CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/FA 19/51/13**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-first Session

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

Replies to CL 2018/28-FA of European Union, South Africa, AMFEP, CEFIC, EFEMA, ETA, EU Specialty Food Ingredients and IOFI

European Union

The European Union and its Member States are proposing to add the following substances to the priority list of substances proposed for evaluation by JECFA:

1) INS 1203 Polyvinyl alcohol – request for amendment of the JECFA monograph as regards solubility in ethanol

Enclosures:

INS 1203 Polyvinyl alcohol

1.1 The form containing information on the request related INS 1203 polyvinyl alcohol (i.e. filled in Annex 2 of CL 2018/28-FA)

1.2 EFSA's statement on a modification of the specification on solubility of polyvinyl alcohol in ethanol

1.3 Regulation (EU) 2015/463 amending specifications for polyvinyl alcohol as regards solubility

1.4 Solubility tests carried out by the applicant

1.1 FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	Polivinyl alcohol (PVOH) - CAS 9002-89-5
Question(s) to be answered by JECFA *(Kindly provide a brief justification of the request in case of re-evaluations)*	Request to change the JECFA monograph: solubility of PVOH in ethanol from "sparingly soluble in ethanol" to "practically insoluble or insoluble in ethanol"

1. Proposal for inclusion submitted by:

JONES DAY, Rue de Régence 4, 1000 Brussels

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

Polyvinyl alcohol

3. Names and addresses of basic producers:

Nippon Synthetic Chemical Industry

4. Has the manufacturer made a commitment to provide data?

Yes

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

Ales Bartl, email: abartl@jonesday.com, Tel: 0032 2 645 1452

6. Justification for use:

Existing food additive INS 1203 used as a glazing agent or thickener

7. 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):

13.6 Food supplements (capsule form), 45,000 mg/kg

8. 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));

European Union

9. List of data available (please check, if available)

N/A

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

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

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.

Other information (as necessary/identified)

The same solubility specification as in the JECFA Monograph was included in the former EU Directive 2008/84/EC (repealed and replaced by Regulation 231/2012).

In August 2011, Nippon carried out a solubility testing using a sample of PVOH that fulfilled all purity criteria set out in Directive 2008/84. The test was carried out according to the testing procedure for solubility testing provided on page 41 of the JECFA Combined Compendium of Food Additive Specifications (Volume 4)[1]. The test results were interpreted based on the solubility description provided therein and it was established that the correct specification should be as follows: *"practically insoluble or insoluble in ethanol".*

Consequently, in 2011 Nippon filed a request to the European Commission to update the EU specification of solubility for PVOH from *"sparingly soluble in ethanol"* to *"practically insoluble or insoluble in ethanol".* The European Commission asked EFSA to provide a technical assistance for a modification of the provision on solubility of the food additive polyvinyl alcohol (E 1203) and its possible impact on the safety assessment.

In September 2014, EFSA issued a document 'Statement on the request for a modification of the specification on solubility of the food additive polyvinyl alcohol (E 1203) in ethanol and its possible impact on the safety assessment'[2]. EFSA stated:

[1] ftp://ftp.fao.ora/docrep/fao/009/a0691e/a0691e.pdf)
[2] http://www.efsa.europa.eu/en/efsaiournal/doc/3820.pdf

"the IHCP report concluded that the solubility of polyvinyl alcohol (E 1203) in ethanol (> 99.8 %) was in the range of 10^6 parts of solvent required for 1 part of polyvinyl alcohol (around 1 mg/kg). According to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additives Specifications (JECFA, 2006), the descriptive term of the solubility of polyvinyl alcohol in ethanol (> 99.8 %) should be "practically insoluble or insoluble."

Consequently, the EU specifications for polyvinyl alcohol were updated by Regulation 2015/463[3] which amended Regulation 231/2012 with the new solubility characteristics as follows: *"Soluble in water; Practically insoluble or insoluble in ethanol (> 99,8 %)".*

In the applicant's view, the available data provide a strong support for the request, without the need for additional testing or analysis. Thus, the request could be completed in a reasonable period of time. In addition, the requested amendment has no impact on the safety of PVOH. The differences in the solubility specifications for PVOH in Regulation 2015/463 and in the JECFA specifications respectively have a negative impact on the international trade and customers' understanding of the PVOH specifications. In this respect, the applicant notes that the Japanese Pharmacopeia includes the correct specification of PVOH as 'practically insoluble or insoluble'.

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

All available data to date are already attached to this application. In particular:

- Copy of the EFSA statement on the request for a modification of the specification on solubility of the food additive polyvinyl alcohol (E 1203) in ethanol and its possible impact on the safety assessment of December 2014
- Copy of regulation (EU) 2015/463
- Two copies of solubility tests carried out by the applicant

Document 1.2, 1.3 and 1.4 are available here (1.2, 1.3, 1.4)

South Africa

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	Fulvic acid
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:

South Africa

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

Name of substance: **Fulvic acid**

Trade name: **Carbohydrate-Derived Fulvic Acid - CHD-FA®**

Chemical name: **7,8-dihydroxy-3-methyl-10-oxo-1*H*,10*H*-pyrano[4,3-b]chromene-9-carboxylic acid**

3. Names and addresses of basic producers:

Fulvimed SA (Pty) Ltd
Stellenbosch Agri-Park
Baden Powell Drive
Stellenbosch
South Africa
The producer is represented by: Stefan Coetzee
Chief Executive Officer
Fulvimed SA
Tel: +27 21 881 3600
Email: stefan@fulvimed.co.za
Website: www.fulhold.com

4. Has the manufacturer made a commitment to provide data?

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0463&rid=

Yes, data will be made available.

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

All data will be provided by:

Stefan Coetzee
Chief Executive Officer
Fulvimed SA
Tel: +27 21 881 3600
Email: stefan@fulvimed.co.za
Website: www.fulhold.com

6. Justification for use:

Preservatives are food additives which prevent decomposition by microbial growth and reducing the risk of foodborne infections, decreasing microbial spoilage and preserving fresh attributes and nutritional quality.

Carbohydrate-Derived Fulvic Acid (CHD-FA®) is novel, pure, biologically-active organic acids embedded in a supramolecular structure, free from heavy metals and safe for human and animal consumption.

CHD-FA® liquid with a low pH is a suitable preservative for acidic foods such as jams, salad dressings, fruit and vegetable juices, pickles and carbonated drinks.

Fulvate (CHD-FA® powder) is a suitable preservative in dry products, such as cereals, maize, soup powders and meal replacements.

7. 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 categories and the intended usage levels are specified in the table below:-

Main food group	**GSFA Foods category**	**CHD-FA® Maximum level mg/kg or L**
Alcoholic beverages	Grape wines (14.2.3) Wines (other than grape) (14.2.4) Aromatized alcoholic beverages (14.2.7)	137.12 mg/L
Non- alcoholic beverages	Fruit and vegetable juices (14.1.2) Fruit and vegetable nectars (14.1.3) Water-based flavoured drinks (14.1.4)	137.12 mg/L
Processed fruit and processed vegetables	Jams, jellies, marmalades (04.1.2.5) Fruit-based spreads (04.1.2.6) Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter) (04.2.2.5)	137.12 mg/L
Cereals	Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 07.0 (06.0)	102.8 mg/kg
Food supplement	Dietetic formulae for slimming purposes and weight reduction (13.4) Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6 (13.5)	102.8 mg/kg

8. 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))

List specific countries and foods in which this substance is currently used in: Used as a nutritional supplement in South Africa, USA, Canada.

9. List of data available (please check, if available)

Toxicological data

(i) Metabolic and pharmacokinetic studies: Data available

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

(iii) Epidemiological and/or clinical studies and special considerations: Data available

(iv) Other data: Data available

Technological data

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

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

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: Data available

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

Other information (as necessary/identified)

Additional data can be provided if required by JECFA

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

All data are currently available and ready for submission to JECFA.

AMFEP (Association of Manufacturers and Formulators of Enzyme Products)

CONFIRMATION OF PREVIOUS REQUESTS AND DATA AVAILABILITY

In completing this form, the sponsor of a request set out in Annex 3 can indicate if the request is still in effect, and if the data to support the request are currently available. The opportunity to later confirm or discontinue the requests will still be available at the in-session working group of the JECFA Priority List.

And indication of "no" to any of the questions will result in the deletion of the request at the following session of the CCFA. In response to the circular letter, separate tables should be prepared for separate requests.

Confirmation of previous requests and data availability	
Name of Substance(s):	*All enzymes*
Is the request still in effect? (yes / no)	*Yes*
Are the data available? (yes / no)	*Yes*
Change to data provider? (yes/no)	*<Specify if "yes"> No*

CEFIC (the European Chemical Industry Council)

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	Magnesium Stearate (INS470(iii))
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	The new specifications prepared at the 80th JECFA refer for the METHOF OF ASSAY to the "ICP-AES technique" principles of the method described in Volume 4. This method is not appropriate for the high content of magnesium in the additive. It should be replaced by the titration method laid down in the monographs of the Food Chemical Codex and other pharmacopoeia monographs.

1. Proposal for inclusion submitted by:

APAG – the European Oleochemicals & Allied Products group, a sector group of CEFIC

Sofia Ferreira Serafim
Rue Belliard 40
1040 Brussels
Belgium

E-Mail: sse@cefic.be
Telephone: +32 2 436 9471

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

Name: Magnesium stearate

Chemical name: Octadecanoic acid, magnesium salt

INS: 470(iii)

CAS No: 557-04-0

3. Names and addresses of basic producers:

APAG – the European Oleochemicals and Allied Products Group

This CEFIC sector group represents the following manufacturers: AAK Sweden AB (SE); Ambrogio Pagani SpA (IT); Baerlocher GmbH (DE) ; BASF PC&N (DE) ; Croda Europe (GB) ; Ecogreen Oleochemicals GmbH (DE); Eigenmann & Veronelli SpA (IT); Emery Oleochemicals GmbH (DE); Evonik Industries AG (DE); Faci SpA (IT); Gattefossé (FR); GOVI N.V. (BE); Green Oleo SrL (IT); Hebron SA (ES) ; ICOF Europe GmbH (DE) ; IOI Oleo GmbH (DE); Italmatch Chemicals SpA (IT); Kao Chemicals Europe (ES); KLK Emmerich GmbH (DE); Oleon NV (BE); Peter Greven GmbH & Co. KG (DE) ; Procter & Gamble Chemicals Ltd (CH) ; Sasol (DE); Shell Chemicals (GB); SO.G.I.S. SpA (IT); Spiga Nord (IT); Stearinerie Dubois Fils (FR); Temix Oleo SrL; Union Derivan (ES); Wilmar (NL)

4. Has the manufacturer made a commitment to provide data?

Yes, APAG will submit the required data (the companies prepared and submitted the dossier for the evaluation by JECFA in 2015)

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

CEFIC -The European Chemical Industry Council

Sofia Serafim, Sector Group Manager
Rue Belliard 40
1040 Brussels
Belgium
E-Mail: sse@cefic.be
Telephone: +32 2 436 9471

6. Justification for use:

Not applicable for this request.

7. 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.

8. 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.

Europe: Magnesium stearate, included in E470b – Magnesium salts of Fatty Acids, can be generally used as additive in foodstuffs (except in unprocessed foods and foods for which the use of additives is prohibited) with no specific maximum level (quantum satis) as determined by Regulation (EC) No. 1333/2008 on food additives.

USA: magnesium stearate is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use: (1) The ingredient is used as a lubricant and release agent; a nutrient supplement; and a processing aid as defined (2) The ingredient is used in foods at levels not to exceed current good manufacturing practice (CFR, Title 21 I, B, Sec. 184.1440).

9. List of data available (please check, if available)

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, and such data/information could include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances; etc.

Toxicological data

Not relevant for question to JECFA.

An ADI "not specified'' was established at the 80th JECFA (2015).

Technological data

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

Description of analytical method and analytical data obtained with several batches

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

Not relevant for question to JECFA, the additive remains unchanged.

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

Not relevant for question to JECFA, no change of use levels.

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

Not relevant for question to JECFA, no change of use levels.

Other information (as necessary/identified)

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

1 December 2019

EFEMA (European Food Emulsifier Manufacturers' Association)

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	Sorbitan monostearate (INS 491), Sorbitan tristearate (INS 492) and Sorbitan monopalmitate (INS 495)
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Revision of the specifications (replacement of the "congealing range" identification parameter by 'Identification test — by acid value, iodine value, gas chromatography')

1. Proposal for inclusion submitted by:

The European Food Emulsifier Manufacturers Association (EFEMA)

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

Sorbitan monostearate (INS 491), Sorbitan tristearate (INS 492) and Sorbitan monopalmitate (INS 495)

3. Names and addresses of basic producers:

DuPont Nutrition and Health
Edwin Rahrs Vej 38
DK 8220 –Brabrand
Denmark.

4. Has the manufacturer made a commitment to provide data?

Yes.

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

The EFEMA contact is Ms Caroline Rey, Secretary General

Avenue de Tervueren 13A
1040 Brussels
Belgium
Email: efema@ecco-eu.com

6. Justification for use:

The JECFA Monograph for Sorbitan monostearate (INS 491)[4] includes the following identification parameter: *"Congealing range (Vol. 4)50° - 52°".*

The JECFA Monograph for Sorbitan tristearate (INS 492)[5] includes the following identification parameter: *"Congealing range (Vol. 4)47°- 50°".*

The JECFA Monograph for Sorbitan monopalmitate (INS 495)[6] includes the following identification parameter: *"Congealing range (Vol. 4)45 - 47°".*

However, the congealing range identification method is obsolete, hardly workable and irrelevant.

This is why EFEMA's submission consists in a request to replace the congealing range as an identification method for Sorbitan monostearate (INS 491), Sorbitan tristearate (INS 492) and Sorbitan monopalmitate (INS 495) by the following Identification test: 'acid value, iodine value, gas chromatography'.

The removal of the congealing range parameter was assessed by the European Food Safety Authority[7] and its replacement by the acid value, iodine value, gas chromatography' is now included into the EU specifications. This is reflected in the Commission Regulation (EU) 2018/1462 of 28 September 2018 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate)[8].

7. 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):

Sorbitan monostearate, Sorbitan tristearate and Sorbitan monopalmitate are part of the Sorbitan esters of fatty acids (INS 491 – 495) group in Tables 1 and 2 of the GSFA. Sorbitan monostearate and Sorbitan tristearate are listed as emulsifiers and stabilizers while Sorbitan monopalmitate is listed as an emulsifier.

According to Table 1 of the GSFA, Sorbitan esters of fatty acids can be used in the following food categories:

[4] http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-434.pdf
[5] http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-435.pdf
[6] http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-433.pdf
[7] EFSA's Opinion on the Re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives.
[8] https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32018R1462

GSFA Provisions for SORBITAN ESTERS OF FATTY ACIDS

Number	Food Category	Max Level	Notes
01.3.2	Beverage whiteners	4,000 mg/kg	Note XS252 Note XS250
07.1.4	Bread-type products, including bread stuffing and bread crumbs	10,000 mg/kg	Note 11
07.1.1	Breads and rolls	3,000 mg/kg	
14.1.4.1	Carbonated water-based flavoured drinks	500 mg/kg	
06.5	Cereal and starch based desserts (e.g. rice pudding, tapioca pudding)	5,000 mg/kg	
05.3	Chewing gum	5,000 mg/kg	
05.1.4	Cocoa and chocolate products	10,000 mg/kg	Note 101
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	2,000 mg/kg	Note 123 Note 97 Note XS141
05.1.3	Cocoa-based spreads, including fillings	10,000 mg/kg	Note XS86
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	500 mg/kg	Note 429
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	500 mg/kg	Note 127
07.1.2	Crackers, excluding sweet crackers	10,000 mg/kg	Note 11
01.4.4	Cream analogues	5,000 mg/kg	Note 349
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	5,000 mg/kg	Note XS243
05.4	Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces	10,000 mg/kg	
13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	5,000 mg/kg	
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	1,000 mg/kg	
13.4	Dietetic formulae for slimming purposes and weight reduction	1,000 mg/kg	
06.4.2	Dried pastas and noodles and like products	5,000 mg/kg	Note 211 Note 11
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5,000 mg/kg	Note 76
03.0	Edible ices, including sherbet and sorbet	1,000 mg/kg	
10.4	Egg-based desserts (e.g. custard)	5,000 mg/kg	
12.6.1	Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip)	5,000 mg/kg	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	5,000 mg/kg	Note 363
02.2.2	Fat spreads, dairy fat spreads and blended spreads	10,000 mg/kg	Note 359
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	10,000 mg/kg	
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	10,000 mg/kg	
01.1.4	Flavoured fluid milk drinks	5,000 mg/kg	
13.6	Food supplements	10,000 mg/kg	Note 364
04.1.2.11	Fruit fillings for pastries	5,000 mg/kg	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	5,000 mg/kg	Note XS314R Note XS240
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	5,000 mg/kg	
05.2.1	Hard candy	10,000 mg/kg	
05.1.5	Imitation chocolate, chocolate substitute products	10,000 mg/kg	
01.5.2	Milk and cream powder analogues	4,000 mg/kg	Note XS251
07.1.6	Mixes for bread and ordinary bakery wares	10,000 mg/kg	Note 11
12.6.3	Mixes for sauces and gravies	50 mg/kg	Note 127
12.5.2	Mixes for soups and broths	250 mg/kg	Note 127 Note XS117
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	500 mg/kg	
05.2.3	Nougats and marzipans	10,000 mg/kg	
07.1.3	Other ordinary bakery products (e.g. bagels, pita, English muffins)	10,000 mg/kg	Note 11
06.4.3	Pre-cooked pastas and noodles and like products	5,000 mg/kg	Note 194 Note 11
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	300 mg/kg	
05.2.2	Soft candy	10,000 mg/kg	Note XS309R
07.1.5	Steamed breads and buns	10,000 mg/kg	Note 11
12.8	Yeast and like products	15,000 mg/kg	

8. 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))

Sorbitan esters are traded and legally used worldwide.

9. List of data available (please check, if available)

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, and such data/information could include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances; etc.

Toxicological data

A group ADI of 0-25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acids was established at the 26th JECFA (1982). The latest versions of the JECFA specifications for Sorbitan monostearate (INS 491), Sorbitan tristearate (INS 492) and Sorbitan monopalmitate (INS 495) are available at the following links:

INS 491 : http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-434.pdf

INS 492 : http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-435.pdf

INS 495 : http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-433.pdf

(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

Technological data

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

The JECFA specifications for Sorbitan monostearate (INS 491), Sorbitan tristearate (INS 492) and Sorbitan monopalmitate (INS 495) are available at the following links:

INS 491: http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-434.pdf

INS 492 : http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-435.pdf

INS 495 : http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-433.pdf

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

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

A group ADI of 0-25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acids was established at the 26th JECFA (1982).

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

Other information (as necessary/identified)

Information and data explaining why the “congealing range” is obsolete, difficult to work with due to poor reproducibility, and irrelevant.

This is why this parameter, previously mentioned in the EU Regulation 231/2012 laying down specifications for food additives[9], was replaced by the ‘Identification test — by acid value, iodine value, gas chromatography’ in the Regulation (EU) 2018/1462 of 28 September 2018 mentioned above.

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

Indeed, in its Opinion on the re-evaluation of sorbitan esters[10], the European Food Safety Authority (EFSA) concluded that the amendment to the specifications as regards the removal of the parameter 'congealing range' for identification of sorbitan monostearate (E 491), sorbitan tristearate (E 492) and sorbitan monopalmitate (E 495) would not give rise to a safety concern. EFSA also concluded that the removal of the congealing range from the Union specifications would result in less characterisation of the various sorbitan esters of saturated fatty acids, and that this identification parameter could be replaced by another one. The Authority noted that out of all analytical methods available, gas chromatography analysis appears to deliver the most accurate and reliable results and is fit for purposes of food controls.

10. Date on which data could be submitted to JECFA:

Immediately.

ETA (Enzyme Technical Association)

Substance(s)	***General information***	***Comments about the request***
D-Allulose 3-epimerase from *Arthrobacter globiformis* expressed in *Escherichi coli*	**Type of request**: Safety assessment and establishment of specifications **Proposed by**: United States of America **Year requested**: 2016 (CCFA48) **Data availability**: December 2018 **Data provider**: Matsutani Chemical Industry Co. Ltd. Mr. Yuma Tani (yuma-tani@matsutani.co.jp)	**Basis for request**: The enzyme is used in the production of D-allulose or ketose sugars from monosaccharides. **Possible issues for trade:** Restrict free trade by having its safety questioned as enzyme used to produce D-allulose or ketose sugars, even though D-allulose or ketose sugars has been approved to use as raw material for food, supplement, and other products.

CONFIRMATION OF PREVIOUS REQUESTS AND DATA AVAILABILITY

In completing this form, the sponsor of a request set out in Annex 3 can indicate if the request is still in effect, and if the data to support the request are currently available. The opportunity to later confirm or discontinue the requests will still be available at the in-session working group of the JECFA Priority List.

And indication of "no" to any of the questions will result in the deletion of the request at the following session of the CCFA. In response to the circular letter, separate tables should be prepared for separate requests.

Confirmation of previous requests and data availability	
Name of Substance(s):	D-Allulose 3-epimerase from Arthrobacter globiformis expressed in Escherichi coli
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes
Change to data provider? (yes/no)	<*Specify if "yes"*> No

EU Specialty Food Ingredients

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	Riboflavin from *Ashbya gossypii*
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Safety assessment including establishment of an ADI and a specification

1. Proposal for inclusion submitted by:

EU Specialty Food Ingredients

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

Riboflavin; Lactoflavin; Vitamin B2; 3,10-dihydro-7,8-dimethyl-10-[(2S,3S,4R)-2,3,4,5-tetrahydroxypentyl]benzo-[g]pteridine-2,4-dione; 7,8-dimethyl-10-(1'-Dribityl)isoalloxazine

3. Names and addresses of basic producers:

[10] See http://www.efsa.europa.eu/en/efsajournal/pub/4788

BASF SE, D-68623 Lampertheim, Germany

4. Has the manufacturer made a commitment to provide data?

Yes

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

Nicola Leinwetter
Senior Manager Regulatory & External Affairs / Human Nutrition, BASF SE
Phone: +49 621 60-28784
Fax: +49 621 60-66-28784
E-Mail: nicola.leinwetter@basf.com

6. Justification for use:

Alternative source of riboflavin for colouring purposes and as nutrient source

7. 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):

Same categories as riboflavins INS 101(i)-(iii)

8. 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))

Permitted as food colour and vitamin B2 source in the EU, USA and other countries

9. List of data available (please check, if available)

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, and such data/information could include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances; etc.

Toxicological data

(i) Metabolic and pharmacokinetic studies: Available

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

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

(iv) Other data

Technological data

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

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

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: Comparable to INS 101 (i)-(iii)

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used: Comparable to INS 101 (i)-(iii)

Other information (as necessary/identified)

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

December 2019

IOFI (International Organization of the Flavor Industry)

On behalf of the International Organization of the Flavor Industry (IOFI), we provide the following comments for consideration at the forthcoming 51st Session of the Codex Committee on Food Additives.

IOFI respectfully requests the addition of 46 flavours to the JECFA Priority List, which include 45 new flavours, 1 material for re-evaluation due to substantial new data since its original evaluation and 14 flavors for which updated specifications data have become available. The flavours in appendix II are sorted by Chemical Group and indicate whether they are new submissions, submissions from previous CCFA session (with session noted), or flavors that JECFA requested additional information to complete its safety evaluation by the Procedure.

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	See Appendix II for list of proposed substances
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Are these substances of no safety concern at the current levels ofexposure? Do the published specifications for the flavouring agents as listed in Annex 3 represent what is in global commerce? *Data have been presented to IOFI that update specific specifications values and identifiers submitted previously.*

1. Proposal for inclusion submitted by:

International Organization of the Flavor Industry

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

List of 45 new flavouring agents and one previously evaluated flavouring agent for reevaluation (See Appendix II for list of chemical names) and a list of 14 previously evaluated flavouring agents (See Annex 3) for updates to their specifications to better reflect the materials currently in commerce.

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. Has the manufacturer made a commitment to provide data?

Yes

5. 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

6. Justification for use:

Flavouring ingredients used in foods for human consumption.

7. 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):

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

8. 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)

9. List of data available (please check, if available)

Toxicological data

(i) Metabolic and pharmacokinetic studies: Yes

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

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

(iv) Other data Yes, where relevant

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 Yes, where relevant

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 Yes for all new and re-evaluation candidates

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used. Yes for all new and re-evaluation candidates

Other information (as necessary/identified) Yes as requested.

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

December 01, 2019

Annex 3 - Priority list of 14 compounds proposed for specifications modification by JECFA Priority List to be considered at the 51st session of the Codex Committee on Food Additives

History	FEMA No	JECFA No	CAS	Principle Name	Most recent Specification Evaluation	Status	Update
Old	4050	2002	774-64-1	3,4-Dimethyl-5-pentylidene-2(5H)-furanone	73rd JECFA	Full	Secondary components
Old	4085	1575	1139-30-6	*beta*-Caryophyllene oxide	65th JECFA	Full	Updated isomeric composition
Old	4249	1604	99583-29-6	2-Acetylpyrroline	65th JECFA	Full	Updated assay value, CAS number and secondary components
Old	4668	2077	504-48-3; 25394-57-4	(2E,6E/Z,8E)-N-(2-Methylpropyl)-2,6,8-decatrienamide	76th JECFA	Full	Updated isomeric mixture
Old	3352	1125	2497-21-4	4-Hexen-3-one	59th JECFA	Full	Updated assay value and isomeric composition
Old	2249	380.1	2244-16-8	d-Carvone	86th JECFA	Tentative	Updated refractive index
Old	3317	1491	3777-69-3	2-Pentylfuran	86th JECFA	Full	Updated specific gravity range and assay value
Old	2494	1497	623-30-3	3-(2-Furyl)acrolein	86th JECFA	Full	Updated melting point range
Old	3586	1502	65545-81-5	2-Phenyl-3-(2-furyl)prop-2-enal	86th JECFA	Full	UpddatedAssay value and physical and odor descriptions
Old	3609	1504	1193-79-9	2-Acetyl-5-methylfuran	86th JECFA	Full	Updated Physical appearance description; specific gravity
Old	3391	1506	10599-70-9	3-Acetyl-2,5-dimethylfuran	86th JECFA	Full	Updated Specific gravity range
Old	2495	1511	623-15-4	4-(2-Furyl)-3-buten-2-one	86th JECFA	Full	Updated Physical appearance and melting point range
Old	2435	1513	10031-90-0	Ethyl 3-(2-furyl)propanoate	86th JECFA	Full	Updated Physical form, refractive index and specific gravity
Old	2865	1517	7149-32-8	Phenethyl 2-furoate	86th JECFA	Full	Updated Refractive index and specific gravity ranges; physical appearance

Appendix II-Priority list of 46 flavors proposed for inclusion on the JECFA Priority List to be considered at the 51st session of the Codex Committee on Food Additives

CCFA listing History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	SIMPLE ALIPHATIC AND AROMATIC SULFIDES AND THIOLS				J20	TRS 896 TRS 922 TRS 947 TRS 960 TRS 974
Submitted at 51st CCFA	4730		1241905-19-0	*O*-Ethyl S-1-methoxyhexan-3-yl carbonothioate		
Submitted at 51st CCFA	4733		1006684-20-3	(±)-2-Mercaptoheptan-4-ol		
Submitted at 51st CCFA	4734		1256932-15-6	3-(Methylthio)-decanal		
Submitted at 51st CCFA	4760		53626-94-1	Prenyl thioisobutyrate		
Submitted at 51st CCFA	4761		75631-91-3	Prenyl thioisovalerate		
Submitted at 51st CCFA	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone		
Submitted at 51st CCFA	4779		1416051-88-1	(±)-2-Mercapto-5-methylheptan-4-one		
Submitted at 51st CCFA	4782		1679-06-7; 1633-90-5	2(3)-Hexanethiol		
Submitted at 51st CCFA	4791		22236-44-8	3-(Acetylthio)hexanal		
Submitted at 51st CCFA	4792		548740-99-4	(±)-3-Mercapto-1-pentanol		
Submitted at 51st CCFA	4817		38634-59-2	S-[(methylthio)methyl]thioacetate		
Submitted at 51st CCFA	4822		61407-00-9	2,6-Dipropyl-5,6-dihydro-2*H*-thiopyran-3-carboxaldehyde		
Submitted at 51st CCFA	4823		33368-82-0	1-Propenyl 2-propenyl disulfide		
Submitted at 51st CCFA	4824		1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate		
Submitted at 51st CCFA	4828		729602-98-6	1,1-Propanedithioacetate		

Submitted at 51st CCFA	4836		137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol		
Submitted at 51st CCFA	4842		911212-28-7	2,4,5-Trithiaoctane		
Submitted at 51st CCFA	4843		1838169-65-5	3-(Allyldithio) butan-2-one		
Submitted at 51st CCFA	4870		17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane		
	PHENOL AND PHENOL DERIVATIVES				J24	TRS 901 TRS 960 TRS 974
Submitted at 51st CCFA	4228		462631-45-4	(-)-Homoeriodictyol, sodium salt		
Submitted at 51st CCFA	4797		480-41-1	(±)-Naringenin		
Submitted at 51st CCFA	4799		1449417-52-0	(2*R*)-3',5-Dihydroxy-4'-methoxyflavanone		
Submitted at 51st CCFA	4830		38183-03-8	7,8-Dihydroxyflavone		
Submitted at 51st CCFA	4833		87733-81-1	(2*S*)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan		
Submitted at 51st CCFA	4834		1796034-68-2	(*R*)-5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one		
Submitted at 51st CCFA	4872		35400-60-3	3-(3-Hydroxy-4-methoxy-phenyl)-1-(2,4,6-trihydroxyphenyl)propan-1-one		
	HYDROXY- AND ALKOXY-SUBSTITUTED BENZYL DERIVATIVES				J29	TRS 909 TRS 952
Submitted at 51st CCFA	4430		99-50-3	3,4-Dihydroxybenzoic acid		
Submitted at 51st CCFA	4431		99-06-9	3-Hydroxybenzoic acid		
Submitted at 51st CCFA	4435		673-22-3	2-Hydroxy-4-methoxybenzaldehyde		
Submitted at 51st CCFA	4606		930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate		
Submitted at 51st CCFA	4622		61683-99-6	Piperonal propyleneglycol acetal		
Submitted at 51st CCFA	4627		6414-32-0	Anisaldehyde propyleneglycol acetal		

Submitted at 51st CCFA	4700		614-60-8	*o-trans*-Coumaric acid		
Submitted at 51st CCFA	4750		65405-77-8	*cis*-3-Hexenyl salicylate		
Submitted at 51st CCFA	4810		60563-13-5	Ethyl-2-(4-hydroxy-3-methoxy-phenyl)acetate		
Submitted at 51st CCFA	4826		10525-99-8	3-Phenylpropyl 2-(4-hydroxy-3-methoxy-phenyl)acetate		
Submitted at 51st CCFA	4871		1962956-83-7	2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate		
	ALICYCLIC KETONES, SECONDARY ALCOHOLS AND RELATED ESTERS				J36	TRS 913 TRS 960
Submitted at 51st CCFA	4724		21862-63-5	*trans*-4-*tert*-Butylcyclohexanol		
Submitted at 51st CCFA	4780		38284-26-3	Caryophylla-3(4),8-dien-5-ol		
	AMINO ACIDS AND RELATED SUBSTANCES				J49	TRS 928 TRS 974
Submitted at 51st CCFA	4223		107-43-7	Betaine		
Submitted at 51st CCFA	4738		16869-42-4	Glutamyl-2-aminobutyric acid		
Submitted at 51st CCFA	4739		38837-71-7	Glutamyl-norvalyl-glycine		
Submitted at 51st CCFA	4740		71133-09-0	Glutamyl-norvaline		
Submitted at 51st CCFA	4752		1188-37-0	*N*-Acetyl glutamate		
Submitted at 51st CCFA	4781		18598-63-5	L-Cysteine methyl ester hydrochloride		
	ALICYCLIC PRIMARY ALCOHOLS, ALDEHYDES, ACIDS AND RELATED ESTERS (RE-EVALUATION)				**J32**	**TRS 913 TRS 960 TRS1009**
Old	3557	973	2111-75-3	*p*-Mentha-1,8-dien-7-al (Perillaldehyde)		