CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/FA 20/52/12**

January 2020

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-second Session

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

Replies to CL 2019/41-FA of Colombia, Japan, CEFIC, EU Specialty Food Ingredients, ICBA, IOFI, ISC, and DSM Food Specialties

Part A: Replies to CL 2019/41-FA, Annex 2 - Form for the submission of substances to be evaluated by JECFA.

Japan

Name of Substance(s):	Glutaminase from *Aspergillus niger*
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Safety evaluation and establishment of specifications

1. Proposal for inclusion submitted by:

Japan Ministry of Health, Labour and Welfare

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

Name of substance: Glutaminase from *Aspergillus niger*

Trade name: Sumizyme GT

Chemical name: Glutaminase (L-glutamine amidohydrolase), CAS No. 9001-47-2 (EC 3.5.1.2)

3. Names and addresses of basic producers:

Shin Nihon Chemical Co., Ltd.

19-10 Showa-cho, Anjo

Aichi 446-0063, Japan

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

Nobuo Okado
Director, Quality Assurance
Shin Nihon Chemical Co., Ltd.
19-10 Showa-cho, Anjo
Aichi 446-0063, Japan

The manufacturer is represented by:

Shahrzad Tafazoli, MASc (Eng.), MSc, PhD
Associate Director, Toxicology, Chemistry & Regulatory Affairs
Food & Nutrition Group
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Intertek, 2233 Argentina Rd., Suite 201W, Mississauga, ON L5N 2X7

5. Justification for use:

Glutaminase from *Aspergillus niger* is intended for use during food and beverage processing tocatalyse the hydrolysis of L-glutamine to L-glutamate. This enzyme is used in the manufacture of glutamic acid-rich yeast extracts and glutamic acid-rich protein hydrolysates. These ingredients can, in turn, be used in finished foods, such as fish products, gravies and sauces, plant protein products, snack foods, and soups and soup mixes to increase the L-glutamate content. L-glutamate has flavouring properties and imparts or enhances the savoury or umami taste of food/beverages or food ingredients. Thus, the technological purpose of this enzyme preparation is to increase the L-glutamate content of food/beverages and in food ingredients for the purpose of imparting or enhancing the flavour profile.

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 food products, food categories, and maximum use levels that Glutaminase from *Aspergillus niger* is intended to be used are outlined in the table below.

GSFA Food Category	**Food Example**	**Maximum Use Level (mg TOS/kg)**
Yeast and like products (12.8), protein products other than from soybeans (12.10)	Yeast extracts	1,285.2
	Protein hydrolysates	1,285.2

Glutamic acid-rich yeast extracts and protein hydrolysates in which Glutaminase from *Aspergillus niger* are used can, in turn, be added to a wide range of foods. These foods include, but are not limited to, fish products, gravies and sauces, plant protein products, snack foods, and soups and soup mixes. Approximately 1 to 10 g of Glutaminase from *Aspergillus niger* is added per 1 kg of yeast extract to produce the glutamic acid-rich yeast extracts and protein hydrolysates (intermediate products).

These intermediate products, in turn, are added to foods at maximum use levels not exceeding 5%, equivalent to 50 g/kg food. Accordingly, the maximum levels of Glutaminase from *Aspergillus niger* that could potentially be present in final foods are minimal (i.e., not exceeding 64.3 mg TOS/kg food).

GSFA Food Category	**Food Example**	**Maximum Use Level (mg TOS/kg)**
Fish and fish products, including mollusks, crustaceans, and echinoderms (9.2, 9.3, 9.4)	Fish products, fish-based entrees	64.3
Seasonings and condiments (12.2.2)	Seasoning mixes (dashi)	64.3
Soups and broths (12.5)	Prepared and canned soups (excluding soups containing meat and poultry)	64.3
Sauces and like products (12.6)	Gravies, tomato-based sauces, white sauces	64.3
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 (12.7)	Salad/ sandwich spreads	64.3
Soybean-based seasonings and condiments (12.9)	Soybean sauce	64.3
Protein products other than from soybeans (12.10)	Plant protein products, meat analogs	64.3
Ready-to-eat savouries (15.0)	Savoury snacks, such as potato chips, popcorn, pretzel, corn-based snacks	64.3

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))

Glutaminase from *Aspergillus niger* is currently authorised for use in Japan [listed as “glutaminase” on Japan’s specifications and standards for food additives 9th edition] and has been commercially marketed since 2009.

A food enzyme dossier regarding glutaminase derived from *Bacillus amyloliquefaciens* strain AE-GT was submitted for review to the European Commission under Regulation (EC) No 1332/2008. According to the Association of Manufacturers and Formulators of Enzyme Products (Amfep), glutaminase derived from *B. amyloliquefaciens* and *Bacillus subtilis* are currently marketed for use in food processing in the European Union (EU). In addition, glutaminase derived from *B. amyloliquefaciens* is currently permitted for use in food processing (uses not specified) in China as listed in the National Standard on Food Safety – Standard for Use of Food Additives GB 2760-2011.

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 glutaminase, the use of the glutaminase enzyme in the processing of glutamic acid-rich protein hydrolysates and yeast extracts is in significant consumer demand for the purpose of reducing sodium intakes and monosodium glutamate (MSG) uses in various food products. As a consequence, a JECFA evaluation will greatly 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.

We are not aware of any on-going assessments.

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

This enzyme will not specifically impact food safety in the developing countries. The use of these ingredients in small quantities not only improves the flavour profile of finished products, but also reduces the intake of sodium or use of MSG in finished products. In addition, the enzyme is used in the processing of protein hydrolysates, which are rich in amino acids and peptides and can be used as a good source of readily absorbable protein in developing countries to prevent and combat malnutrition[1,2,3]. Protein hydrolysates, in turn, will also be added to plant-based protein products and meat analogues, among other food applications. In recent years, there has been an unprecedented demand for use of plant-based proteins, as an alternative and sustainable source of protein.

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 (90-Day subchronic toxicity study, In vitro bacterial reverse mutation assay, In vitro chromosome aberration test, In vivo alkaline comet assay*
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	*N*

[1] https://www.sciencedirect.com/science/article/abs/pii/S0924224401000073
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3210250/
[3] https://journals.sagepub.com/doi/abs/10.1177/147323000303100308

(iv) Other data (please specify)	*Y (Data on allergenicity and toxigenicity potential)*
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**)

Already available.

CEFIC (Conseil Européen de l'industrie Chimique)

Name of Substance(s):	Pentasodium Triphosphate (INS 451(i))
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	• **Align the assay as P2O5 to "not more than 59.0%"** In the Pentasodium Triphosphate monograph prepared at the 55th JECFA (2000) and published in FNP 52 Add 8 (2000) the Assay values expressed as P2O5 not less than 56.0 % and not more than 58.0 %. This maximum value of 58.0 % is not realistic because it is the theoretical P2O5 content of 100% pure Pentasodium Triphosphate. In practice this value might be often exceeded. We would request to align the maximum value to 59.0 % P_2O_5 as mentioned in the EU Commission Regulation No EU/231/2012[4] • **Align the maximum pH value to 10.2** In addition, the pH value in the FNP 52 Add 8 is 9.1 – 10.1 whereas the pH value in the EU legislation is 9.1 – 10.2. The difference in maximum value can mislead and we would request to align the maximum value to 10.2 as mentioned in the EU commission Regulation EU/231/2012

1. Proposal for inclusion submitted by:

PAPA - the "Phosphoric Acid and Phosphate Association", a Sector Group of Cefic.

Miguel Angel Prieto Arranz
PAPA Sector Group Manager
European Chemical Industry Council - Cefic aisbl
Rue Belliard 40, Box 15, B-1040 Brussels, Belgium
Tel. +32-2-436 94 68

map@cefic.be

2. Name of substance; trade name(s); chemical name(s):

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&from=EN

Pentasodium Triphosphate (INS 451(i))

3. Names and addresses of basic producers:

Prayon S.A.
rue Joseph Wauters 144
4480 Engis
Belgique

4. Identification of the manufacturer that will be providing data

Frederic Martens
Prayon S.A.
rue Joseph Wauters 144
4480 Engis
Belgique

5. Justification for use:

Not applicable for this request

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):

Not applicable for this request

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))

Not applicable for this request

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 applicable for this request

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.

EFSA Re-evaluation of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives and the safety of proposed extension of use (June 2019) [5]

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

Not applicable for this request

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

Toxicological data

(i) Metabolic and pharmacokinetic studies

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies

(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

Not applicable for this request

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Not applicable for this request

[5] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5674

Intake 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

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Not applicable for this request

Other information (as necessary/identified)

None

12. Date on which data could be submitted to JECFA.

Immediately.

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

Name of Substance(s):	Lycopene (synthetic) INS 160d(i) and Lycopene from *Blakeslea trispora* , INS 160d(iii)
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Revise both JECFA specifications with regards to the parameter "solubility".

1. Proposal for inclusion submitted by:

European Specialty Food Ingredients

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

Lycopene (synthetic), Lycopene from *Blakeslea trispora*
Ψ,Ψ-carotene

all-trans-lycopene
(all-E)-lycopene
(all-E)-2,6,10,14,19,23,27,31-octamethyl-
2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
CAS number: 502-65-8

3. Names and addresses of basic producers:

BASF SE, 67056 Ludwigshafen, Germany (for Lycopene (synthetic)
DSM Nutritional Products Europe Ltd., 4002 Basel, Switzerland (for Lycopene (synthetic), and Lycopene from *Blakeslea trispora*)

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

Nicola Leinwetter
Head of Regulatory & External Affairs Asia Pacific / Human Nutrition, BASF SE
Phone: +65 6432 3263
Mobile: +65 9638 7840
E-Mail: nicola leinwetter@basf.com

Dirk Cremer
Sen. Regulatory Affairs Manager
Phone: +41 618157965
Mobile: +41 795722410
E-Mail: dirk.cremer@dsm.com

2. Justification for use:

Both lycopenes are approved food colours.

3. 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):

Both lycopenes are permitted in many food categories of the GSFA as this food colour is listed in table 3 of the GSFA.

4. 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))
To the best of our knowledge and in addition to its GMP permission in the GSFA, lycopene is approved for colour use in Europe, Australia, Brasil, Columbia, China, and many more countries.

5. 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.

Currently unidentified/not relevant as this is a request for specification revision of an already JECFA safety evaluated substance.

6. 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.

JECFA at its 67th (2006) and 71st (2009) session, and also The European Food Safety Authority (EFSA) of the Europe Union in 2008.

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

Currently unidentified

8. 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)	Not applicable
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Not applicable
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	Not applicable
(iv) Other data (please specify)	Not applicable
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Not applicable
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Not applicable
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	Not applicable
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Not applicable
Other information: (please specify) New information on solubility of lycopene as a existing parameter of the INS 160d(i) and INS 160d(iii) monograph. For more information see *.	Available

***Other information:**

This is to request a revision of the JECFA monograph for INS 160d(i) and 160d(iii) regarding the parameter "solubility". Presently the specifications require the use of chloroform when determining this parameter of the specifications. As the use of chloroform should be avoided where possible, and a more suitable alternative had been identified, the applicants wish to get the monographs revised regarding this parameter. The solubility data of lycopene in an alternative solvent are available. Chloroform had been evaluated by JECFA at its 23rd session (TRS Report 648), a toxicological monograph been prepared (FAS 14-JECFA 23/24) and the ADI been determined as: "not to be used".

9. 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**.)

December 2020

ICBA (International Council of Beverages Associations)

ICBA[6] has available (or soon to be available) new evidence – both toxicological and exposure assessments – that warrants a JECFA re-review of aspartame. An update to existing JECFA assessments would be reflective of today's consumer practices in key markets. ICBA requests that the Codex Committee on Food Additives (CCFA) re-prioritize aspartame for JECFA re-review.

The new data supplied by ICBA will allow JECFA to perform a highly refined intake assessment for aspartame in food category 14.1.4 based on the guidelines provided in Chapter 6 "Dietary Exposure Assessment of Chemicals in Food" of the WHO Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009).

Name of Substance(s)	Aspartame
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluation)*	ICBA is seeking a JECFA re-review not only based on a refined exposure assessment reflective of actual consumer practices but also on toxicological considerations. The new data shall comprise: • Refined intake assessments reflective of actual uses weighted according to market volume data to ensure quantitative representativeness for corresponding beverage types. • A systematic assessment of all available mechanistic data in the context of an overall carcinogenicity assessment for aspartame.

1. Proposal for inclusion submitted by:

Maia Jack, Ph.D.,
Chair, ICBA CCFA Task Force in c/o the International Council for Beverages Associations
Vice President Science and Regulatory Affairs (American Beverage Association)
1 202.463.6756
E-mail: mjack@ameribev.org

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

Substance: Aspartame
Trade Name: N/A
Chemical Name(s): 3-Amino-N-(alpha-carbomethoxy-phenethyl)-succinamic acid, N-L-alphaaspartyl-L-phenylalanine-1-methyl ester
Aspartame (CAS number 22839-47-0)

3. Names and addresses of basic producers:

Manufacturers include Ajinomoto, SinoSweet, HSWT, and others.

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

Dietary Intake Assessment:
Nga Tran, Dr.P.H., M.P.H. (ntran@exponent.com; 202-772-4915)

[6] The International Council of Beverages Associations (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.

Principal Scientist, Chemical Regulation & Food Safety
Exponent
1150 Connecticut Ave, NW
Washington, DC
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Danika Martyn, Ph.D. (Danika.martyn@intertek.com; (303) 927-3344)
Senior Manager, Regulatory Affairs and Dietary Intakes, Food & Nutrition Group
Intertek Scientific & Regulatory Consultancy
2233 Argentia Road, Suite 201
Mississauga, Ontario, Canada L5N 2X7
www.intertek.com

Systematic Assessment of Mechanistic Data in context of overall carcinogenicity assessment:
Daniele Wikoff, Ph.D. (dwikoff@toxstrategies.com, 828.348.6833)
Health Sciences Practice Leader
ToxStrategies, Inc.
31 College Place, Suite B118
Asheville, NC 28801
https://toxstrategies.com/

5. Justification for use:

The use of **aspartame** is advantageous in beverage products and technologically justified.

Criteria for Low- and No-Calories Sweeteners (LNCS) in Section 3.2 of the Preamble to the GSFA.

Criteria	Rationale
Techno-logical Justifica-tion	Low- and no-calorie sweeteners are utilized for sugar replacement. LNCS provide desirable sweet taste in products according to consumer preferences.
Advantage	LNCS provide sweet taste without the calories.
Absence of Potential to Mislead consumer	As this category encompasses water-based carbonated, non-carbonated and powdered drinks or concentrates, sweeteners are expected. Each LNCS is appropriately labeled on the ingredient statement so that the consumer cannot be misled. LNCS do not change the nature (both product and process), freshness (e.g., quality of ingredients) or the nutritional quality of the product, including its fruit and vegetable content.

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):

Among others, 14.1.4 Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks

Maximum use of aspartame at a level of 600 mg/kg as consumed in food category 14.1.4 with footnote Note 127 “On the served to the consumer basis”.

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. Worldwide. Australia, Brazil, Canada, China, European Union, United States of America, and hundreds of others.

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.

JECFA last evaluated aspartame safety in 1981. Consumption patterns may have changed since then, and more safety-related studies have been published as well. An update to the 1981 JECFA opinion will ensure that future impediments to international trade are not introduced for this critical sweetener.

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

The 2013 European Food Safety Authority (EFSA) opinion on aspartame. Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive. (EFSA Journal 2013;11(12):3496)

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

Not Applicable

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

(Highlighted in Yellow)

Toxicological data

(i) Metabolic and pharmacokinetic studies (please specify)

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies

(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

X -Mechanistic data in context of totality of evidence on potential carcinogenicity

The systematic assessment of all available mechanistic data in the context of an overall carcinogenicity assessment for aspartame has been completed. (*See* D.S. Wikoff, G.A. Chappell, S. Fitch, C.L. Doepker, and S.J. Borghoff. **2019**. Lack of potential carcinogenicity for aspartame – systematic evaluation and integration of mechanistic data into the totality of the evidence. *Food and Chemical Toxicology*. https://doi.org/10.1016/j.fct.2019.110866)

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Dietary exposure assessment data

(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

X (brand-specific for identified beverage types in Brazil, Canada, Mexico and U.S.A.)

X (application of global reported levels in high intake markets such as U.S.A. and U.K. to set ceiling of possible intakes for the world and the European Union region, respectively.)

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

X (adapted from guidance in EHC240 Chapter 6) – Individual survey data

An International Council of Beverages Associations (ICBA) member on behalf of the beverage industry already is in the process of conducting an intake assessment data with confidential brand-specific use level information and brand-specific market volume data.

Other information (as necessary/identified)

X – Brand-specific market volume data to seek quantitative “representativeness” weighting for levels utilized in the assessment when appropriate.

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.)

Available now – Systematic assessment of mechanistic evidence in the context of all evidence streams relative to potential carcinogenicity

December 2020 – Intake assessments.

IOFI (International Organization of the Flavor Industry)

IOFI respectfully requests the addition of 61 new flavourings to the JECFA Priority List. These are included on Appendix IIa. IOFI also provides within this package Appendix IIb, which is a list of 68 flavourings that were previously submitted to CCFA for inclusion on the priority list. Finally, Appendix III of this package includes 4 flavourings for which updated specifications data have become available.

The required information for the flavours as requested in Annex II of CL 2019/41-FA are attached as Appendix_IIa_2020CCFA52, Appendix_IIb_2020CCFA52 and Appendix_IIc_CCFA52.

Name of Substance(s):	See Annex 3 for list of proposed substances
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Do the published specifications for the flavouring agents as listed in Annex 3 represent what is on global commerce? Data have been presented to IOFI that update specific specification values and identifiers which were submitted previously.

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):

List of 61 new flavourings (See Appendix IIa for list of chemical names)
List of 68 previously submitted flavours (See Appendix IIb)
List of four (4) flavouring agents (See Appendix IIc for list of chemical names).

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):

International Organization of the Flavor Industry (IOFI)
Brussels, Belgium
Sean V. Taylor, Ph.D. (Science Director)
1101 17th Street NW
Suite 700
Washington, DC 20036
P: 202-293-5800
staylor@vertosolutions.net

5. Justification for use:

The additions are flavouring agents previously evaluated using the Procedure by the Committee with status of No Safety Concern at current levels of dietary exposures. Their currently published specifications are impeding commerce because they do not reflect current materials in commerce.

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):

Not applicable

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))

Not applicable

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 applicable

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.

Not applicable

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

Not applicable

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

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

interest; all components of the final products; detailed manufacturing process; possible carryover of substances; etc.

	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	**Yes**
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	**Yes**
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	**Yes**
(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)	**Yes**
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	
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**
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	**Yes**
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**.)

December 1, 2020

Appendix IIa. Sixty-one (61) flavourings newly proposed for inclusion on the JECFA Priority List to be considered at the 52nd session of the Codex Committee on Food Additives

CCFA History	FEMA	CAS	PRINCIPAL NAME	STRUCTURAL CLASS
New 52nd	4902	22122-36-7	3-Methyl-2(5*H*)-furanone	III
New 52nd	4915	2142634-65-7	(5*Z*)-3,4-Dimethyl-5-propylidene-2(5*H*)-furanone	III
New 52nd	4927	934534-30-2	4,7-Decadienal	I
New 52nd	4887	56219-03-5	*cis*-9-Dodecenal	I
New 52nd	4918	68820-38-2	Tridec-5-enal	I
New 52nd	4886	126745-61-7	*cis*-6-Dodecenal	I
New 52nd	4904	115018-39-8	*trans*-Tetradec-4-enal	I
New 52nd	4905	2119671-25-7	2,6-Dimethylheptenyl formate	I
New 52nd	4885	68820-34-8	*trans*-5-Dodecenal	I
New 52nd	4898	41547-29-9	*trans*-5-Octenal	I
New 52nd	4891	2088117-65-9	(*E*)-3-Methyl-4-dodecenoic acid	I
New 52nd	4917	22032-47-9	(*Z*)-9-Dodecenoic acid	I
New 52nd	4926	65398-36-9	(*Z*)-8-Pentadecenal	I
New 52nd	4841	16676-96-3	*cis*-5-Dodecenyl acetate	I
New 52nd	4784	57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	i
New 52nd	4939	2180135-09-3	*S*-Methyl 5-(1-ethoxyethoxy)decanethioate	I
New 52nd	4894	116229-37-9	2-Mercapto-3-methyl-1-butanol	I

New 52nd	4883	556-27-4	*S*-Allyl-*L*-cysteine sulfoxide	II
New 52nd	4935	98139-71-0	3-Methylbutane-1,3-dithiol	III
New 52nd	4916	124831-34-1	2-Methyl-3-butene-2-thiol	I
New 52nd	4938	2180135-08-2	S-Methyl 5-(1-ethoxyethoxy)tetradecanethioate	I
New 52nd	4901	2097608-89-2	*O*-Ethyl *S*-(3-methylbut-2-en-1-yl)thiocarbonate	I
New 52nd	4900	64580-54-7	Hexyl propyl disulfide	I
New 52nd	4914	24963-39-1	bis-(3-Methyl-2-butenyl)disulfide	III
New 52nd	4889	3877-15-4	Methyl propyl sulfide	I
New 52nd	4903	26516-27-8	Ethyl 3-methyl-2-oxopentanoate	I
New 52nd	4804	61789-44-4	Mixture of Ricinoleic acid, Linoleic acid, and Oleic acid	
New 52nd	4930	159017-89-7	4-Isopropoxycinnamaldehyde	I
New 52nd	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
New 52nd	4879	21145-77-7	1-(3,5,5,6,8,8-Hexamethyl-5,6,7,8-tetrahydronaphthalen-2-yl)ethanone	II
New 52nd	4893	4912-58-7	2-Ethoxy-4-(hydroxymethyl)phenol	I
New 52nd	4892	4707-61-3	*cis*-2-Hexylcyclopropaneacetic acid	II
New 52nd	4890	27841-22-1	3-*p*-Menthen-7-al	I
New 52nd	4928	554-14-3	2-Methylthiophene	II
New 52nd	4839	163460-99-9 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	II
New 52nd	4813	1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	II
New 52nd	4884	1569-60-4	6-Methyl-5-hepten-2-ol	I
New 52nd	4827	6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	I
New 52nd	4869	886449-15-6	4-(*l*-Menthoxy)-2-butanone	II
New 52nd	4844	118026-67-8	(2*E*,4*E*)-2,4-Decadien-1-ol acetate	I
New 52nd	4747	91212-78-1	(±)-2,5-Undecadien-1-ol	II
New 52nd	4913	18478-46-1	3,7-Dimethyl-2-methyleneoct-6-en-1-ol	II
New 52nd	4785	25234-33-7	2-Octyl-2-dodecenal	II
New 52nd	4786	13893-39-5	2-Hexyl-2-decenal	II
New 52nd	4929	60857-05-8	4-Methylidene-2-(2-methylprop-1-enyl)oxane	III
New 52nd	4920	220462-51-9	1-Ethyl-2-(1-pyrrolylmethyl)pyrrole	III
New 52nd	4832	108715-62-4	2-(3-Benzyloxypropyl)pyridine	III
New 52nd	4829	616-45-5	2-Pyrrolidone	I
New 52nd	4818	1370711-06-0	*trans*-1-ethyl-2-methylpropyl 2-2-butenoate	I
New 52nd	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

New 52nd	4840	38427-80-4	Tetrahydronootkatone	II
New 52nd	4807	1078-95-1	Pinocarvyl acetate	II
New 52nd	4906	36687-82-8	*L*-Carnitine tartrate	III
New 52nd	4868	61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5*H*)-furanone	III
New 52nd	4896	2186611-08-3	*N*-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	III
New 52nd	4882	1857330-83-9	*N*-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
New 52nd	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
New 52nd	4880	2015168-50-8	2-(4-Ethylphenoxy)-*N*-(1*H*-pyrazol-3-yl)-*N*-(thiophen-2-ylmethyl)acetamide	III
New 52nd	4881	1857331-84-0	*N*-(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
New 52nd	4877	76733-95-4	(*E*)-3-(3,4-Dimethoxyphenyl)-*N*-[2-(3- methoxyphenyl)-ethyl]-acrylamide	III
New 52nd	4835	877207-36-8	2,4-Dihydroxy-*N*-[(4-hydroxy-3-methoxyphenyl)methyl]benzamide	III

Appendix IIb. Sixty-eight (68) 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 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	4688	105-82-8	1,1-Dipropoxyethane	I
Submitted at the 43rd CCFA	4432	25334-93-4	(+/-) Acetaldehyde ethyl isopropyl acetal	I
Submitted at the 43rd CCFA	4528	6986-51-2	Acetaldehyde ethyl isobutyl acetal	I
Submitted at the 43rd CCFA	4527	5669-09-0	Acetaldehyde di-isobutylacetal	I
Submitted at the 43rd CCFA	4335	10486-19-8	Tridecanal	I
Submitted at the 43rd CCFA	4334	1002-84-2	Pentadecanoic acid	I
Submitted at the 43rd CCFA	4336	638-53-9	Tridecanoic acid	I
Submitted at the 43rd CCFA	4010	123-63-7	Paraldehyde	III
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	4749	35852-42-7	4-Methylpentyl 4-methylvalerate	I
Submitted at the 45th CCFA	4346	180348-60-1	5-Methylhexyl acetate	I
Submitted at the 45th CCFA	4347	850309-45-4	4-Methylpentyl isovalerate	I
Submitted at the 45th CCFA	4343	25415-67-2	Ethyl 4-methylpentanoate	I
Submitted at the 45th CCFA	4344	2983-38-2	Ethyl 2-ethylbutyrate	I
Submitted at the 45th CCFA	4345	2983-37-1	Ethyl 2-ethylhexanoate	I
Submitted at the 45th CCFA	4735	13552-95-9	(4*Z*,7*Z*)-Trideca-4,7-dienal	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
Submiited at the 51st CCFA	4836	137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol	III
Submiited at the 51st CCFA	4842	911212-28-7	2,4,5-Trithiaoctane	III
Submiited at the 51st CCFA	4817	38634-59-2	*S*-[(methylthio)methyl]thioacetate	I
Submiited at the 51st CCFA	4870	17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane	II
Submiited at the 51st CCFA	4828	729602-98-6	1,1-Propanedithioacetate	III
Submiited at the 51st CCFA	4824	1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate	III
Submiited at the 51st CCFA	4843	1838169-65-5	3-(Allyldithio) butan-2-one	III
Submiited at the 51st CCFA	4822	61407-00-9	2,6-Dipropyl-5,6-dihydro-2H-thiopyran-3-carboxaldehyde	II
Submiited at the 51st CCFA	4823	33368-82-0	1-Propenyl 2-propenyl disulfide	II
Submiited at the 51st CCFA	4782	1679-06-7; 1633-90-5	2(3)-Hexanethiol	I
Submiited at the 51st CCFA	4779	1416051-88-1	(±)-2-Mercapto-5-methylheptan-4-one	I
Submiited at the 51st CCFA	4792	548740-99-4	(±)-3-Mercapto-1-pentanol	I
Submiited at the 51st CCFA	4791	22236-44-8	3-(Acetylthio)hexanal	III
Submiited at the 51st CCFA	4769	851768-51-9	5-Mercapto-5-methyl-3-hexanone	I
Submiited at the 51st CCFA	4730	1241905-19-0	*O*-Ethyl S-1-methoxyhexan-3-yl carbonothioate	III
Submiited at the 51st CCFA	4734	1256932-15-6	3-(Methylthio)-decanal	I

Submiited at the 51st CCFA	4733	1006684-20-3	(±)-2-Mercaptoheptan-4-ol	III
Submiited at the 51st CCFA	4761	75631-91-3	Prenyl thioisovalerate	I
Submiited at the 51st CCFA	4760	53626-94-1	Prenyl thioisobutyrate	I
Submitted at the 45th CCFA	4745	62439-41-2	(±)-6-Methoxy-2,6-dimethylheptanal	I
Submitted at the 45th CCFA	4765	1367348-37-5	Ethyl 5-formyloxydecanoate	III
Submitted at the 45th CCFA	4719	110-15-6	Succinic acid	I
Submiited at the 51st CCFA	4871	1962956-83-7	2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate	I
Submiited at the 51st CCFA	4826	10525-99-8	3-Phenylpropyl 2-(4-hydroxy-3-methoxy-phenyl)acetate	I
Submiited at the 51st CCFA	4810	60563-13-5	Ethyl-2-(4-hydroxy-3-methoxy-phenyl)acetate	I
Submitted at the 45th CCFA	4750	65405-77-8	*cis*-3-Hexenyl salicylate	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	4606	930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate	I
Submitted at the 43rd CCFA	4627	6414-32-0	Anisaldehyde propyleneglycol acetal	III
Submitted at the 43rd CCFA	4435	673-22-3	2-Hydroxy-4-methoxybenzaldehyde	I
Submitted at the 43rd CCFA	4430	99-50-3	3,4-Dihydroxybenzoic acid	I
Submitted at the 43rd CCFA	4431	99-06-9	3-Hydroxybenzoic acid	I
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	*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

Annex IIc – Four (4) flavourings proposed for specifications modification by JECFA Priority List addition, to be considered at the 52nd session of the Codex Committee on Food Additives

History	FEMA No	JECFA No	CAS	Principle Name	Most recent Specification Evaluation	Status	Update
Old	3862	489		S-Methyl hexanethioate	2003 (session 61)	full	CAS number should be 2432-77-1; update the chemical formula and molecular
Old	4047	1383	67746-30-9	(E)-2-hexenal diethyl acetal	2004(Session 63)	full	The specification requires clarity. 92% 2E-isomer and 3-5% 2Z-
Old	3333	1170	551-08-6	3-Butylidenephthalide	2003 (Session 61)	Full	The assay value is currently not reflective of the material in commerce.
Old	2962	755		Isopulegol	2000 (Session 55)	Full	The currently listed CAS number is for the L-isomer but the substance is a mixture of D and L-isomers, which are better represented by CAS 7786-67-6

ISC (International Stevia Council)

Name of Substance(s):	Steviol glycosides
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	The request is for the completion of the safety evaluation of those steviol glycosides produced via novel technologies that was initiated during the 87th JECFA meeting including bioconversion, fermentation and glucosylation. Nine (9) separate monographs were submitted to JECFA for review at the 87th meeting to support a "framework" for future safety evaluations and for the preparation of specifications for each new technology. These monographs were evaluated by the Committee and as part of this process "A framework was adopted for developing specifications for steviol glycosides by four different methods of production". As a consequence, specifications for those steviol glycosides produced by novel production methods were developed. In addition, the Committee determined at the 87th meeting that "no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% purity as per existing specifications". While the Committee supported the fact that "no safety concerns exist" a formal safety opinion for each new technology was not conducted. The reevaluation is therefore requested to build upon the extensive work conducted by the JECFA at the 87th meeting regarding the safety of each of the individual dossiers produced using the novel technologies.

1. Proposal for inclusion submitted by:

International Stevia Council (ISC)

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

Steviol Glycosides

3. Names and addresses of basic producers:

Cargill Incorporated, 15497 McGinty Road West, M.S. 163 - Wayzata, MN 55391 - USA
DSM Food Specialties, Alexander Fleminglaan 1, 2613 AX, Delft, The Netherlands
Daepyung Co., Ltd., Leaders Building 604, 14, Hwangsaeul-ro 311beon-gil, Bun Dang Gu, Sung Nam Si, Gyeonggi Do, Republic of Korea (ZIP: 13590)
HB Natural Ingredients, 18301 Von Karman Ave. Suite 910, Irvine, CA 92612 – USA
PureCircle Limited, 200 West Jackson Blvd. Suite 800, Chicago, IL 60606 - USA
SweeGen, Inc. 30321 Esperanza Avenue, Rancho Santa Margarita, CA 92688 – USA
Tate & Lyle, 5450 Prairie Stone Parkway, Hoffman Estates, Illinois, 60182 - USA

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

Maria Teresa Scardigli - Executive Director, International Stevia Council - Global Office - Avenue de Tervuren 188A - 1150 - Brussels - Belgium - globaloffice@internationalsteviacouncil.org
Nicole Cuellar-Kingston, Principal Scientist, Scientific & Regulatory Affairs - Cargill Incorporated - Nicole_Cuellar-Kingston@cargill.com
Jeanine A. G. van de Wiel (PhD), Global Regulatory Affairs – Group Leader - DSM Food Specialties - Jeanine.Wiel-van-de@DSM.COM
Dongjoo (David) Kim, Senior Managing Director - Daepyung Co., Ltd. - djkim@daepyung.co.kr
Shyhyuan (CN) Liao (Ph.D.), VP, Applications, Technical Services and Regulatory Affairs, HB Natural Ingredients - cnliao@hbnaturalingredients.com
Sidd Pukayastha (PhD), VP, Head of Global Scientific & Regulatory Affairs - PureCircle Limited - Sidd.Purkayastha@purecircle.com
Hadi Omrani, Director, Technical & Regulatory Affairs – SweeGen, Inc. - hadi.omrani@sweegen.com
Susan M. Potter (PhD), Director, Regulatory and Scientific Affairs - Tate & Lyle – susan.potter@tateandlyle.com

5. Justification for use:

Sweetener. The benefits to the consumer would mirror those for other steviol glycosides currently permitted Internationally. Steviol glycosides produced through the novel technologies would be used in foods and beverages to replace sugar, which will benefit consumers seeking products that have reduced caloric content.

In addition, this would also include consumers with specific medical conditions that require reduced sugar intake, such as those with diabetes, as the consumption of steviol glycosides does not interfere with glucose homeostasis. The novel technologies are capable of selecting those minor glycosides that have more favourable sensory characteristics than the major glycosides, present within the leaf, prompting development of technologies that enhance the proportion of minor glycosides to modify the sensory profile of the articles of commerce (JECFA 87th report).

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

Details can be found within the GSFA reference for steviol glycosides at link:
http://www.fao.org/gsfaonline/groups/details.html?id=309

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

Steviol glycosides manufactured via bioconversion, fermentation and glucosylation have been approved on an international basis.

- Bioconversion products are approved in Australia/New Zealand, Canada, Ecuador, Columbia, Peru, Europe (EFSA positive safety opinion), Mexico and the United States
- Fermentation products are approved in Australia/New Zealand, Canada, the United States and Mexico
- Glucosylation products are approved in Japan, Malaysia, Korea, China, and the United States

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

A JECFA evaluation and Codex standard is internationally recognized and is adopted by many countries around the world who currently do not have the recognized capability for scientific evaluation. Therefore, a Codex standard supports the global acceptance of those glycosides offering improved sensory quality, produced by the novel technologies, providing additional opportunities and a broader freedom to operate in a wider international marketplace.

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

A risk assessment for steviol glycosides meeting ≥95% purity was conducted at the 69th JECFA and other major International Regulatory Authorities, including EFSA, FSANZ, Health Canada and the FDA. In 2017, JECFA reassessed steviol glycosides from stevia rebaudiana Bertoni due to expansion of the SG specification. A risk assessment for the various new technologies including bioconversion, fermentation and glucosylation has also been conducted by International Regulatory authorities outlined in section 6 above. In 2017, JECFA reviewed the safety of rebaudioside A manufactured via fermentation using GM Yarrowia lipolyica and adopted a new specification.

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

From the expansion of the production of steviol glyocosides with improved sensory qualities via the new production methods, the economic opportunities will increase globally. The global footprint of steviol glycoside production will expand into new geographies resulting in new opportunities for local/regional entities.

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.

As per the outcome of the 87th meeting of the JECFA, a novel safety framework supported by 9 separate detailed product dossiers were submitted and reviewed by the Committee. These individual dossiers included all of the required technological and safety information and the safety of the different production technologies were assessed with the following comments:

"The Committee determined that no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% steviol glycosides as per existing specifications. The Committee indicated that the ADI of 0–4 mg/kg bw established at the sixty-ninth meeting of JECFA for steviol glycosides (expressed as steviol) applies to steviol glycosides produced by the four methods indicated in the annexes of the specifications monograph produced at the current meeting".

Specifications for those steviol glycosides produced by the different production methods were also developed as outlined below:

- Steviol Glycosides from Stevia rebaudiana Bertoni (revised from the specifications monograph for Steviol glycosides from Stevia rebaudiana Bertoni prepared at the eighty-fourth JECFA (INS 960a)).
- Steviol Glycosides from Fermentation (specifications for Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica (INS 960b(i)) prepared at the eighty-second JECFA were revised to include other steviol glycosides from Saccharomyces cerevisiae and Yarrowia lipolytica).
- Enzyme Modified Steviol Glycosides (new specifications).
- Enzyme Modified Glucosylated Steviol Glycosides (new specifications, tentative pending further information concerning the analytical methods).

Based upon the knowledge that the JECFA were able to develop full specifications for those steviol glycosides produced via bioconversion and fermentation and that tentative specifications were developed for the glucosylation product pending further information concerning the analytical methodology only indicates that the JECFA were comfortable in the knowledge that sufficient toxicological data, technological data and dietary exposure assessment data are available for the purpose of developing specifications.

	available? (Y / N)
Toxicological data	A full safety data package is available for steviol glycosides.
(i) Metabolic and pharmacokinetic studies (please specify)	
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	
(iv) Other data (please specify)	
Technological data	All technological data have previously been provided - Additional data is available upon request or upon publication of the JECFA 87th Meeting Report.
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	
Dietary exposure assessment data	Data previously provided.
(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used	
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	
Other information: (please specify)	

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**.)

Data is available and can be resubmitted immediately upon request.

Part B: Replies to CL 2019/41-FA Annex 4 - Confirmation of previous requests and data availability.

Colombia

Colombia according to the provisions of Table 1 "LIST OF SUBSTANCES USED AS FOOD ADDITIVES PROPOSED FOR ASSESSMENT BY JECFA" has the request for pending data to finalize the safety assessment and establish the specifications: Evaluation of JECFA84 for Additive Jagua (Genipin-Glycine) Blue, for which data availability was requested for December 2019.

So, Colombia is allowed to make the following indications in accordance with the Confirmation of Previous Requests table found in Annex 4 of Circular Letter CL 2019/41-FA.

Name of Substance (as it appears in Annex 3):	Jagua (Genipin-Glycine) Blue
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, the data was provided by email on December 6, 2019, as indicated by JECFA to the following recipients: 1. Technical information to jecfa@fao.org addressed to Dr. Markus Lipp. 2. Toxicological information to jecfa@who.int addressed to Dr. Kim Petersen. 3. Complete information for the study to emails jecfa@fao.org and jecfa@who.int without recipient.
Change to data provider? (yes/no)	No

Japan

Name of Substance (as it appears in Annex 3):	Flavouring agents:(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 Data on 2-pentylfuran (No.1491), 3-(2-Furyl)acrolein (No.1497), 3-Acetyl-2,5-dimethylfuran (No.1506), and 4-(2-furyl)-3-buten-2-one (No.1511) have already been submitted to IOFI as a response to the JECFA data call for 89th meeting, and will be provided by IOFI as compiled data with its available data. For the rest of the substances, data can be available upon the request from JECFA and will be provided through IOFI, as compiled data with its available data.
Change to data provider? (yes/no)	Yes, will be provided through IOFI

IOFI (International Organization of the Flavor Industry)

Name of Substance (as it appears in Annex 3):	Flavouring agents
Is the request still in effect? (yes / no)	Yes

Are the data available? (yes / no)	Yes, December 1, 2020
Change to data provider? (yes/no)	No

DSM Food Specialties

DSM Food Specialties would like to confirm the previous requests and data availability of the following substances used as processing aids, already included in the priority list of substances proposed for evaluation by JECFA:

- (No. 2) Acid prolyl endopeptidase from *Aspergillus niger* expressing a gene from *Aspergillus niger*
- (No. 9) Asparaginase from *Aspergillus niger* expressing a modified gene from *Aspergillus niger*
- (No. 17) Glucose oxidase from *Penicillium chrysogenum* expressed in *Aspergillus niger*
- (No. 22) Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of *Pseudomonas fluorescens*
- (No. 24) Phospholipase A2 from pig pancreas expressed in *Aspergillus niger*
- (No. 29) Xylanase from *Talaromyces emersonii* expressed in *Aspergillus niger*

Herewith find enclosed the forms (Annex 4) for the abovementioned substances.

We would like to note that for one of these substances, Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of *Pseudomonas fluorescens*, a JECFA call for data has been already received and the data relative to this enzyme will be submitted according to the deadline, namely by 15 February 2020.

We would like to bring to your consideration the fact that the data provider has changed. The contact persons, and their details, are different. The contact details in the previous requests are not valid anymore and we are not be able to receive communication from Codex when addressed to those persons.

Name of Substance (as it appears in Annex 3):	Acid prolyl endopeptidase from *Aspergillus niger* expressing a gene from *Aspergillus niger*
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	Yes, December 2020
Change to data provider? (yes/no)	Yes, DSM Food Specialties **Mrs. Paola Montaguti (paola.montaguti@dsm.com)**
Name of Substance (as it appears in Annex 3):	Asparaginase from *Aspergillus niger* expressing a modified gene from *Aspergillus niger*
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	Yes, December 2020
Change to data provider? (yes/no)	Yes, DSM Food Specialties **Mrs. Paola Montaguti (paola.montaguti@dsm.com)**
Name of Substance (as it appears in Annex 3):	Glucose oxidase from *Penicillium chrysogenum* expressed in *Aspergillus niger*
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	Yes, December 2020
Change to data provider? (yes/no)	Yes, DSM Food Specialties **Mrs. Paola Montaguti (paola.montaguti@dsm.com)**
Name of Substance (as it appears in Annex 3):	Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of *Pseudomonas fluorescens*
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	Yes, **a JECFA call for data has been already received and the data for this enzyme will be submitted according to the deadline, namely by 15 February 2020**
Change to data provider? (yes/no)	Yes, DSM Food Specialties

	Dr. Jeanine van de Wiel (Jeanine.Wiel-van-de@dsm.com)
Name of Substance (as it appears in Annex 3):	Phospholipase A2 from pig pancreas expressed in *Aspergillus niger*
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	Yes, December 2020
Change to data provider? (yes/no)	Yes, DSM Food Specialties **Dr. Jeanine van de Wiel (Jeanine.Wiel-van-de@dsm.com)**
Name of Substance (as it appears in Annex 3):	Xylanase from *Talaromyces emersonii* expressed in *Aspergillus niger*
Is the request still in effect? (yes / no)	yes
Are the data available? (yes / no)	Yes, December 2020
Change to data provider? (yes/no)	Yes, DSM Food Specialties **Mrs. Paola Montaguti (paola.montaguti@dsm.com)**

ICBA (International Council of Beverages Associations)

Benzoic Acid and its salts (INS 210-212) – CL 2019/41-FA, Annex 3 'Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up'

	Substance(s)	***General information***	***Comments about the request***	***Priority****
3.	Benzoic acid and its salts (INS 210-212)	**Type of request**: Data pending – safety assessment **Proposed by**: CCFA49 **Year requested:** 2018 (CCFA50) **Data availability**: December 2020 **Data provider**: International Council of Beverages Associations (ICBA) Ms. Katherine Loatman (Kate@icba-net.org)	**Basis for request:** To confirm ICBA's commitment to provide new toxicological evaluation of benzoates. The studies include extended one-generational reproductive toxicity testing (EOGRT Study, OECD 443) and findings relative to benzoate's chemical-specific adjustment factor, default uncertainty factors and intake assessment assumptions. **Possible issues for trade**: Identified:	1
			CCFA50 suggested extending the interim level of 250 ppm (as benzoic acid) for the beverage category 14.1.4 to CCFA53.	

ICBA is pleased to **confirm** that the full data package – both the toxicological evaluation and the updated dietary intake assessment – should be ready for submission by January 2021, around JECFA's call-for-data deadline. In view of the one-year delay in submitting relevant data, ICBA requests that CCFA52 **extend** the ***interim*** 250 mg/L level for benzoates (as benzoic acid) in the 14.1.4. beverage category from CCFA53 (2021) **to CCFA54 (2022)**.