CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/FA 25/55/10**

January 2025

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-fifth Session

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2024/59-FA)

(Submitted by the European Union, Japan, CCC, EFEMA, IACM, ICBA, IFAC, IOFI, ISA, ISC, NATCOL and OENOPPIA)

Part A: Replies to CL 2024/59-FA, Annex 2 - Form for the submission of substances to be evaluated by JECFA

The Calorie Control Council (CCC)

Name of Substance(s):	*Monk fruit extract*
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	*Toxicological and safety evaluation and exposure assessment*

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

   Calorie Control Council

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

   Common names: Monk fruit (extract), Luo Han Guo (extract), Arhat fruit (extract), *Momordica grosvenori* (extract), *Siraitia grosvenorii* extract

   Components of the food additive: Mogroside V (CAS No. 88901-36-4), 11-Oxo-Mogroside V (CAS No. 126105-11-1), Siamenoside I (CAS No. 126105-12-2), Mogroside IIA2 (CAS No. 88901-45-5), Mogroside IE (CAS No. 88901-39-7), Mogroside IIE (CAS No. 88901-38-6), Mogroside III (CAS No. 130567-83-8), Mogroside IVe (CAS No. 88915-64-4).

   Chemical Formula: $C_{60}H_{102}O_{29}$ (Mogroside V)

   Chemical Name: (3β,9β,10α,11α,24R)-3-[(6-O-β-D-Glucopyranosyl-β-D-glucopyranosyl)oxy]-11,25-dihydroxy-9-methyl-19-norlanost-5-en-24-yl O-β-D-glucopyranosyl-(1->2)-O-[β-D-glucopyranosyl-(1-> 6)]-β-D-glucopyranoside]

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

   Guilin Layn Natural Ingredients Corporation

   19 South Renmin Road, Lingui County Guilin, Guangxi 541199 Guilin, China

   Saraya Co Ltd

   2-2-8 Yuzato, Higashisumiyoshi-ku, Osaka, 546-0013, Japan

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

   Tate & Lyle

   5450 Prairie Stone Pkwy, Hoffman Estates, IL 60192, USA

   Contact Person: Juan Cristian Santa Maria, Senior Director, Scientific and Regulatory Affairs, Tate & Lyle

5. **Justification for use:**

   Monk Fruit, also known as Siraitia grosvenorii or Luo Han Guo, is known for its intense sweetness, and its extracts are used in the food industry to exploit this property.

The sweetness is due to the presence of non-caloric sweet compounds called mogrosides. Indeed, Mogroside V is identified as analytical marker compound in the extract proposed by this technical dossier. It must be said, however, that all mogrosides present in the plant show sweetening properties, in different intensities. Mogroside V seems to show 250 times more sweetness than sucrose; meanwhile, mogroside IV has a similar sweetness intensity as mogroside V, and mogrosides I and II have a similar sweetness intensity as sucrose. Compared to other sweeteners or sugars, Monk Fruit is one of the more potent sweeteners.

From a stability point of view, studies indicate that monk fruit's sweetness remains stable across a range of temperatures and pH levels, making it versatile for food production, including baked goods, beverages, and processed foods. The mogrosides' chemical stability during cooking or in acidic environments further enhances monk fruit's attractiveness as a sweetener. It is intended to be used instead of or alongside other approved sweeteners and offers consumers and producers alike an alternative option when choosing a sweetener to replace sugar.

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 Category	**Max. Use levels (mg/kg or mg/L) 100% Mogroside V Equivalent**
01.1.4 - Flavoured fluid milk drinks	700
03.0 - Edible ices	600
04.1.2. - Processed fruit 04.2.2. – Processed vegetables	700
05.2 – Confectionery	6750
05.3 - Chewing gum	6750
06.3 - Breakfast cereals	700
09.2 - Processed fish and fishery products including molluscs and crustaceans	600
10.2 - Processed eggs and egg products	750
11.6 - Table Top Sweeteners	2500
12.4 - Mustards	350
12.5 - Soups and broths	110
12.6 - Sauces	400
12.7 - Salads and (savoury) sandwich spreads	750
13.3 – Dietetic foods intended for special medical purposes	1000
13.4 – Dietetic formulae for slimming purposes and weight reduction	800
13.6 - Food supplements	5500
14.1.4 Water-based flavoured drinks	700
14.2 Alcoholic beverages, including alcohol-free and low-alcohol counterparts	600
15.1 – Snacks – potato, cereal, flour or starch based	500
15.2 - Processed nuts, including coated nuts and nut mixtures	500
16 - Desserts excluding products covered in category 1, 3 and 4	750

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 sweetener is already permitted for use in a range of foods in a number of countries globally. For example

it is considered to be a GRAS sweetener in the USA and is permitted for use in table top sweeteners in Canada. It is also approved for use as a food additive for use in a wide range of products in United States, Canada (as table top sweetener), Colombia, Ecuador, Mexico, Singapore, China, Australia, New Zealand, 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.

As noted above, the sweetener is already permitted for use in a range of foods in a number of countries globally. It is noted that a large number of Codex Member countries refer to the General Standard for Food Additives (GSFA) as the main determinant of national controls on food additives. Given the sweetener is considered acceptable for use in certain countries already, it's inclusion in the GSFA would ensure products containing monk fruit extract can be available in those countries that use the GSFA as the basis for their national approvals.

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.

Monkfruit extract has previously been reviewed and considered acceptable for use as a food additive in several countries: United States, Canada (as table top sweetener), Colombia, Ecuador, Mexico, Singapore, China, Australia, New Zealand, and Japan. Specific evaluations have been undertaken in China, Australia / New Zealand and Canada. The regulatory reference for Colombia is the following: INVIMA/SEAB Acta 11/2011: https://www.invima.gov.co/sites/default/files/alimentos-y-bebidas-alcoholicas/2024-01/acta-11-2011.pdf. In the US monk fruit extract preparations are considered to be Generally Recognized as Safe (GRAS) and several notifications have been submitted to the Food and Drug Administration, on which FDA had no questions. Most recently (January 2025) an application has been submitted in the European Union and also in the United Kingdom for approval of monk fruit extract for use as a sweetener in a range of foodstuffs.

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	
(i) Metabolic and pharmacokinetic studies (please specify) ADME in rodents	*Y*
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify) Genotoxicity studies Sub-chronic (90-day) toxicity study, reproductive and developmental toxicity studies, Chronic (12 months) toxicity study	*Y*
(iii) Epidemiological and/or clinical studies and special considerations (please specify) Human study on effects on blood glucose concentration and liver enzyme activity	
(iv) Other data (please specify)	
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) Monk fruit extract was previously included in the priority list of substances to be evaluated by JECFA for addition to the Codex Alimentarius as a food additive. However, it was removed from the 'priority list of substances proposed for evaluation by the JECFA between April 2014 and May 2015 due to the information required for the evaluation to be undertaken not being submitted and as such it has not been considered by committee.	

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 required data are available immediately

The International Association of Color Manufacturers (IACM)

Name of Substance(s):	*Butterfly Pea Flower Extract*
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	*Review of additional data to support the Safety assessment and establishment of specifications for use as a color*

1. Proposal for inclusion submitted by:

International Association of Color Manufacturers on behalf of Sensient Colors LLC

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

Butterfly Pea Flower Extract, INS number: 163(xi)

3. Names and addresses of basic producers:

Sensient Colors LLC, 2526 Baldwin St. St. Louis, MO 63106

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

IACM or its member company can provide the available published data in a submission dossier. IACM contact is Sarah Codrea, Executive Director, IACM, 1101 17th St NW, Suite 700, Washington, DC 20036, email scodrea@iacmcolor.org. Sensient contact is Penny Marsh, Sensient Technologies Corporation; 777 East Wisconsin Avenue; Milwaukee, WI 53202-5304, USA Penny.marsh@sensient.com

5. Justification for use:

Used as a food color

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):

Butterfly pea flower extract is not currently listed in the GSFA

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, butterfly pea flower extract is currently approved for use in Canada as an anthocyanin and Thailand as a color additive. It is permitted in by the US FDA per 21 CFR Sec 73.69.

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.

While there have been no impediments in international trade due to lack of a JECFA evaluation to date for butterfly pea flower extract, the use of a greater number of globally approved naturally derived color extracts is in significant demand. Therefore, a JECFA evaluation will positively impact trade moving forward.

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, US FDA, Ninety-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives

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

The plant source for this color is currently being grown in Thailand and the Philippines.

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

Data	***Data available? (Y / N)***
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y – previously submitted Published ADME data for the coloring component of BPF extract (anthocyanin/delphinidins) and other minor flavonol components such as kaempferol and quercetin.
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y – previously submitted 1) 28-day subacute range finding feeding study in rats; 2) bacterial reverse mutation test and an in vitro micronucleous test addressing possible mutagenicity and genotoxicity of butterfly pea flower extract; 3) 90-day feeding study in rats; 4) *in vivo* somatic mutation and recombination test conducted on the unprocessed butterfly pea flower parts; 5) *in vivo* genotoxicity data from published literature on anthocyanins (including delphinidin) and flavonol components
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	Y –previously submitted Clinical human studies of anthocyanins (including delphinidin) and spray-dried butterfly pea flower extract
(iv) Other data (please specify)	Y – **new** **Uterotrophic assay (OECD 440) report** The assay is a short-term study - estrogenic mechanistic study
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Yes – previously submitted data and additional data to address gaps identified by the 99th JECFA. This includes but is not limited to detailed methods for determination of water content, Brix and color strength. **Additional information will be provided to address the cited alkaline saponification and acid hydrolysis method.**
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Yes – previously submitted data and additional data to address gaps identified by the 99th JECFA. **This includes but is not limited to quantitative composition of non-coloring components (e.g., carbohydrates, proteins and plant lipids) of butterfly pea flower extract from at least five batches of the article of commerce.**

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	Yes – previously submitted
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Yes – previously submitted
Other information: (please specify)	**The sponsor will provide a uterotrophic assay to address gaps identified by the 99th JECFA.**

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.)**

    IACM or its member company can provide this data by December 2025

The International Organization of the Flavor Industry (IOFI)

Name of Substance(s):	See Appendix IIa 2025CCFA55, to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents. See Appendix IIc 2025CCFA55 for substances that have updates to the online edition of "Specifications for Flavourings"
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	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 2025CCFA55 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 Sates, 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	
(v) Metabolic and pharmacokinetic studies (please specify)	***Y***
(vi) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	***Y***
(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)	

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; <u>do NOT include any data intended for JECFA to this form</u>.)

The earliest date that the data can be made available to JECFA is December 15, 2025.

<u>Appendix IIa 2025CCFA55</u>

Thirteen (13) flavourings newly proposed for inclusion on the JECFA Priority List to be considered at the 55th session of the Codex Committee on Food Additives.

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
New 55th	4981	6820-02-6	8-Methyl-4-methylenenon-7-en-2-one	II
New 55th	4982	2492342-84-2	4-(4-Methylpent-3-en-1-yl)-5,6-dihydro-2*H*-pyran-2-one	III
New 55th	4983	2491702-14-6	4-Mercapto-1-octanol	I

New 55th	4984	2099712-94-2	2,11-Tetradecadienal	III
New 55th	4985	1801275-27-3	4,9-Dodecadienal	I
New 55th	4993	34776-60-8	Methyl 3-methyl-2-buten-1-yl disulfide	III
New 55th	5003	149231-57-2	2,6-Octadienal	III
New 55th	5004	40556-69-2	2-Methyloctan-4-olide	II
New 55th	5005	10191-24-9	3-Hydroxyhexanoic acid	I
New 55th	5006	58156-49-3	3-Methyl-3-butene-1-thiol	I
New 55th	5012	2762033-61-2	Ethyl 5-acetoxyoctadecanoate	I
New 55th	5021	2775350-66-6	S-(3-Methylbut-3-en-1-yl) 4-(formyloxy)butanethioate	III
New 55th	5022	2775350-67-7	S-Butan-2-yl 4-(formyloxy)butanethioate	III

Appendix IIb 2025CCFA55

One-hundred eleven (111) flavourings previously submitted to the Codex Committee on Food Additives for inclusion on the JECFA Priority list.

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
Submitted at the 51st CCFA	3557 (JECFA 973)	2111-75-3	*p*-Mentha-1,8-dien-7-al (Perillaldehyde)	
Submitted at the 43rd CCFA	4074	6321-45-5	Allyl valerate	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	*delta*-Hexadecalactone	I
Submitted at the 45th CCFA	4682	23333-91-7	Octahydro-4,8a-dimethyl-4a(2*H*)-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

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
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	*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

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
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	*beta*-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 52nd CCFA	4902	22122-36-7	3-Methyl-2(5*H*)-furanone	III
Submitted at the 52nd CCFA	4915	2142634-65-7	(5*Z*)-3,4-Dimethyl-5-propylidene-2(5*H*)-furanone	III
Submitted at the 52nd CCFA	4784	57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	I
Submitted at the 52nd CCFA	4939	2180135-09-3	*S*-Methyl 5-(1-ethoxyethoxy)decanethioate	I
Submitted at the 52nd CCFA	4894	116229-37-9	2-Mercapto-3-methyl-1-butanol	I
Submitted at the 52nd CCFA	4883	556-27-4	*S*-Allyl-*L*-cysteine sulfoxide	II
Submitted at the 52nd CCFA	4935	98139-71-0	3-Methylbutane-1,3-dithiol	III
Submitted at the 52nd CCFA	4916	124831-34-1	2-Methyl-3-butene-2-thiol	I
Submitted at the 52nd CCFA	4938	2180135-08-2	S-Methyl 5-(1-ethoxyethoxy)tetradecanethioate	I
Submitted at the 52nd CCFA	4901	2097608-89-2	*O*-Ethyl *S*-(3-methylbut-2-en-1-yl)thiocarbonate	I
Submitted at the 52nd CCFA	4900	64580-54-7	Hexyl propyl disulfide	I
Submitted at the 52nd CCFA	4914	24963-39-1	bis-(3-Methyl-2-butenyl)disulfide	III
Submitted at the 52nd CCFA	4889	3877-15-4	Methyl propyl sulfide	I
Submitted at the 52nd CCFA	4930	159017-89-7	4-Isopropoxycinnamaldehyde	I
Submitted at the 52nd CCFA	4888	1945993-01-0;	Mixture of 5-hydroxy-4-(4´-hydroxy-3´-methoxyphenyl)-7-methylchroman-2-	III

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
		828265-08-3	one and 7-hydroxy-4-(4´-hydroxy-3´-methoxyphenyl)-5-methylchroman-2-one	
Submitted at the 52nd 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 52nd CCFA	4892	4707-61-3	*cis*-2-Hexylcyclopropaneacetic acid	II
Submitted at the 52nd CCFA	4890	27841-22-1	3-*p*-Menthen-7-al	I
Submitted at the 52nd CCFA	4928	554-14-3	2-Methylthiophene	II
Submitted at the 52nd CCFA	4839	163460-99-9 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	II
Submitted at the 52nd CCFA	4813	1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	II
Submitted at the 52nd CCFA	4884	1569-60-4	6-Methyl-5-hepten-2-ol	I
Submitted at the 52nd CCFA	4827	6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	I
Submitted at the 52nd CCFA	4869	886449-15-6	4-(*l*-Menthoxy)-2-butanone	II
Submitted at the 52nd CCFA	4844	118026-67-8	(2*E*,4*E*)-2,4-Decadien-1-ol acetate	I
Submitted at the 52nd CCFA	4747	91212-78-1	(±)-2,5-Undecadien-1-ol	II
Submitted at the 52nd CCFA	4913	18478-46-1	3,7-Dimethyl-2-methyleneoct-6-en-1-ol	II
Submitted at the 52nd CCFA	4785	25234-33-7	2-Octyl-2-dodecenal	II
Submitted at the 52nd CCFA	4786	13893-39-5	2-Hexyl-2-decenal	II
Submitted at the 52nd CCFA	4929	60857-05-8	4-Methylidene-2-(2-methylprop-1-enyl)oxane	III
Submitted at the 52nd CCFA	4920	220462-51-9	1-Ethyl-2-(1-pyrrolylmethyl)pyrrole	III
Submitted at the 52nd CCFA	4832	108715-62-4	2-(3-Benzyloxypropyl)pyridine	III
Submitted at the 52nd CCFA	4829	616-45-5	2-Pyrrolidone	I
Submitted at the 52nd CCFA	4818	1370711-06-0	*trans*-1-ethyl-2-methylpropyl 2-2-butenoate	I
Submitted at the 52nd CCFA	4867	18374-76-0	(3*S*,5*R*,8*S*)-3,8-Dimethyl-5-prop-1-en-2-yl-3,4,5,6,7,8-hexahydro-2*H*-azulen-1-one	II
Submitted at the 52nd CCFA	4840	38427-80-4	Tetrahydronootkatone	II

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
Submitted at the 52nd CCFA	4807	1078-95-1	Pinocarvyl acetate	II
Submitted at the 52nd CCFA	4906	36687-82-8	*L*-Carnitine tartrate	III
Submitted at the 52nd CCFA	4868	61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5*H*)-furanone	III
Submitted at the 52nd CCFA	4896	2186611-08-3	*N*-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	III
Submitted at the 52nd CCFA	4882	1857330-83-9	*N*-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at the 52nd CCFA	4899	1622458-34-7; 2079034-28-7	*N*-(1-((4-amino-2,2-dioxido-1*H*-benzo[c][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)-2,6-dimethylisonicotinamide	III
Submitted at the 52nd CCFA	4880	2015168-50-8	2-(4-Ethylphenoxy)-*N*-(1*H*-pyrazol-3-yl)-*N*-(thiophen-2-ylmethyl)acetamide	III
Submitted at the 52nd CCFA	4881	1857331-84-0	*N*-(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
Submitted at the 52nd CCFA	4877	76733-95-4	(*E*)-3-(3,4-Dimethoxyphenyl)-*N*-[2-(3-methoxyphenyl)-ethyl]-acrylamide	III
Submitted at the 52nd CCFA	4835	877207-36-8	2,4-Dihydroxy-*N*-[(4-hydroxy-3-methoxyphenyl)methyl]benzamide	III
Submitted at the 53rd CCFA	4948	1129-69-7	2-Hexylpyridine	II
Submitted at the 53rd CCFA	4958	2308574-23-2	4-Formyl-2-methoxyphenyl l-menthyl glutarate	I
Submitted at the 53rd CCFA	4959	301310-73-6; 79894-05-6	9-Dodecen-12-olide	III
Submitted at the 53rd CCFA	4960	13474-59-4	*trans-alpha*-Bergamotene	I
Submitted at the 53rd CCFA	4961	2369713-22-2	4-Methyltrideca-2*E*,4-dienal	I
Submitted at the 53rd CCFA	4965	1622458-32-5	N-(1-((4-Amino-2,2-dioxido-1*H* benzo[c][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide	III
Submitted at the 53rd CCFA	4966	6137-11-7	4-Methylheptan-3-one	II
Submitted at the 53rd CCFA	4967	483-76-1	*delta*-Cadinene	I
Submitted at the 53rd CCFA	4970	2413115-68-9	2-Methyl-1-(2-(5-(p-tolyl)-1*H*-imidazol-2-yl)piperidin-1-yl)butan-1-one	III
Submitted at the 53rd CCFA	4971	18794-84-8	*beta*-Farnesene	I
Submitted at the 53rd CCFA	4972	23060-14-2	Diethyl mercaptosuccinate	I

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
Submitted at the 53rd CCFA	4973	2411762-60-0	3-Mercapto-3-methyl-1-pentyl acetate	I
Submitted at the 53rd CCFA	4974	23986-74-5	Germacrene D >85%	I
Submitted at the 53rd CCFA	4977	65210-18-6	10-Hydroxy-4,8-dimethyldec-4-enal	I
Submitted at the 53rd CCFA	4979	142062-38-2	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	III
Submitted at the 53rd CCFA	4980	2415657-73-5	Mixture of (8*Z*,11*Z*)-heptadeca-8,11-dienal and (*Z*)-heptadec-8-enal	
Submitted at the 54th CCFA	4943	111-20-6	Decanedioic acid	I
Submitted at the 54th CCFA	4944	6402-36-4	*trans*-2-Dodecenedioic acid	I
Submitted at the 54th CCFA	4945	174155-46-5	*cis*-8-Decenal	I
Submitted at the 54th CCFA	4825	2277-20-5	*(E)*-6-Nonenal	I
Submitted at the 54th CCFA	3811	20702-77-6	Neohesperidin dihydrochalcone	III
Submitted at the 54th CCFA	3038	126-14-7	Sucrose octaacetate	III

Appendix IIc 2025CCFA55

JECFA Priority List additions/changes for eleven (11) compounds proposed for specifications modification to be considered at the 55th session of the Codex Committee on Food Additives.

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
Old	3488	214	39255-32-8	Ethyl 2-methyl pentanoate	2000 (Session 55)	Full	The Refractive Index does not reflect the material currently in commerce.
Old	2563	315	928-96-1	cis-3-Hexen-1-ol	1998 (Session 51)	Full	The Refractive Index does not reflect the material currently in commerce.
Old	2665	427	89-78-1	Menthol	2018 (Session 86)	Full	The Specific Gravity and Refractive Index could be removed, as they are not meaningful parameters for this substance. The Solidification Point/Melting Point could be added to reflect the material currently in commerce.
Old	3748	433	61597-98-6	l-Menthyl l-lactate	2018 (Session 86)	Full	The Melting Point does not reflect the material currently in commerce
Old	2656	1480	118-71-8	Maltol	2018 (Session 86)	Full	The Melting Point does not reflect the material currently in commerce
Old	3163	1503	1192-62-7	2-Furyl methyl	2018 (Session 86)	Full	The Specific Gravity, Refractive Index and Acid Value could be

				ketone			removed, as they are not meaningful parameters for this substance. The Melting Point could be added to reflect the material currently in commerce.
Old		1506	10599-70-9	3-Acetyl-2,5-dimethylfuran	2020 (Session 89)	Full	IOFI proposes to remove the specifications for this material
Old	3159	1520	13679-46-4	Furfuryl methyl ether	2018 (Session 86)	Full	The Minimum Assay Value, Refractive Index, and Specific Gravity do not reflect the material currently in commerce. The Acid Value could be removed as it is not a meaningful parameter for this material.
Old	3539	1338	13877-91-3	3,7-Dimethyl-1,3,6-octatriene	2004 (Session 63)	Full	The Minimum Assay Value does not reflect the material currently in commerce.
Old	2160	1388	125-12-2	Isobornyl acetate	2004 (Session 63)	Full	The Minimum Assay Value does not reflect the material currently in commerce.
Old	3513	499	13679-85-1	2-Methyltetrahydrothiophen-3-one	2000 (Session 55)	Full	The Minimum Assay Value does not reflect the material currently in commerce.

The International Sweeteners Association (ISA)

Name of Substance(s):	Neohesperidin Dihydrochalcone
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Evaluation of Neohesperidin Dihydrochalcone as food additive, with a technological function of a sweetener.

1. Proposal for inclusion submitted by:

Internation Sweeteners Association (ISA)

Avenue de Tervueren 13, Box 3

B – 1040 Brussels, Belgium

Tel.: +32 2 736 53 54

E-mail: joanna.jaskolska@isasecretariat.org

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

Substance Name: Neohesperidin Dihydrochalcone

Trade Name(s): Neohesperidin DC, NHDC, Citrosa

Chemical Names:
1-[4-[[2-O-(6-Deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-2,6-dihydroxyphenyl]-3-(3-hydroxy-4-methoxyphenyl)propan-1-one or 3,5-Dihydroxy-4-[3-(3-hydroxy-4-methoxyphenyl)propanoyl]phenyl 2-O-(α-l-rhamnopyranosyl)-β-d-glucopyranoside

IUPAC Name: 1-(4-((2-O-(6-deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl)oxy)-2,6-dihydroxyphenyl)-3-(3-hydroxy-4-methoxyphenyl)- 1-Propanone

CAS Number: 20702-77-6

3. Names and addresses of basic producers:

HEALTHTECH BIOACTIVES, S.L.U.

Carretera de Zeneta, 143-145 El Raiguero - La Villa

30130 Beniel (Murcia), Spain

Tel.: +34 968 01 2000

E-mail: regulatory@htba.com

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

HEALTHTECH BIOACTIVES, S.L.U.

Contact person: Jesús Cano Hernández, Scientific & Regulatory Affairs Manager

Tel.: +34 968 012 000

E-mail: jcano@htba.com

5. Justification for use:

Neohesperidin Dihydrochalcone (NHDC), also known as Neohesperidin DC (INS 959, E 959), is a highly potent, low-calorie sweetener and flavor enhancer derived from the hydrogenation of neohesperidin, a flavonoid found in bitter oranges. NHDC is 1500-1800 times sweeter than sucrose. This high sweetness intensity allows for significant reductions in sugar content, aiding in calorie control and the management of obesity and diabetes.

Structurally, NHDC is a flavonoid dihydrochalcone, similar to naturally occurring compounds in many plants. It is metabolized by intestinal flora into breakdown products similar to its natural analogues, ensuring safety and compatibility with human metabolism. The European Food Safety Authority (EFSA) has assessed NHDC's safety, setting an Acceptable Daily Intake (ADI) of 20 mg/kg body weight. It is approved for use in various foods, beverages, and tabletop sweeteners in the EU under Regulation 1333/2008. NHDC is also approved (GRAS) in the United States, being included in the Food Chemical Codex.

In addition to its sweetness, NHDC is particularly effective in masking bitter tastes and enhancing flavor profiles, making it a valuable additive in a wide range of food products. Its use supports healthier dietary choices by reducing sugar intake while maintaining desirable taste and flavor.

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):

Neohesperidin Dihydrochalcone is approved in different food categories included in the US GRAS Notice – details here.

In the EU, Neohesperidin Dihydrochalcone (E-959) is approved in different food categories according to EU regulation, as presented below and correlated with respective Codex GSFA food categories.

GSFA categories	EU Food categories	Max. Use levels
01.7 - Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	Cat. 1.4 Flavoured fermented milk products including heat-treated products	50 mg/L max, only energy-reduced products or with no added sugar
01.7 - Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	Cat 16 Desserts excluding products covered in category 1, 3 and 4	50 mg/kg max, only energy-reduced or with no added sugar
02.3 - Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	Cat 2.2.2 Other fat and oil emulsions	5 mg/kg max, only as flavour enhancer, only in the fat groups B & C in Annex XV to Regulation (EC) No 1234/2007
03.0 - Edible ices, including sherbet and sorbet	Cat .3 Edible ices	50 mg/kg max, only energy-reduced or with no added sugar
04.1.2.5 - Jams, jellies, marmalades	Cat 4.2.5 Jam, jellies and marmalades and similar products	50 mg/kg max, only energy-reduced jams, jellies and marmalades 5 mg/kg max, only fruit jellies as flavour enhance
04.1.2.5 - Jams, jellies,	Cat 4.2.5.1 Extra jam	50 mg/kg max, only energy-reduced jams, jellis

GSFA categories	EU Food categories	Max. Use levels
marmalades	and extra jelly	and marmalades
04.1.2.6 - Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	Cat 4.2.5.3 Other similar fruit or vegatable spreads	50 mg/kg max, only energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar
04.1.2.8 - Fruit preparations, including pulp, purees, fruit toppings and coconut milk	Cat 4.2.4.1 Fruit and vegetable preparations excluding compote	50 mg/kg max, only energy-reduced
04.2.2.3 - Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	Cat 4.2.2 Fruit and vegetables in vinegar oil or brine	100 mg/kg max, only sweet-sour preserves of fruit and vegetables
04.2.2.4 - Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	Cat 4.2.3 Canned of bottled fruit and vegetables	50 mg/kg max, only fruit energy-reduced or with no added sugar
05.1.4 - Cocoa and chocolate products	Cat 5.1 Cocoa and chocolate products	100 mg/kg max, only energy-reduced or with no added sugar
05.2 - Confectionery including hard and soft candy, nougats, etc.	Cat 5.2 Other confectionery including breath freshening microsweets	100 mg/kg max, only cocoa or dried fruit based, energy-reduced or with no added sugar - 50 mg/kg max, only cocoa milk, dried-fruit- or fat-based sandwich spreads, energy-reduced or with no added sugar - 150 mg/kg max, only starch based confectionery energy-reduced or with no added sugar - 100 mg/kg max, only confectionerty with no added sugar - 400 mg/kg max, only breath-refreshening micro-sweets, with no added sugar
05.3 - Chewing gum	Cat 5.3 Chewing gum	150 mg/kg max, only with added sugar or polyols, as flavour enhancer 400 mg/kg max, only with no added sugar
05.4 - Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	Cat 5.4 Decorations coatings and fillings	150 mg/kg max, only starch-based confectionery, energy-reduced or with no added sugar - 50 mg/kg max, only sauces - 100 mg/kg max, only confectionery with no added sugar - 100 mg/kg max, only cocoa- or dried fruit-based, energy-reduced or wiht no added sugar
06.3 - Breakfast cereals, including rolled oats	Cat 6.3 Breakfast cereals	50 mg/kg max, only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy-reduced or with no added sugar
07.2 - Fine bakery wares (sweet, salty, savoury) and mixes	Cat 7.2 Fine bakery wares	50 mg/kg max, only cornets and wafers, for ice-cream, with no added sugar
08.3.1 - Non-heat treated processed comminuted meat, poultry, and game products	Cat 8.3.1 Non-heat-treated processed meat	5 mg/kg max, as a flavour enhancer only
08.3.2 - Heat-treated processed comminuted meat, poultry, and game products	Cat 8.3.2 Heat-treated processed meat	5 mg/kg max, as flavour enhancer only, except for foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben

GSFA categories	EU Food categories	Max. Use levels
09.2 - Processed fish and fish products, including mollusks, crustaceans, and echinoderms	Cat 9.2 Processed fish and fisheries products	30 mg/kg max, only sweet-sour preserves and semipreserves of fish and marinades of fish, crustaceans and molluscs
11.6 - Table-top sweeteners, including those containing high-intensity sweeteners	Cat 11.4.1 Table-top sweeteners in liquid form	quantum satis
11.6 - Table-top sweeteners, including those containing high-intensity sweeteners	Cat 11.4.2 Table-top sweeteners in powder form	quantum satis
11.6 - Table-top sweeteners, including those containing high-intensity sweeteners	Cat 11.4.3 Table-top sweeteners in tablets	quantum satis
12.10 - Protein products other than from soybeans	Cat 12.9 Protein products excluding products covered in category 18	5 mg/kg max, only vegetable protein products, only as flavour enhancer
12.4 - Mustards	Cat 12.4 Mustard	50 mg/kg max
12.5 - Ready-to-eat soups and broths, including canned, bottled, and frozen	Cat 12.5 Soups and broths	50 mg/kg max, only energy-reduced soups
12.6 - Sauces and like products	Cat 12.6 Sauces	50 mg/kg max
12.7 - Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	Cat 12.7 Salads and savoury-based sandwich spreads	50 mg/kg max, only Feinkostsalat
13.2 - Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	Cat 13.2 Dietary foods for special medical purposes	100 mg/kg max
13.4 - Dietetic formulae for slimming purposes and weight reduction	Cat 13.3 Dietary foods for weight control diets	100 mg/kg max
13.6 - Food supplements	17.1 Food supplements supplied in a solid form	100 mg/kg max - 400 mg/kg max, only food supplements in chewable form
13.6 - Food supplements	17.2 Food supplements supplied in a liquid form	50 mg/L max - 400 mg/L max, only food supplements in syrup form
14.1.3 - Fruit and vegetable nectars	Cat 14.1.3 Fruit nectars as defined by Directive 2001/112/EC	30 mg/L max, only energy-reduced or with no added sugar
14.1.4 - Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	Cat 14.1.4 Flavoured drinks	30 mg/L max, only energy-reduced or with no added sugar, except milk and milk derivative based flavoured drinks 50 mg/L max, only milk and milk derivative based flavoured drinks, energy-reduced or with no added sugar
14.2.1 - Beer and malt beverages	Cat 14.2.1 Beer and malt beverages	10 mg/L max, only alcohol-free beer or with alcohol content not exceeding 1.2% vol; 'Bière

GSFA categories	EU Food categories	Max. Use levels
		de table/Tafelbier/Table beer' (original wort content less than 6%) except for 'Obergäriges Einfachbier'; Beers with a minimum acidity of 30 milliequivalents expressed as NaOH; Brown beers of the 'oud bruin' type - 10 mg/L max, only energy-reduced beer
14.2.2 - Cider and perry	Cat 14.2.3 Cider and perry	20 mg/L max
14.2.7 - Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	Cat 14.2.8 Other alcoholic drinks including mixtures of alcoholic drinks	30 mg/L max
15.1 - Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	Cat 15.1 Potato-cereal- flour- or starch-based snacks	50 mg/kg max
15.2 - Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	Cat 15.2 Processed nuts	50 mg/kg max

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, Neohesperidin Dihydrochalcone is approved as food additive (sweetener) in following areas/countries:

- European Union: E-959 (EU Commission Regulation No 1129/2011 of 11 November 2011)
- United States: GRAS Notice No. GRN 000902 (Nov 23, 2020)
- México: E-959 (Diario Oficial de la Federación, 16 de julio de 2012)
- Southern Common Market (Mercosur): INS 959 (MERCOSUR/GMC/RES. Nº 11/06)
- Central American Common Market (CACM): INS 959 (Reglamento Técnico Centroamericano RTCA 67.04.54:10)
- Other countries: Turkey, Egypt, Azerbaijan, Israel, Iran, Jordan, Lebanon, Kazakhstan, and Uzbekistan.

This is a non-exhaustive list, and HealthTech BioActives might not be aware of the approval of this ingredient in countries other than listed.

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.

Neohesperidin Dihydrochalcone (NHDC) has not been evaluated by JECFA as a food additive, meaning there are no JECFA specifications available for it. As a result, NHDC has not been included in the Codex General Standard on Food Additives, leading to inconsistencies in its acceptance and use across different countries.

This lack of evaluation and standardization creates regulatory uncertainties and barriers. Countries that rely on JECFA and Codex standards for their food safety regulations may not permit the use of NHDC, affecting its international trade. Although NHDC has been evaluated and accepted by some regulatory bodies, such as in the EU, the absence of a global standard continues to pose challenges.

In summary, the lack of a JECFA evaluation and Codex standard for NHDC creates impediments in international trade due to regulatory uncertainties and inconsistencies across different countries.

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.

Yes, safety of Neohesperidin Dihydrochalcone has been evaluated in the last 10 years in the following risk assessments:

- EU: EFSA Panel on Food Additives and Flavourings (FAF), Younes, M., Aquilina, G., Castle, L., Degen, G., Engel, K. H. & Vianello, G. (2022). Re-evaluation of neohesperidin dihydrochalcone (E 959) as a food additive. EFSA Journal, 20(11), e07595.
- USA: US FDA No Objection letter on GRAS Notice No. GRN 000902 (Nov 23, 2020)

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

Neohesperidin Dihydrochalcone (NHDC) is a highly potent, low-calorie sweetener derived from citrus fruits, making it particularly relevant for developing countries. Its intense sweetness, being 1500-1800 times sweeter than sucrose, allows for significant reductions in sugar content, which is crucial for managing obesity and diabetes. This can help improve public health by reducing calorie intake and associated health risks.

Additionally, NHDC's production can stimulate local economies by creating demand for immature citrus fruits, that are used as starting material for the production of this food additive, providing additional income opportunities for farmers.

Finally, NHCD, like other sweeteners, plays an important role in the process of reformulation of food in order to lower their calory content. This is crucial in a time when the rates of obesity and non-communicable diseases (NCDs) including diabetes and dental caries continue to increase worldwide, and public health authorities including the United Nations are encouraging food manufacturers to replace sugar and reduce calories as part of their reformulation goals.

Overall, NHDC supports healthier dietary choices, improves food safety, and boosts local economies, making it a valuable food additive for developing countries.

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

Data	***Data available? (Y / N)***
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y Data on absorption, distribution, metabolism, and excretion (ADME) data is available both in-vitro and in vivo (rats). Studies show that neohesperidin dihydrochalcone is absorbed, metabolized, and excreted mainly in urine.
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y Shorth term toxicity: Acute oral toxicity in rats. Sub-chronic toxicity: Ninety-day repeated dose oral toxicity in rats Reproductive and developmental toxicity: Prenatal developmental toxicity study in rats Genotoxicity: Bacterial Reverse Mutation, In vitro Mammalian Chromosomal Aberration Test, and In vivo Mammalian Micronucleus Test. No adverse effects identified.
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N No human studies were available, nor were previously required.
(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 Specifications defined in Commission Regulation (EU) No 231/2012; purity of ≥96%. Impurity levels assessed, e.g., lead, arsenic, cadmium, mercury, and other related compounds.
(ii) Technological and nutritional considerations relating to the manufacture	Y Details of manufacturing process.

and use of the listed substance	Use as a sweetener confirmed. Stability of the food additive as such, as well as in various food matrices.
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 Maximum use levels set for various food categories; both in EU and USA. Reported uses in different food categories, primarily as a sweetener in soft drinks.
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y Exposure estimates for different population groups; mean and 95th percentile exposure levels available. All exposure estimates were below the acceptable daily intake (ADI) of 20 mg/kg bw/day.
Other information: (please specify)	N

Specify the 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**.):

Data is ready for submission to JECFA.

Oenological Products and Practices International Association (OENOPPIA)

Name of Substance(s):	**Potassium bisulfite (INS 228)**
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Safety assessment and establishment of specifications

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

   OENOPPIA

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

   Potassium bisulfite, Potassium hydrogen sulphite (INS 228)

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

   ESSECO GROUP

   Via San Cassiano 99

   28 069 SAN MARTINO DI TRECATE

   ITALY

   Phone: + 39 0321 790 1

   Fax: + 39 0321 779646

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

   ESSECO GROUP

   Via San Cassiano 99

   28 069 SAN MARTINO DI TRECATE

   ITALY

   Phone: + 39 0321 790 1

   Fax: + 39 0321 779646

   Contact: Stéphane La Guerche, General Manager of OENOPPIA ; slaguerche@oenoppia.com

5. Justification for use:

Sulfur dioxide is used as both an antimicrobial agent and antioxidant in wine making to preserve wine quality and freshness. Potassium bisulfite is often used in 18–20% solutions due to the proportion of sulfur dioxide it contains which assists in protecting musts from oxidation. Potassium bisulfite is beneficial as it is less odorous than some of the other sources of sulfur dioxide.

The amount and timing of sulfur dioxide additions depends on the style of wine that is being made and the composition of the wine to which it is being added. Similarly, the addition of excess sulphur dioxide has the potential to adversely affect the quality of the wine. Sulfur dioxide is naturally occurring in small amounts in wine produced by yeast during fermentation.

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):

This additive is proposed for use at maximal level of 350 mg/kg in food category 14.2.3 “Grape wines” and its sub-categories.

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))

Potassium bisulfite is a legal additive for wine in Argentina, Australia, Brazil, Canada, Chile, European Union, Japan, Peru, Russia, Ukraine, United Kingdom, and Uruguay.

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.

Export difficulties of wines containing potassium bisulfite to different countries such as the Popular Republic of China or South Korea.

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.

Follow-up of the re-evaluation of sulfur dioxide (E 220), sodium sulfite (E 221), sodium bisulfite (E 222), sodium metabisulfite (E 223), potassium metabisulfite (E 224), calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228) by EFSA (European Food Safety Authority in 2022.

https://doi.org/10.2903/j.efsa.2022.7594

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

Not concerned.

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

Data	***Data available?*** ***(Y / N)***
Toxicological data Potassium bisulfite has been previously evaluated by JECFA in 1998 and assigned a group ADI expressed as sulfur dioxide of 0.7 mg/kg bw. Report: TRS 891-JECFA 51/30 Tox Monograph: FAS 42-JECFA 51/95 https://www.inchem.org/documents/jecfa/jeceval/jec_1981.htm	
(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) (iv) Other data (please specify)	

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 See OIV INTERNATIONAL OENOLOGICAL CODEX - Potassium Bisulfite (COEI-1-POTBIS: 2019).
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	N
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	N
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	N
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**.)

As soon as necessary.

Part B: Replies to CL 2024/59-FA, Annex 4 - Confirmation of previous requests and data availability

European Union

Name of Substance (as it appears in Annex 3):	Endo-1,4-ß-xylanase from Thermotoga maritima produced by B. subtilis, strain LMG S-27588
Is the request still in effect? (yes/no)	NO
Are the data available? (yes/no)	NA
Change to data provider? (yes/no)	NO

Japan

Name of Substance (as it appears in Annex 3):	Ethyl 2-methyl pentanoate (No.214), cis 3 Hexen-1-ol(No.315), Menthol (No.427), l-Menthyl l-lactate (No.433), Myrcene (No.1327), Maltol (No.1480), 2-pentylfuran (No.1491), 3-(2-Furyl) acrolein (No.1497), 3-(5-Methyl-2-furyl)-butanal (No.1500), 2-Furyl methyl ketone (No.1503), 3-Acetyl-2,5-dimethylfuran (No.1506), (2-Furyl)-2-propanone (No.1508), 4-(2-furyl)-3-buten-2-one (No.1511), and Furfuryl methyl ether (No.1520)
Is the request still in effect? (yes/ no)	Yes
Are the data available? (yes/no)	Yes (except for No. 1506) / No (for No.1506)
Change to data provider? (yes/no)	Yes IOFI Sean V. Taylor, Ph.D. (staylor@vertosolutions.net) Note: The substantive data provider is the Japan Flavor and Fragrance Materials Association (JFFMA); since JFFMA provides data through IOFI, it was decided to delete Japan and unify the data providers to IOFI. No. 1506 has been prohibited to be used as flavoring in Japan from the beginning of 2023, thus no specification data can be provided for this substances from Japan.

The International Council of Beverages Associations (ICBA)

ICBA represents the interests of the worldwide non-alcoholic beverage industry. ICBA members include national and regional beverage associations and international beverage companies that operate in more than 200 countries and territories and produce, distribute and sell a variety of non-alcoholic sparkling (carbonated) and still (non-carbonated) beverages including soft drinks, sports drinks, energy drinks, bottled waters, flavored and/or enhanced waters, ready-to-drink teas and coffees, 100% fruit or vegetable juices, nectars and juice drinks, and dairy-based beverages. ICBA is a recognized observer at the Codex Alimentarius Commission.

Part A, Line 25 – Propylene Glycol

As noted under the basis for the request, “Propylene glycol has the functions of carrier, emulsifier, glazing agent and humectant in food products. The committee requests for safety re-evaluation for use of propylene glycol as a carrier in foods in general and specifically its use as carrier for flavour in FC 14.1.4. Due to a possible exposure concern related to the proposed maximum use level of 3000mg/l in the food category 14.1.4, CCFA54 agreed to request that JECFA assessment also take into account the use level of 1000mg/l to compare the impact of these use levels on the overall assessment.” As the focus remains with beverages, **ICBA commits to provide relevant use level information for the beverage category**. Further, as this is a safety evaluation, **ICBA will also provide other appropriate data such as an exposure assessment, its review of toxicodynamic factors among others**:

> “Lewis, A.S., S.R. Boomhower, C.M. Marsh, M.M. Jack. **2024**. Considerations for Deriving a Safe Intake of Propylene Glycol. Food and Chemical Toxicology. 5:186:114460 doi: 10.1016/j.fct.2024.114460”.

ICBA thanks the CCFA for taking the above comments into consideration as these and other important matters are further deliberated. ICBA very much looks forward to actively participating in CCFA's upcoming in-session JECFA working group and Plenary sessions.

The International Food Additives Council (IFAC)

Name of Substance (as it appears in Annex 3):	Propylene Glycol (INS 1520)
Is the request still in effect? (yes/ no)	Yes
Are the data available? (yes/no)	No
Change to data provider? (yes/no)	Yes. Data provider for use in food: International Food Additives Council (IFAC) Berit Dockter, Senior Manager, Scientific & Regulatory Affairs bdockter@foodingredientfacts.org Data provider for use in beverages: International Council of Beverages Associations (ICBA) Maia Jack mjack@americanbeverage.org

The International Organization of the Flavor Industry (IOFI)

Name of Substance (as it appears in Annex 3):	See Appendix_IIb_2025CCFA55, 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 15, 2025*
Change to data provider? (yes/no)	*No*

The International Stevia Council (ISC)

Name of Substance (as it appears in Annex 3):	Steviol glycosides
Is the request still in effect? (yes / no)	Yes – A comment on the 'possible issues for trade' which is 'currently unidentified': Without JECFA approval, the industry encounters regulatory challenges in countries that rely on JECFA evaluations to establish national standards. While the requested manufacturing changes are already acknowledged in countries such as the USA, Singapore and those aligning with FSANZ standards, certain markets face restrictions which limit global market access for steviol glycosides and impact competition, market diversity and availability for consumers.
Are the data available? (yes / no)	Yes – Already available as of December 2023.
Change to data provider? (yes/no)	No change in data provider – but the manufacturer is now represented by: Jakub Rusek, Executive Director, International Stevia Council, Global Office – Avenue de Tervueren 188A, 1150 Brussels, Belgium.

The European Food Emulsifiers Manufacturers Association (EFEMA)

Name of Substance (as it appears in Annex 3):	• 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)
Is the request still in effect? (yes/ no)	Yes
Are the data available? (yes/no)	Yes
Change to data provider? (yes/no)	No (European Food Emulsifier Manufacturers Association – EFEMA supports this entry)

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
Change to data provider? (yes/no)	No (The European Food Emulsifier Manufacturers Association – EFEMA – supports this entry)

Name of Substance (as it appears in Annex 3):	• 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)	Yes
Are the data available? (yes/no)	Yes
Change to data provider? (yes/no)	No (The European Food Emulsifier Manufacturers Association – EFEMA – supports this entry)

The Natural Food Colours Association (NATCOL)

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 We wish to thank the Codex Secretariat for the opportunity to provide comments on our ongoing efforts to collect robust and globally applicable use level data for beta-apo-8'-carotenal and beta-carotenes. As the association representing producers of these additives, NATCOL remains fully committed to supporting JECFA's work and providing relevant data to contribute to a realistic and accurate exposure assessment. However, considering the history of how this request got into the JECFA priority list (REP23/FA para 79ff, 137ff, Appendix XI, No. 5 and REP 24/FA Appendix XI, N. 5), we note with concern that NATCOL is still mentioned as the sole data provider for this request in the priority list of substances proposed for evaluation by JECFA (Part A). This places significant responsibility on our association, while the collection of comprehensive and representative data for such long-used additives requires broader collaboration.

	Despite our proactive outreach to stakeholders, including trade associations, we have encountered challenges in obtaining reliable and globally representative use-level data for these additives. We believe it is critical that the exposure assessment process includes input not only from NATCOL but also from users of these additives and Codex members. Data provided directly by the users would ensure a more accurate representation of most realistic use patterns. Similarly, national monitoring data and exposure estimates from Codex members could greatly enhance the robustness and reliability of the assessment. To address these challenges and foster a transparent and inclusive process, we kindly ask you to encourage other stakeholders and Codex member to actively contribute data in response to this request. NATCOL remains dedicated to supporting this important work and will continue to provide data to the best of our ability. However, we believe a collective effort is essential to achieve the accuracy and reliability that Codex standards demand. We thank you for your understanding and consideration of our request and look forward to further discussions at the 55th session of CCFA.
Change to data provider? ***(yes/no)***	No