycerol. Acylglycerol lipase also catalyses the ester synthesis reactions under the micro-aqueous conditions. The enzyme does not act on triglycerides. The enzyme can be used in the following processes as described below:

- Milk processing: Produce enzyme modified cheese (EMC), enzyme modified dairy products (EMD), improvement of the flavor by the increment of free fatty acids.
- Fats and Oil processing:
 - The enzyme can hydrolyze diglycerides without hydrolyzing triglycerides, thereby improving the relative purity of triglyceride in oil. This has the advantage of improving the crystallinity and thermal stability of fats and oils. The acylglycerol lipase enzyme is used to increase the triglyceride purity, which will consequently improve the physical properties without changing the triglyceride composition, leading to products that will meet customers' expectation for use.
 - The enzyme is able to produce monoglyceride from fatty acids and glycerol under the micro-aqueous conditions. The acylglycerol lipase is used to produce the monoglyceride for exocrine pancreatic insufficiency (EPI).

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):

The enzyme is used as a processing aid in milk processing (i.e. EMC, EMD), fats and oils processing (i.e. monoglyceride production, increase the triglyceride purity).

Food Category	Maximal recommended use level (mg TOS/Kg food)
01.0 Dairy products and analogues, excluding products of category 02.0	0.22 mg TOS/Kg food
02.0 Fats and oils, and fat emulsions	0.65 mg TOS/Kg food According to EFSA guidance, the enzyme is removed in this application. Process-specific technical data used in exposure assessment of food enzymes (wiley.com)
13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	20.7 mg TOS/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))

Currently, the enzyme is approved in U.S, FDA Notification GRAS Status (GRN No.908), and Japan. In Europe, the dossier is under evaluation by EFSA.

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

exhaustive list of authorisations of Acylglycerol lipase produced by <i>Penicillium crustosum</i> / <i>Penicillium camemberti</i>		
Authority	Description	Reference
Japan	Lipase	Japan's Specifications and Standards for Food Additives (JSFA)
U.S.	Lipase from <i>Penicillium camemberti</i>	GRN No. 908

	GRAS Notices (fda.gov)
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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.

Not aware of any.

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.

Date	Organization	Address
On-going	European commission Health and Consumer Directorate-General	Directorate E – Safety of the food chain Unit E3 – Chemicals, contaminants, pesticides B-1049 Brussels
Feb. 5, 2021	U.S. Food and Drug Administration	U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

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

Not aware of any.

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)	N
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify) Comments to the Toxicological data: <ul style="list-style-type: none"> Bacterial reverse mutation test performed in accordance with the test guidelines of Japanese Ministry of Health and Welfare (JMHW, 1999), equivalent standard to OECD Guideline 471 In vitro micronucleus test in TK6 cells was performed according to OECD Guideline for the Testing of Chemicals 487(revised 2016) and OECD GLP (revised 1997). 90-day Oral (gavage) Study in rats performed in accordance with the test guidelines of Japanese Ministry of Health and Welfare (JMHW, 1999), equivalent standard to OECD Guideline 408 	Y
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N
(iv) Other data (please specify) <ul style="list-style-type: none"> The Confirmation for the absence of viable cells from the production strain in the food enzyme The confirmation for the absence of DNA from the production strain in the food enzyme 	Y

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) · Results of mycotoxin analysis	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.**)

As soon as requested.

Substance(s):	Triacylglycerol lipase from <i>Limtongozyma cylindracea</i>
Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	<i>Safety evaluation when used as processing aid and establishment of specifications.</i>

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; Triacylglycerol lipase from *Limtongozyma cylindracea*

Trade name; Lipase AY“Amano”30SD (Main commercial name)

Chemical name; Triacylglycerol lipase (Accepted IUBMB name)

EC(IUBMB) number; 3.1.1.3

CAS RN; 9001-62-1

3. Names and addresses of basic producers:

Amano Enzyme Inc.

2-7, 1-Chome, Nishiki, Naka-ku, Nagoya, Aichi, 460-8630, Japan

Tel: +81 (0)52-211-3032

Fax: +81 (0)52-211-3054

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

Yasuhiro Nomura

Managing Director, Quality assurance division

Amano Enzyme Inc.

2-7, 1-chome, Nishiki, Naka-ku, Nagoya, Aichi 460-8630 Japan

TEL: +81(0)52-211-3032 FAX: +81(0)52-211-3054

E-mail : yasuhiro_nomura@amano-enzyme.com

Hikomichi Yoshida
 RA Specialist
 Amano Enzyme Inc.
 27, Hanno, Kunotsubo, Kitanagoya, Aichi 481-8533 Japan
 Tel: +81(0)568-21-4044 FAX: +81(0)568-26-6160
 E-mail : hiromichi_yoshida@amano-enzyme.com

5. Justification for use:

The *Limtongozyma cylindracea* Lipase catalyses breakdown of lipids into fatty acids and mono-, di-glycerides or glycerol. This enzyme catalyses hydrolysis triglyceride with short (under C6), middle (until C12) and long (over C12) carbon chain fatty acids at 1, 2 and 3 positions of tri-, di- and monoglycerides. The enzyme can be used to in the following processes as described below.

- Milk product processing: Produce enzyme modified cheese (EMC), enzyme modified dairy products (EMD), improvement of the flavor by the increment of free fatty acids.
- Fats and oils processing: Used in the production of unsaturated fatty acids such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA). Also, it is used in the production of free fatty acid to utilize it as a donor substance for a transesterification reaction by utilizing another lipase.
- Baking: By addition of the lipase enzyme in dough mixing step, monoglycerides are produced, which can act as an emulsifier and improve the stability and elasticity of the dough. As a result, bread volume is increased, and softness is improved.

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):

The enzyme is used as a processing aid in the milk product processing (i.e. EMC, EMD), fats and oils processing (i.e. free fatty acid production, DHA, EPA) and baking (i.e. bread, pastry).

Food Category	Maximal recommended use level (mg TOS/Kg food)
01.0 Dairy products and analogues, excluding products of category 02.0	2.5 mg TOS/Kg food
02.0 Fats and oils, and fat emulsions	10 mg TOS/Kg food
07.0 Bakery wares	1 mg TOS/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))

The enzyme is approved in Japan, Australia/New Zealand, Canada, China, Denmark, and France. In Europe, the dossier is under evaluation by EFSA. The source organism, *Limtongozyma cylindracea* (previous name: *Candida cylindracea*) has qualified presumption of safety (QPS) status.

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

Non-exhaustive list of authorisations of Triacylglycerol lipase produced by <i>Limtongozyma cylindracea</i> / <i>Candida cylindracea</i>		
Authority	Description	Reference
Japan	Lipase from <i>Candida sp.</i>	Japan's Specifications and Standards for Food Additives (JSFA)
Australia/New Zealand	Lipase, triacylglycerol (EC 3.1.1.3) sourced from <i>Candida cylindracea</i>	Commonwealth of Australia Gazette No. FSC 117, Amendment No.176

Canada	Lipase from <i>Candida cylindracea</i>	5. List of Permitted Food Enzymes (Lists of Permitted Food Additives) - Canada.ca
China	Lipase from <i>Candida cylindracea</i>	Chinese Standards for Food Additives GB2760-2015
Denmark	Triacylglycerol lipase from <i>Candida cylindracea</i>	Mutual recognition with France DVFA File number: 2019-29-7101-00136
France	Lipase from <i>Candida cylindracea</i>	Article Annexe I C - Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires - Légifrance (legifrance.gouv.fr)

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.

Not aware of any.

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.

Date	Organization	Address
Nov. 2, 2017	Australia/New Zealand (FSANZ)	PO Box 5423, KINGSTON ACT 2604 AUSTRALIA
Mar. 13, 2019	Denmark (DVFA)	Stationsparken 31-33 DK-2600 Glostrup
Apr. 20, 2017	France (ANSES)	14 rue Pierre et Marie Curie, 94701 Maisons-Alfort Cedex
Aug. 18, 2017	Canada (Health Canada)	Postal Locator 2202E 251 Sir Frederick Banting Driveway Ottawa, Ontario, Canada, K1A 0K9
On-going	European commission Health and Consumer Directorate-General	Directorate E – Safety of the food chain Unit E3 – Chemicals, contaminants, pesticides B-1049 Brussels

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

Not aware of any.

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)	N
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y
Comments to the Toxicological data:	

<ul style="list-style-type: none"> Bacterial reverse mutation test performed in accordance with the test guidelines of Japanese Ministry of Health and Welfare (JMHW, 1999), equivalent standard to OECD Guideline 471 Chromosome Aberration Test performed in accordance with the test guidelines of Japanese Ministry of Health and Welfare (JMHW, 2010), equivalent standard to OECD Guideline 473 90-day Oral (gavage) Study in rats performed in accordance with the test guidelines of Japanese Ministry of Health and Welfare (JMHW, 1999), equivalent standard to OECD Guideline 408 	
(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)	N

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.**)

As soon as requested.

IOFI (International Organization of the Flavor Industry)

On behalf of the International Organization of the Flavor Industry (IOFI), in response to the aforementioned request for information and comments related to the JECFA Priority List, I am providing the following information and comments for consideration at the forthcoming 54th Session of the Codex Committee on Food Additives.

IOFI respectfully requests the addition of 6 new flavorings to the JECFA Priority list on Appendix IIa. IOFI also provides within this package Appendix IIb, which is a list of 105 flavourings that were previously submitted to CCFA for inclusion on the priority list. Finally, Appendix IIc of this package includes 10 flavourings for which updated specifications data have become available.

The required information for the flavours as requested in Annex II of CL 2023/47-FA are attached as Appendix IIa_2024CCFA54, Appendix IIb_2024CCFA54, and Appendix IIc_2024CCFA54. If there are any questions or concerns, please do not hesitate to contact me at staylor@iofi.org.

Name of Substance(s):	<p>See Appendix_Ila_2024CCFA54, to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents.</p> <p>See Appendix_Ilc_2024CCFA54 for substances that have updates to the online edition of "Specifications for Flavourings"</p>
<p>Question(s) to be answered by JECFA</p> <p><i>(Provide a brief justification of the request in case of re-evaluations)</i></p>	<p>1. Are the substances in Appendix Ila and IIb of no safety concern at the current levels of exposure?</p> <p>2. Do the published specifications for the flavouring agents as listed in Appendix Ilc represent what is in global commerce?</p>

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_Ila_2024CCFA54 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. (staylor@iofi.org)

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.

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 1, 2024.

Appendix IIa. Six (6) flavourings newly proposed for inclusion on the JECFA Priority List to be considered at the 54th session of the Codex Committee on Food Additives

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
<i>New 54th</i>	3038	126-14-7	Sucrose octaacetate	III
<i>New 54th</i>	3811	20702-77-6	Neohesperidin dihydrochalcone	III
<i>New 54th</i>	4825	2277-20-5	(E)-6-Nonenal	I
<i>New 54th</i>	4943	111-20-6	Decanedioic acid	I
<i>New 54th</i>	4944	6402-36-4	trans-2-Dodecenedioic acid	I
<i>New 54th</i>	4945	174155-46-5	cis-8-Decenal	I

Appendix IIc - Priority additions list of ten (10) compounds proposed for specifications modification by JECFA Priority List to be considered at the 54th session of the Codex Committee on Food Additives

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
Old	3415	461	505-10-2	(3-Methylthio)propanol	2001 (Session 57)	Full	The Specific Gravity, Solubility Description and possibly Purity does not reflect the material currently in commerce.
Old	3376	500	23550-40-5	4-(Methylthio)-4-methyl-2-pentanone	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3897	510	75-33-2	2-Propanethiol	2001 (Session 57)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3475	543	828-26-2	Trithioacetone	2001 (Session 57)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	2911	896	120-57-0	Piperonal	2001 (Session 57)	Full	The Melting Point does not reflect the material currently in commerce.
Old	3557	973	2111-75-3	<i>p</i> -Mentha-1,8-dien-7-al	2018 (Session 86)	Full	The Purity Specification, Acid Value and Specific Gravity do not reflect the material currently in commerce.
Old	2349	1093	622-45-7	Cyclohexyl acetate	2002 (Session 59)	Full	The Specific Gravity does not reflect the material currently in commerce.
Old	2467	1529	97-53-0	Eugenol	2005 (Session 65)	Full	The Density Range does not reflect the material currently in commerce.
Old	4321	1763	116505-60-3	Pyrrolidino-[1,2e]-4H-2,4-dimethyl-1,3,5-dithiazine	2007 (Session 68)	Full	The melting point does not reflect the material in commerce.
Old	3507	49	2050-01-3	Isoamyl isobutyrate	1997 (Session 49)	Full	The specific gravity and refractive index does not reflect the material in commerce.

Part B: Replies to CL 2023/47-FA, Annex 3 -- Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up (comments on substances already included in the priority list of substances proposed for evaluation by JECFA)

Peru

No.	Substance(s)	General Information	Priority*	RATIONALE
1	ADIPATES	<p>Type of request: Exposure assessment</p> <p>Proposed by: JECFA</p> <p>Supported by: CCFA53</p> <p>YEAR REQUESTED: 2023 (CCFA53)</p>	<p>Position</p> <p>Peru supports the proposed priority (Priority 1).</p>	<p>The priority is based on consumer protection from the point of view of health, the terms of reference of JECFA, the terms of reference of the CCFA, consistent with the considerations of the Codex Procedural Manual</p>
2	Ascorbyl palmitate (INS 304)	<p>Type of request: Re-evaluation of safety, notably to address consumption by infants under 12 weeks of age</p> <p>Proposed by: CCNFSDU</p> <p>Year requested: 2023 (CCFA53)</p>		
3	Acesulfame potassium (INS 950), Saccharins (INS 954(i)-(iv)), Amaranth (INS 123), Annatto extracts, norbixin based (INS 160b(ii))	<p>Type of request: Re-evaluation of exposure</p> <p>Proposed by: CCFA52</p> <p>Year requested: 2021 (CCFA52)</p>		
5	Beta-apo- 8'- carotenal, (INS 160e) and Beta- carotenes (INS 160a(i), 160a(ii), 160a(iii), 160a(iv))	<p>Type of request: Exposure assessment</p> <p>Proposed by: JECFA</p> <p>Year requested: 2023 (CCFA53)</p>		
8	Carob bean gum (INS 410)	<p>Type of request: Data pending – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas</p> <p>Proposed by: JECFA</p> <p>Year requested: 2016 (CCFA48)</p>		
9	Diocetyl sodium sulfosuccinate (INS 480)	<p>Type of request: Exposure assessment</p> <p>Proposed by: CCFA51</p> <p>Year requested: 2019 (CCFA51) 2023</p>		
14	Natamycin (INS 235)	<p>Type of request: Re-evaluation of safety and revision of specifications</p> <p>Proposed by: Russian Federation</p> <p>Year requested: 2017 (CCFA49)</p>		
	NISIN (SIN 234)	<p>Type of request: Re-evaluation of safety and revision of</p>		

No.	Substance(s)	General Information	Priority*	RATIONALE
		specifications Proposed by: Russian Federation Year requested: 2017 (CCFA49)		
15	Phosphates <ul style="list-style-type: none"> • Sodium dihydrogen phosphate (INS 339(i)) • Disodium hydrogen phosphate (INS 339(ii)) • Trisodium phosphate (INS 339(iii)) • Potassium dihydrogen phosphate (INS 340(i)) • Dipotassium hydrogen phosphate (INS 340(iii)) Tripotassium phosphate (INS 340(iii))	Type of request: Re-evaluation of safety: consumption by infants under 12 weeks of age Proposed by: CCNFSDU Year requested: 2023 (CCFA53)		
18	Polyoxyethylene (20) sorbitan monolaurate (INS 432), Polyoxyethylene (20) sorbitan monooleate (INS 433), Polyoxyethylene (20) sorbitan monopalmitate (INS 434), Polyoxyethylene (20) sorbitan monostearate (INS 435), Polyoxyethylene (20) sorbitan tristearate (INS 436)	Type of request: Re-evaluation of safety Proposed by: JECFA Year requested: 2021 (CCFA52)		
19	Rosemary extract (INS 392)	Type of request Data pending: Studies required for (1) the developmental toxicity of rosemary extract; and ((2) determining whether the effects noted on rodent pup thyroid hormone levels can be replicated. Proposed by: JECFA Year requested: 2021 (CCFA52)		
20	Silicon dioxide, amorphous (INS 551)	Type of request: Safety re-evaluation of Silicon Dioxide, Amorphous (INS 551), including toxicological evaluation, exposure assessment, and specifications Proposed by: IFAC	Position Peru supports the proposed priority (Priority 1).	

No.	Substance(s)	General Information	Priority*	RATIONALE
		Supported by: USA Year requested: 2023 (CCFA53)		
21	Sorbitan monostearate (INS 491); Sorbitan tristearate (INS 492); Sorbitan monolaurate (INS 493), Sorbitan monooleate (INS 494); Sorbitan monopalmitate (INS 495)	Type of request: Safety re-evaluation of safety and revision of specifications Proposed by: JECFA Year requested: 2021 (CCFA52)		
23	Sucroglycerides (INS 474)	Type of request: Exposure assessment Proposed by: CCFA 51 Year requested: 2019 (CCFA51)		
24	Sucrose esters of fatty acids (INS 473)	Type of request: Data pending: Exposure assessment Proposed by: JECFA Year requested: 2021 (CCFA52)		
25	Sucrose oligoesters ,type I and type II (INS 473a)	Type of request: Data pending - exposure assessment Proposed by: JECFA Year requested: 2021 (CCFA52)		
26	Tocopherol concentrate, mixed (INS 307b)	Type of request: Re-evaluation of safety: consumption by infants under 12 weeks of age Proposed by: CCNFSDU Year requested: 2023 (CCFA53)		

No.	SUBSTANCE	INFORMATION	PRIORITY	RATIONALE
6	Black carrot extract (INS 163((vi))	Type of request: Data pending data: characterization and toxicological information Proposed by: JECFA Year requested: 2021 (CCFA52)	Position Peru supports the proposed priority (Priority 2).	The priority is based on proposals from CCFA52, CCFA53, work already initiated by JECFA and the national legislations, considered in the Codex Procedure Manual.
7	Butterfly Pea Flower Extract	Type of request: Safety assessment and establishment of specifications Proposed by: IACM Supported by: Canada Year requested: 2021 (CCFA52)		
11	Gardenia blue (INS 165)	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2023 (CCFA53)		
27	THAUMATIN II	Type of request: Safety evaluation Proposed by: Calorie Control Council Supported by: Colombia; United States of America Year requested: 2021 (CCFA52)		

SUBSTANCE(S)		INFORMATION	PRIORITY	RATIONALE
4	Bentonite (INS 558)	<p>Type of request: Establishment of specifications (lead)</p> <p>Proposed by: CCFA52</p> <p>Year requested: 2021 (CCFA52)</p>	<p>Position</p> <p>Peru supports the proposed priority (Priority 3).</p>	<p>The priority is based on proposals from CCFA51, CCFA52, considered in the Codex Procedure Manual.</p>
16	Polyglycerol esters of fatty acids (INS 475)	<p>Type of request: The completeness of the information for safety assessment Proposed by: CCFA51</p> <p>Year requested: 2019 (CCFA51)</p>		
22	Steviol glycosides	<p>Type of request: Safety evaluation</p> <p>Proposed by: ISC</p> <p>Supported by: USA</p> <p>Year requested: 2023 (CCFA53)</p>		

No.	Substance(s)	General Information	Priority*	RATIONALE
12	Gellan gum, low acyl clarified	<p>Type of request: Establishment of specifications</p> <p>Proposed by: CCNFSDU</p> <p>Year requested: 2023 (CCFA53)</p>	<p>Position</p> <p>Peru proposes Priority 1.</p>	<p>The priority is based on consumer protection from the point of view of health, the terms of reference of JECFA, the terms of reference of the CCFA, considered</p>

				in the Codex Procedural Manual.
17	Polyglycerol esters of interesterified fatty acids (INS 476)	<p>Type of request Re-evaluation of safety</p> <p>Proposed by: FoodDrinkEurope</p> <p>Supported by: Colombia; European Union</p> <p>Year requested: 2021 (CCFA52)</p>	<p>Position</p> <p>Peru proposes Priority 2.</p>	The priority is based on work already initiated by European Bodies, requests from the CCFA, considered in the Codex Procedure Manual.

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

Part C: Replies to CL 2023/47-FA, Annex 4 - Confirmation of previous requests and data availability**Japan**

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Protease from <i>Bacillus amyloliquefaciens</i>
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes December 2023
Change to data provider? (yes)	Yes HBI Enzymes Inc. Atsushi Kawahara (Quality Assurance Dept. General Manager) E-mail: akawahara@hbi-enzymes.com Tel: +81-790-64-1201; Fax: +81-790-64-1202

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: Intertek Health Sciences Inc. Shahrazad Tafazoli, Ph.D. Director, Safety & Regulatory Food & Nutrition Group Mobile +1 647 233 9561 Office +1 905 542-2900 ext. 0268 Intertek, 2233 Argentia Rd., Suite 201W, Mississauga, ON L5N 2X7

AMFEP (Association of Manufacturers and Formulators of Enzyme Products)

We were informed by AMFEP that Codex would like to know which entries on the JECFA positive are still supported by the data providers.

Chr. Hansen A/S has one enzyme on the JECFA priority list, CL 2023/47-FA, for safety assessment and establishment of specifications, which is

- **Chymosin from *Camelus dromedarius* expressed in *Aspergillus niger* (Item no. 10)**

We can confirm that the needed data are available, and that we are prepared for a call for data. Also the contact details are still valid.

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10.	Chymosin from <i>Camelus dromedaries</i> expressed in <i>Aspergillus niger</i>	Type of request: Safety assessment and establishment of specifications Proposed by: European Union Year requested: 2021 (CCFA52) Data availability: December 2021 Data provider: Chr-Hansen A/S Christina Westphal Christensen dkchwe@chr-hansen.com	Basis for request: The chymosin catalyze the hydrolysis, at a very particular site in the amino acid chain, of κ-casein - the main protein in milk. This is the absolute first key step in all cheese-making, through which the liquid milk is coagulated (precipitated) and converted to a semi-solid form by the catalytic action of coagulants, such as chymosin. Therefore, the most important production process in which chymosin is used is the production of cheese. Moreover, chymosin can be used in the production of fermented milk products, where it can be used to increase the viscosity of the preparation. Quarg (quark) is an example of fermented milk product in which coagulants, like chymosins, are used to increase the final viscosity of the product. Possible issues for trade: currently unidentified
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Calorie Control Council (CCC)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	THAUMATIN II
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, the data are available for submission to JECFA as soon as a call for data is issued.
Change to data provider? (yes/no)	Karima Kendall Senior Director, Scientific & Nutrition Affairs Calorie Control Council kkendall@caloriecontrol.org Robert Rankin President Calorie Control Council rrankin@caloriecontrol.org Yuri Gleba CEO Nomad Bioscience GmbH gleba@nomadbioscience.com

DSM

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Phospholipase A2 (PLA2) from porcine pancreas expressed in <i>Aspergillus niger</i>
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, available September 1 st 2023
Change to data provider? (yes/no)	No

EU Specialty Food Ingredients (Federation of European Specialty Food Ingredients Industries)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	See REP23/FA Appendix XI: 12. Gellan gum, lowacyl clarified 16. Polyglycerol esters of fatty acids (INS 475) 17. Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476) 18. Polyoxyethylene (20) sorbitan monolaurate (INS432), Polyoxyethylene (20) sorbitan monooleate (INS 433), Polyoxyethylene (20) sorbitan monopalmitate (INS 434), Polyoxyethylene (20) sorbitan monostearate (INS 435), Polyoxyethylene (20) sorbitan tristearate (INS 436) 19. Rosemary extract (INS 392) 21. Sorbitan monostearate (INS 491); Sorbitan tristearate (INS 492); Sorbitan monolaurate (INS 493), Sorbitan monooleate (INS 494); Sorbitan monopalmitate (INS 495)
Is the request still in effect? (yes / no)	
Are the data available? (yes / no)	
Change to data provider? (yes/no)	Data providers: Sponsor and main contact: EU Specialty Food Ingredients (EUSFI) Avenue de Tervuren 13, 1040 Bruxelles,Belgium info@specialtyfoodingredients.eu In addition : For Gellan gum, low acyl clarified: Biopolymer International secretariat@biopolymer-international.com (EU Specialty Food Ingredients member) For INS 475; 476; 432-436 and 491-495: EFEMA info@efema.org (EU Specialty Food Ingredients member) For INS 392: severin.mueller@givaudan.com (EU Specialty Food Ingredients member) and barbara.nikiel@intertek.com

FoodDrinkEurope

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, basis for re-evaluation subject to available data evaluated in EFSA 2017 re-evaluation
Change to data provider? (yes/no)	No

IACM (International Association of Color Manufacturers)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Butterfly pea flower extract
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	<If yes, specify the earliest date on which the data can be made available> December 31, 2023
Change to data provider? (yes/no)	<If yes, specify the new data provider including contact person> No Contact info: Sarah Codrea, IACM, scodrea@iacmcolor.org Sue Ann McAvoy, Sensient, Sueann.mcavoy@sensient.com

IFAC (International Food Additives Council)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Glycolipids
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, all data are available and can be submitted in response to a JECFA call for data as soon as it is published.
Change to data provider? (yes/no)	Berit Dockter Senior Manager, Scientific & Regulatory Affairs International Food Additives Council bdockter@foodingredientfacts.org Robert Rankin Executive Director International Food Additives Council rrankin@foodingredientfacts.org Andrea Bosse Senior Regulatory Affairs Manager Lanxess Corporation Andrea.Bosse@lanxess.com

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3): Silicon Dioxide, Amorphous (INS 551)	
Is the request still in effect? Yes	
Are the data available?	Yes, all data will be available to submit to JECFA by December 31, 2024.
Change to data provider?	Berit Dockter Senior Manager, Scientific & Regulatory Affairs International Food Additives Council bdockter@foodingredientfacts.org Robert Rankin Executive Director

	International Food Additives Council rrankin@foodingredientfacts.org Joel Carpenter Executive Director Synthetic Amorphous Silica and Silicate Industry Association (SASSI) Joel.F.Carpenter@gmail.com Caroline Andersson Secretariat Association of Synthetic Amorphous Silica Producers (ASASP) CAN@cefic.be
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Intertek

On behalf of Kalsec, Inc., Mane Kancor Ingredients Pvt. Ltd., Givaudan International SA, and Vitiva d.o.o., and in response to CL 2023/47-FA, attached please find Annex 4 (*Confirmation of Previous Requests and Data Availability*) of CL 2023/47-FA completed for rosemary extract (INS 392) which is currently listed in PART A of the *PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA* (Annex 3 – Entry No. 19).

We would greatly appreciate prioritization of rosemary extract for evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at the spring/summer 2025 meeting such that the results of the newly generated data may be shared with and reviewed by the Committee at the earliest opportunity.

Rosemary extract was last reviewed by the JECFA at the 87th Meeting (04 to 13 June 2019) at which time the Committee retained the temporary acceptable daily intake (ADI) of 0 to 0.3 mg/kg bw (expressed as carnosic acid plus carnosol) as had been previously established for rosemary extract at the 82nd meeting and requested the following additional data:

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 studies addressing the Committee's request for additional information as related to the potential developmental toxicity of rosemary extract and thyroid hormone levels in rodent pups following rosemary extract exposure are immediately available.

Furthermore, the manufacturers of rosemary extract would like to additionally propose an amendment to the technical uses and levels of use for rosemary extract (an updated exposure assessment will be provided), and an amendment to the specifications monograph for rosemary extract (*i.e.*, the limit for levels of residual acetone). Data to support these requests would be provided alongside the requested toxicological data.

We would like to thank you for the consideration of the above request. Should you have any questions please do not hesitate to contact us.

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 are available immediately.
Change to data provider? (yes / no)	No

IOFI (International Organization of the Flavor Industry)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	See Appendix IIb_2024CCFA54, to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents.
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	December 1, 2024
Change to data provider? (yes/no)	No

Appendix IIb. One-hundred five (105) flavourings previously submitted to the Codex Committee on Food Additives for inclusion on the JECFA Priority list

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
Submitted at the 51st CCFA	3557 (JECFA 973)	2111-75-3	<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(2 <i>H</i>)-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	4828	729602-98-6	1,1-Propanedithioacetate	III

CCFA				
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	o-trans-Coumaric acid	III
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 45th 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

CCFA				
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 52 nd CCFA	4888	1945993-01-0; 828265-08-3	Mixture of 5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one and 7-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-5-methylchroman-2-one	III
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	cis-2-Hexylcyclopropaneacetic acid	II
Submitted at the 52 nd CCFA	4890	27841-22-1	3-p-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>l</i> -Menthoxy)-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-Benzoyloxypropyl)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>)-	III

CCFA			furanone	
Submitted at the 52 nd CCFA	4896	2186611-08-3	<i>N</i> -(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	III
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
Submitted at the 53 rd CCFA	4948	1129-69-7	2-Hexylpyridine	II
Submitted at the 53 rd CCFA	4958	2308574-23-2	4-Formyl-2-methoxyphenyl <i>l</i> -menthyl glutarate	I
Submitted at the 53 rd CCFA	4959	301310-73-6; 79894-05-6	9-Dodecen-12-olide	III
Submitted at the 53 rd CCFA	4960	13474-59-4	trans-alpha-Bergamotene	I
Submitted at the 53 rd CCFA	4961	2369713-22-2	4-Methyltrideca-2 <i>E</i> ,4-dienal	I
Submitted at the 53 rd CCFA	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
Submitted at the 53 rd CCFA	4966	6137-11-7	4-Methylheptan-3-one	II
Submitted at the 53 rd CCFA	4967	483-76-1	delta-Cadinene	I
Submitted at the 53 rd CCFA	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

Submitted at the 53 rd CCFA	4971	18794-84-8	beta-Farnesene	I
Submitted at the 53 rd CCFA	4972	23060-14-2	Diethyl mercaptosuccinate	I
Submitted at the 53 rd CCFA	4973	2411762-60-0	3-Mercapto-3-methyl-1-pentyl acetate	I
Submitted at the 53 rd CCFA	4974	23986-74-5	Germacrene D >85%	I
Submitted at the 53 rd CCFA	4977	65210-18-6	10-Hydroxy-4,8-dimethyldec-4-enal	I
Submitted at the 53 rd CCFA	4979	142062-38-2	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	III
Submitted at the 53 rd CCFA	4980	2415657-73-5	Mixture of (8Z,11Z)-heptadeca-8,11-dienal and (Z)-heptadec-8-enal	

NATCOL (Natural Food Colours Association)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Beta-apo-8'- carotenal (INS 160e) and beta-carotenes (INS 160a(i), 160a(ii), 160a(iii), 160a(iv))
Is the request still in effect? (yes / no)	YES
Are the data available? (yes / no)	YES – December 2025
Change to data provider? (yes/no)	The Natural Food Colours Association (NATCOL) Lorenza Squarci – Secretary General Rond-Point Schuman 6 1040 Etterbeek – Brussels Belgium Email : Secretariat@natcol.org

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Black carrot extract (INS 163(vi))
Is the request still in effect? (yes / no)	YES
Are the data available? (yes / no)	YES – December 2027
Change to data provider? (yes/no)	The Natural Food Colours Association (NATCOL) Lorenza Squarci – Secretary General Rond-Point Schuman 6 1040 Etterbeek – Brussels Belgium Email : Secretariat@natcol.org