CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7a **CX/FA 15/47/16**
January 2015

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Seventh Session

Xi'an, China, 23-27 March 2015

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

(Replies to CL 2014/13-FA)

Replies of Australia, Chile, Colombia, Costa Rica, Egypt, Japan, Norway, Paraguay, South Africa, United States of America, CEFIC, ELC, FoodDrinkEurope, IACM and ISDI

AUSTRALIA

Australia has requested to add the following substances to the priority list of substances proposed for evaluation by JECFA:

- **Tannins (Tannic acid) (INS 181)** - Safety assessment and establishment of specifications
- **Metatartaric acid (INS 353)** - Safety assessment and establishment of specifications
- **Yeast mannoproteins (INS 455)** - Safety assessment and establishment of specifications
- **Potassium bisulfite (INS 228)** - Safety assessment and establishment of specifications

These additives were discussed at the 46th Session of the CCFA and were proposed to be added to the priority list as an outcome from Agenda Item 5c – Food Additive Provisions for Grape Wine based on specific functional effects. Australia wishes to take this opportunity to provide information on these additives for evaluation by JECFA.

Australia also indicated at the 46th Session of the CCFA that information will be made available for an exposure assessment of **benzoates** to assist in the decision on Note 301 "Interim maximum level" and Food Category 14.1.4 "Water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulated drinks". Australia has recently conducted an updated dietary exposure assessment for benzoates and these data are being made available to JECFA through the joint FAO/WHO JECFA Secretaries.

TANNINS (TANNIC ACID) (INS 181)

Name of Substance(s):	Tannins (Tannic acid) (INS 181)
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations):*	Safety assessment and establishment of specifications for use as emulsifier, stabiliser, thickener.

1. Proposal for inclusion submitted by:

Australia

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

Tannins (Tannic acid) (INS 181)

Chemical names: 1,2,3,4,6-Pentakis-O-{3,4-dihydroxy-5-[(3,4,5-trihydroxybenzoyl)oxy]benzoyl}-β-D-glucopyranose

3. Names and addresses of basic producers:

SILVATEAM
Via Torre, 7
12080 San Michele Mondovi (CN)

ITALY
Contact: Stefano Battaglia (sbattaglia@silvateam.com)

LAFFORT
7, rue Franc Samson
33100 Bordeaux
FRANCE
Contact: Luc Laffort (Luc.Laffort@laffort.com)

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):

Please contact the International Association of Oenological Products and Practices (Oenoppia) as coordinator of the mentioned producers.

Contact person: Sophie Pallas- spallas@oenoppia.com
Phone: + 33 6 29 43 27 83

6. Justification for use:

Winemakers are primarily concerned with proteins in regards to wine stability. Protein precipitation in bottled wines (whites and reds with low amounts of polyphenols) causes 'protein haze' or crystalline deposits; these are likely a combination of soluble proteins, polysaccharides, insoluble protein-polyphenol complexes, and metal-protein complexes.

Tannins are, by definition, substances capable of producing stable combinations with proteins and other plant polymers such as polysaccharides. The addition of oenological tannins acts as natural fining agents by binding to and precipitating haze-causing proteins. Wines with high polyphenol concentrations will often remove a sufficient amount of proteins to make the wine stable; thus, white wines and lower phenol red varietals have more issues with protein instability (color loss and instability in red varietals such as Pinot Noir are highly correlated to protein concentration). Due to the tannins in wood, wines fermented or stored in barrels also have far less problems with protein stability when compared to those held in stainless steel.

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):

This additive is proposed for use at GMP in food category 14.2.3 "Grape wines" and its sub-categories.

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))

Tannins is a legal additive in wine in Australia, European Union, Chile, Japan, Mercosur (Argentina, Brazil, Paraguay, Uruguay), New Zealand, South Africa and USA.

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

Further information is available on request in relation to toxicological, technological and intake assessment data and is in the process of being finalised.

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

As soon as necessary.

METATARTARIC ACID (INS 353)

Name of Substance(s):	Metatartaric acid (INS 353)
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations):*	Safety assessment and establishment of specifications for use as emulsifier, stabiliser, thickener.

1. Proposal for inclusion submitted by:

Australia

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

Metatartaric acid (INS 353)

3. Names and addresses of basic producers:

ESSECO GROUP
Via San Cassiano 99
28 069 SAN MARTINO DI TRECATE
ITALY
Contact: Marco Manfredini (marco.manfredini@esseco.it)

LAFFORT
7, rue Franc Samson
33100 Bordeaux
FRANCE
Contact: Luc Laffort (Luc.Laffort@laffort.com)

DAL CIN GILDO SPA
Dal Cin Gildo Spa- Via Primo Maggio, 67
Concorezzo (MB) 20863
ITALY
Contact: Dr. Alberto Granata (info.tech@dalcin.com)

LALLEMAND
19, rue des Briquetiers - BP 59
31702 Blagnac Cedex
FRANCE
Contact: Claude Espeillac (cespeillac@lallemand.com)

AGROVIN
Pgno Industrial Alces - Avda de los Vinos, s/n
13600 ALCAZAR DE SAN JUAN (C. Real)
SPAIN
Contact: Eva Navascues (enavascues@agrovin.com)

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):

Please contact the International Association of Oenological Products and Practices (Oenoppia) as coordinator of the mentioned producers.

Contact person: Sophie Pallas- spallas@oenoppia.com
Phone: + 33 6 29 43 27 83

6. Justification for use:

Metatartaric acid is widely used in winemaking as a stabiliser to prevent the precipitation of tartrate in wine into the relatively insoluble crystals of potassium bitartrate and calcium tartrate. This precipitation occurs depending on the pH value of the wine and other variables, resulting in an undesirable product with crystals settling at the bottom of the bottle.

Metatartaric acid is used by the wine industry at doses up to 10 g/hL and acts to make wine stable to crystal growth by opposing the growth of the submicroscopic nuclei around which the tartrate crystals are formed. The large uncrystallised molecules of metatartaric acid are in the way during the tartrate crystal building process, preventing the growth of the tartrate crystals.

Metatartaric acid is a polyester resulting from the intermolecular esterification of tartaric acid at a legally imposed minimum rate of 40%. When tartaric acid is heated, possibly at low pressure, a loss of acidity occurs and water is released. A polymerised substance is formed by an esterification reaction between an acid function of one molecule and a secondary alcohol function of another molecule. Metatartaric acid is, therefore, not a single compound but a dispersed polymer or a mixture of polymers of different molecular weights.

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):

This additive is proposed for use at GMP in food category 14.2.3 “Grape wines” and its sub-categories.

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))

Metatartaric acid is a legal additive in wine in Australia, New Zealand, Canada, the European Union, South Africa, Chile and Mercosur (Argentina, Brazil, Paraguay, Uruguay).

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

Further information is available on request in relation to toxicological, technological and intake assessment data and is in the process of being finalised.

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

As soon as necessary.

YEAST MANNOPROTEINS (INS 455)

***Name of Substance(s)**:*	Yeast mannoproteins (INS 455)
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations):*	Safety assessment and establishment of specifications for use as emulsifier, stabiliser, thickener.

1. Proposal for inclusion submitted by:

Australia

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

Yeast mannoproteins (INS 455)

3. Names and addresses of basic producers:

LAFFORT
7, rue Franc Samson
33100 Bordeaux
FRANCE
Contact: Luc Laffort (Luc.Laffort@laffort.com)

LALLEMAND
19, rue des Briquetiers - BP 59
31702 Blagnac Cedex
France
Contact: Claude Espeillac (cespeillac@lallemand.com)

DSM- Oenobrands
Parc Agropolis II. Bat. 5, Boulevard de la Lironde
34397 Montpellier Cedex
France
Contact : Isabelle Van Rolleghem (Isabelle.van.Rolleghem@oenobrands.com)

FERMENTIS LESAFFRE
Fermentis division of S.I. Lesafre
137, rue Gabriel Peri BP 3029
59703 Marcq-en-Baroeul cedex
France
Contact: Stéphane Meulemans (smeulemans.fermentis@lesaffre.fr)

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):

Please contact the International Association of Oenological Products and Practices (Oenoppia) as coordinator of the mentioned producers.

Contact person: Sophie Pallas- spallas@oenoppia.com
Phone: + 33 6 29 43 27 83

6. Justification for use:

Mannoproteins extracted from yeast cell walls are used as a food additive in wine to inhibit the crystallisation of potassium bitartrate which are commonly formed in bottled wine. The presence of potassium bitartrate crystals in wine is not an issue related to safety or wine taste but rather one of aesthetics and consumer acceptability.

Mannoproteins are yeast cell wall components that are proteins with large numbers of mannose groups (sugar units) attached. Mannoproteins are extracted from the cell walls of the common yeast Saccharomyces cerevisiae using an enzyme treatment. The enzyme used is permitted for use in food manufacture. The yeast mannoproteins are proposed to be added to wine in a concentration range of 100-300 mg/L (giving a maximum total concentration of 400 mg/L taking account of initial levels in wine), which is consistent with levels used internationally. Yeast mannoproteins also occur naturally in wine and many other foods.

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):

This additive is proposed for use at a level of 400 mg/L in food category 14.2.3 “Grape wines” and its sub-categories.

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))

Yeast mannoproteins are a legal additive in wine in Argentina, Australia and New Zealand.

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

Further information is available on request in relation to toxicological and technological data. Food Standards Australia New Zealand conducted a detailed assessment of yeast mannoproteins as a food additive for wine. This document is available from: http://www.foodstandards.gov.au/code/applications/documents/A605_Mannoproteins_FAR.pdf

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

As soon as necessary.

POTASSIUM BISULFITE (INS 228)

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

1. Proposal for inclusion submitted by:

Australia

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

Potassium bisulfite, Potassium hydrogen sulphite (INS 228)

3. Names and addresses of basic producers:

ESSECO GROUP
Via San Cassiano 99
28 069 SAN MARTINO DI TRECATE
ITALY
Phone : + 39 0321 790 1
Fax : + 39 0321 779646
Contact: Marco Manfredini (marco.manfredini@esseco.it)

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):

ESSECO GROUP
Via San Cassiano 99
28 069 SAN MARTINO DI TRECATE
ITALY

Phone : + 39 0321 790 1
Fax : + 39 0321 779646
Contact: Marco Manfredini (marco.manfredini@esseco.it)

6. Justification for use:

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

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

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):

This additive is proposed for use at GMP in food category 14.2.3 “Grape wines” and its sub-categories.

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))

Potassium bisulfite is a legal additive in wine in Argentina, Australia, European Union, Brazil and Chile.

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

Further information is available on request and is in the process of being finalised.

Toxicological data

Potassium bisulfite has been previously evaluated by JECFA in 1998 and assigned a group ADI expressed as sulfur dioxide of 0.7 mg/kg bw.

Report: TRS 891-JECFA 51/30

Tox Monograph: FAS 42-JECFA 51/95

Technological data

See INTERNATIONAL OENOLOGICAL CODEX - Potassium Bisulfite (COEI-1-POTBIS: 2000).

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

As soon as necessary.

CHILE

The CCFA subcommittee of Chile agrees with the proposal of assign high priority for aspartame (INS 951) and suggests that high priority be given also to benzoates and the two work related with steviol issues: a) evaluation of Stevia extract, steviol glycosides (INS 960), purity 85% and 90% proposed by the Paraguay and b) steviol glycosides proposed by Malaysia and the United States. For these steviol issues, we propose that they are treated in a single evaluation by JECFA.

EGYPT

Egypt does not have new request on substances to be included in the priority list for evaluation by JECFA .

COLOMBIA

Name of Compound(s):	Jagua (*Genipa americana*) Extract
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Safety evaluation when used as colour.

1. Proposal for inclusion submitted by:

Ministry of Health and Social Protection

Nutritional Health Branch, Food and Beverages
Carrera 13 No. 32-76, Bogotá D.C.

Tel: (+571) 3305000

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

Name of compound: Jagua (Genipa americana) Extract

Trade names: No

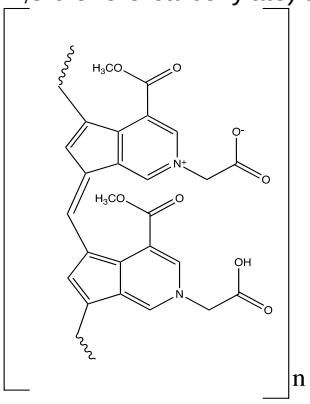
Chemical names: Polymer produced by the natural reaction between genipin (Methyl (1R,2R,6S)-2-hydroxy-9-(hydroxymethyl)-3-oxabicyclo[4.3.0]nona-4,8-diene-5-carboxylate) and amino acids.

CAS number 1314879-21-4

Chemical formula (C27H25O8N2)10-12

Molecular weight: 6,000

Chemical Structure of the Polymer



3. Names and addresses of basic producers:

ECOFLORA S.A.S
Address: Calle 80 Sur Numero 47D-65, Urbanización Industrial La Holanda – Interior 103.
Sabaneta, Antioquia, Colombia.
Phone: (+574) 444 89 74
agiraldo@ecofloracares.com / www.ecofloracares.com

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):

Manufacturer:

ECOFLORA CARES S.A.S
Primary Contact:
Name: Adrian Giraldo.
Position: VP Business Development
E-mail address:agiraldo@ecofloracares.com
Contact phone number: (+574) 444-89-74 Ext- 107

Secondary Contact:

Name: Juan Fernando Botero M.
Position: CEO
E-mail address:jbotero@ecofloracares.com
Contact Phone Number: (+574) 444-89-74 Ext -106

6. Justification for use:

Jagua (*Genipa americana*) Extract is a natural color system with several applications in the food industry, these applications include: Dairy Products, Cereals, Candy containing and non-containing chocolate, Jams and Jellies, Snacks, beverages and others.

When the product is applied individually, it will give a blue coloration to formulations, depending on the natural color of the matrix in which the product is added, different shades of blue may occur.

Genipa Americana Extract can be used as a blend ingredient in other formulations in order to obtain other colors. In those blends the amount of color additive will be considerably less than the one used for achieving blue coloration.

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

The Jagua (*Genipa americana*) Extract preparation is used as colour in Dairy Products, Cereals, Candy containing and non-containing chocolate, Jams and Jellies, Snacks, Beverages and others. The dosage of the colour varies between 100 and 300 mg/kg depending on the specific application and raw material.

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

The Genipa Americana Extract preparation is authorized in Colombia by the health authority, National Institute of Food and Drug Surveillance - INVIMA, since March 2014, according to the assessment made by the Specialized Committee of Food and Beverages.

The Genipa Americana is a resource of the Amazonian biodiversity used as food and cosmetic dye since Pre-Columbian times, which grows naturally in tropical zones, widely distributed in the Amazon basin of Bolivia, Brazil, Colombia, Ecuador, Peru, Venezuela and Guyana. In the Peruvian Amazon region grows throughout the lowland and highland forests

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

Toxicological data

(i) Metabolic and pharmacokinetic studies

Not available

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

The following studies have been conducted in accordance with internationally accepted guidelines

(OECD/EU/FDA) and do not give any concerns:

Test for mutagenic activity (Ames Test).

Clastogenicity (Micronucleus test in-vivo)

Allergeniciy testing

HET CAM

In-vitro 3T3 photo toxicity (OECD 432)

90- day Oral Repeated Dose Toxicity Study in Wistar rats

28- day Oral Repeated dose Toxicity Study in Wistar rats

The conclusion of the safety studies can be summarized as follows:

Mutagenicity (AMES, Mouse Lymphoma):	Non mutagenic
Clastogenicity (Micronucleus test in-vivo):	No chromosomal damage
Allergenicity testing:	Negative Acute Toxicity (OECD 420): at 2000 mg/kg no LD50 achieved
HET CAM:	No ocular irritation
In-vitro percutaneous penetration:	No penetration Repeat insult patch test: no irritation or allergic contact dermatitis in human
In-vitro 3T3 photo toxicity (OECD 432):	Non-phototoxic
28-day oral Repeated Dose Toxicity study in Wistar rats:	Dark discoloration on testes and kidneys NOAEL at 2000 mg/kg
90-day oral Repeated Dose Toxicity study in Wistar rats:	No effect at all NOEL at 1000 mg/kg

Based on the knowledge of century-long common use of Jagua fruits by consumption, the use as a tattoo ink and hair dye stuff and the use in traditional medicines in the absence of any reported case of toxic insults, products by Jagua fruits are deemed to be safe. The toxicity studies performed by now lead to the conclusion that Jagua extract has a no toxic potential.

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

Not applicable.

(iv) Other data None.

Technological data

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

Test	**Specification**
Polymer (%)	20-40
Moisture (%)	<10
Absorbance a 590 nm (0.015 g/ 40 mL of water)	0.90-1.30
Total coliform count CFU/g	<100
E.Coli Detection CFU/g	Negative
Aerobic Plate count CFU/g	<1000
Molds and Yeast count CFU/g	<1000
Coagulase positive S.aureus CFU/g	Negative
Cadmium (ppm)	<1
Mercury (ppm)	<1
Lead (ppm)	<2
Arsenic (ppm)	<1
Genipin (%)	0.3

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

None

Intake assessment data

Levels of the listed compound used in food or expected to be used in food based on technological function and the range of foods in which they are used

Recommended dosage of Jagua (*Genipa americana*) extract ranges from 0,01% to 0,03% Depending on the final application as follows.

Food Matrix	**Suggested Dose of Additive %p/p**
	Max
Dairy Products and Analogues	0,03%
Cereals	0,03%
Candy containing chocolate	0,03%
Jams and Jellys	0,03%
Snacks	0,03%
Candy not containing chocolate	0,02%
Beverages, excluding dairy	0,01%

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

Several studies show a maximum intake of 120 mg/day of the color considering high consumptions of the food products containing Jagua (*Genipa americana*) extract as mentioned before. Following calculation directions contained in “Redbook 2000” “Toxicological Principles for the Safety Assessment of Food Ingredients”, a 60 kg body weight is used to normalize the general population intake, This calculation results in a daily normalized intake of **2 mg/kg BW – day**.

Other information as necessary

None

10. Date on which data could be submitted to JECFA

As soon as necessary.

COSTA RICA

Costa Rica welcomes and supports the work done on the Priority list of substances proposed for evaluation by JECFA, however we have analized the document and at the moment we don't have comments.

JAPAN

Name of Substance(s):	Microcrystalline Cellulose (INS 460(i))
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Revision of specification (Change of solubility in characteristics) Change from "Slightly soluble in sodium hydroxide solution" to "Slightly soluble, practically insoluble or insoluble in sodium hydroxide solution"

1. Proposal for inclusion submitted by:

Japan

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

Microcrystalline Cellulose; Cellulose

3. Names and addresses of basic producers:

ASAHI KASEI CHEMICALS CORPORATION
nda Jinbocho, Chiyoda-ku, Tokyo, 101-8101, Japan

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):

Yoshinaga Tamura Ph.D.
General Manager, Quality Assurance Department, Functional Additives Division
ASAHI KASEI CHEMICALS CORPORATION
TEL: +81-3-3296-3361 FAX: +81-3-3296-3467
E-mail: tamura.yb@om.asahi-kasei.co.jp

6. Justification for use:

Emulsifier, stabilizer, anticaking agent, dispersing agent

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):

Food Cat No	Food Category	Max Level
01.2.1.1	Fermented milks (plain), not heat-treated after fermentation	GMP
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	GMP
01.2.2	Renneted milk (plain)	GMP
01.4.1	Pasteurized cream (plain)	GMP
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	GMP
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 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))

Yes. Microcrystalline Cellulose is used all over the world including Japan, the U.S.A., Europe.

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

Toxicological data

(i) Metabolic and pharmacokinetic studies

Not Applicable

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

Not Applicable

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

Not Applicable

(iv) Other data

None

Technological data

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

We would like to propose revision of specification (Change of solubility in characteristics) as follows:

Change from “Slightly soluble in sodium hydroxide solution” to “Slightly soluble, practically insoluble or insoluble in sodium hydroxide solution”

<Rationale>

The solubility test in sodium hydroxide solution was performed according to the method in the Combined Compendium of Food Additive Specifications (JECFA). Nine samples were obtained from the market. The results of all samples showed that the solubility of Microcrystalline Cellulose in sodium hydroxide solution was “Practically insoluble or insoluble”.

The following official compendia describe that the solubility of Microcrystalline Cellulose in sodium hydroxide solution are either “Insoluble” or “Practically insoluble” Food Chemical Codex (FCC) 9th, U.S. Pharmacopeia (USP) 37 and European Pharmacopeia (EP) 8th

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

Not Applicable

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 Applicable

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

Not Applicable

Other information as necessary

None

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

Until December 1, 2015

Name of Substance(s):	Sucrose esters of fatty acids (INS 473)
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Revision of specifications (Change the statements for solubility in Identification)

1. Proposal for inclusion submitted by:

JAPAN

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

Sucrose esters of fatty acids (INS 473)

3. Names and addresses of basic producers:

(i) Mitsubishi Chemical Corporation, 1-1, Marunouchi 1-chome, Chiyoda-ku, Tokyo 100-8251, Japan

(ii) Dai-ichi Kogyo Seiyaku Co.,Ltd, 5 Ogawara-cho, Kisshoin, Minami-ku, Kyoto 601-8391, Japan

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):

Mitsubishi Chemical Corporation
Scientific Regulatory Affairs Manager

Food Ingredients Department
Performance Product Division
Ms. Yukino Nagai
nagai.yukino@me.m-kagaku.co.jp

6. Justification for use:

Used in various foods as an emulsifier and a stabilizer

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):

See the Attachment-1

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. Sucrose esters of fatty acids is approved and used in foods in Japan, the USA, the EU, Australia and New Zealand, China, Korea, Taiwan, Vietnam, Philippines, Indonesia, Malaysia, Singapore, India and many other countries.

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

Toxicological data and Intake assessment data:

An ADI for Sucrose esters of fatty acids together with Sucroglycerides, Sucrose oligoesters Type I and Type II, and Sucrose monoesters of lauric, palmitic or stearic acid was established at the 73rd JECFA(2010).

Technological data:

Sucrose esters of fatty acids (INS 473; SEFA) are consisted of mono-, di- and tri-esters of sucrose with fatty acids, and the assay is not less than 80% of sucrose esters. Hydrophilicity of this food additive depends both on fatty acid type and the content of monoesters.

We investigated the solubility of globally marketed products and the results are shown in Table 1. Some samples did not meet current solubility specification (Note; those products met all specifications except for solubility). Especially samples 4 and 6, of which the safety was evaluated by JECFA and which are major products currently used as a food additive around the world, did not meet solubility specification in water and ethanol.

Based on the results of the investigation, we would like to propose revisions of the solubility as follows: “Soluble, sparlingly soluble or dispersible in warm water. Soluble in warm ethanol.”

Table 1. Results of solubility test of SEFA samples with current specification and proposing specification

SEFA Sample	Fatty acid type	ester composition		current spacification		proposing specification	
		Monoester (%)	Di and higher esters(%)	Water (20 ° C)	Ethanol (20 ° C)	Water (60° C)	Ethanol(50 ° C)
				Sparlingly soluble	Soluble	Soluble, sparlingly soluble or dispersible	Soluble
1	C12 (lauric)	ca. 80	ca. 20	Pass	Pass	Pass (soluble)	Pass
2	C16 (palmitic)	ca. 80	ca. 20	Not pass	Pass	Pass (sparlingly soluble)	Pass
3	C18 (stearic)	ca. 75	ca. 25	Not pass	Pass	Pass (sparlingly soluble)	Pass
4*	C18 (stearic)	ca. 55	ca. 45	Not pass	Not pass	Pass (dispersible)	Pass
5	C12 (lauric)	ca. 30	ca. 70	Not pass	Pass	Pass (dispersible)	Pass
6*	C18 (stearic)	ca. 30	ca. 70	Not pass	Not pass	Pass (dispersible)	Pass

Samples 4* and 6* are products of which the safety was evaluated by JECFA, and are major products used as a food additive around the world.

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

December 2015

Name of Compound(s):	**Tamarind seed polysaccharide**
Question(s) to be answered by JECFA	Safety assessment and establishment of specifications

1. Proposal for inclusion submitted by:

Japan

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

Name of compound:

Tamarind seed polysaccharide, tamarind seed gum, tamarind gum

Chemical name:

Tamarind seed polysaccharide, is a polysaccharide, composed of a linear chain of β(1-4)-linked D-glucan residues that is partially substituted with α(1-6)-linked D-xylopyranose, some of which are β-D-galactosylated at O-2.

3. Names and addresses of basic producers:

DSP GOKYO FOOD & CHEMICAL Co., Ltd. HERBIS OSAKA 20th Fl.
2-5-25 Umeda, Kita-ku, Osaka
530-0001
Japan

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):

Dr. Hiroshi Egawa
Executive Director, Research, Development & Technology DSP GOKYO FOOD & CHEMICAL Co., Ltd.
HERBIS OSAKA 20th Fl.
2-5-25 Umeda, Kita-ku, Osaka 530-0001
Japan
Tel: 81 6 7177 6874
Fax: 81 6 6453 0941
E-mail: hiroshi-egawa@dsp-gokyo-fc.co.jp

6. Justification for use:

Tamarind seed polysaccharide is intended to be used as a thickener, stabilizer, emulsifier, and gelling agent.

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):

Category number	Food Category	Max use level (mg/kg)
01.1.2	Dairy-based drinks, flavored and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	2000
01.4	Cream (plain) and the like	5000
01.6.1	Unripened cheese	5000
01.6.4	Processed cheese	5000
01.6.5	Cheese analogues	5000
01.7	Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt)	5000
02.2.2	Fat spreads, dairy fat spreads and blended spreads	5000
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	5000
03.0	Edible ices, including sherbet and sorbet	5000
04.1.2.5	Jams, jellies, marmalades	10000
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	10000
04.1.2.9	Fruit-based desserts, incl. fruit-flavored water-based desserts	10000
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	10000
04.2.2.6	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nut and seed pulps and preparations (e.g. vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	5000
04.2.2.7	Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and	10000

Category number	Food Category	Max use level (mg/kg)
	12.9.2.3	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed	10000
05.1.3	Cocoa-based spreads, incl. fillings	5000
05.1.4	Cocoa and chocolate products	5000
05.1.5	Imitation chocolate, chocolate substitute products	5000
05.2.2	Soft candy	5000
05.3	Chewing gum	5000
05.4	Decorations (e.g. for fine bakery wares), toppings (non-fruit), and sweet sauces	5000
06.4	Pastas and noodles and like products (e.g. rice paper, rice vermicelli, soybean pastas and noodles)	5000
06.5	Cereal and starch based desserts	15000
06.6	Batters (e.g. for breading or batters for fish or poultry)	5000
06.8.1	Soybean-based beverages	2000
07.0	Bakery wares	5000
10.4	Egg-based desserts (e.g. custard)	5000
11.4	Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings)	5000
12.4	Mustard	10000
12.5	Soups and broths	2000
12.6	Sauces and like products	10000
12.7	Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa-and nut-based spreads of food categories 04.2.2.5 and 05.1.3	10000
12.9.2.3	Other soybean sauce	10000
12.10	Protein products other than from soybeans	5000
13.2	Complementary foods for infants and young children	10000
13.4	Dietetic foods intended for slimming purposes and weight reduction	5000
13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1-13.4 and 13.6	5000
13.6	Food supplement	10000
14.1.3	Fruit and vegetable nectars	2000
14.1.4.2	Non-carbonated water-based flavored drinks, including punches and ades	2000

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)) :

Tamarind seed gum is authorized as food additives in the following countries:

Japan: Japan’s specifications and standards for food additives

USA: GRN 503

China (limited to frozen drink, cocoa products, chocolate and chocolate products and candy, jelly) Korea

Taiwan (as food)

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

Toxicological data and Intake assessment data:

(i) Metabolic and pharmacokinetic studies

Tamarind seed polysaccharide is a dietary fiber, is not digested by human digestive enzymes.

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

The following safety studies have been conducted on the tamarind seed polysaccharide:

- Acute oral toxicity in rats and mice

No deaths or adverse clinical signs were seen in either mice or rats of either sex, and the LD50 for male and female mice and rats was >5000 mg/kg bw.

- A 28-day oral toxicity in rats

- A 13-week oral toxicity in mice

In both studies all animals survived to study termination and there were no treatment-related, toxicologically relevant changes observed at the highest level tested, which corresponds to 10,597 and 10,691 mg tamarind seed polysaccharide/kg bw/day for male and female rats, respectively, in the 28-day study; and 8,200 and 10,600 mg tamarind seed polysaccharide/kg bw/day for male and female mice, respectively, in the 13-week study.

- A 2-year feeding toxicity in rats

There was no evidence of toxicity at the highest level tested, which corresponds to 8,300 and 9,400 mg tamarind seed polysaccharide/kg bw/day in male and female rats.

- Carcinogenicity study in mice

In this 78-weeks test, there were no significant differences in the incidence of neoplastic and non- neoplastic lesions or in benign and malignant tumors between the controls and tamarind seed polysaccharide-treated animals in either sex, at the highest level tested, which corresponds to 6,658 and 8,575 mg tamarind seed polysaccharide/kg bw/day in male and female mice. These results demonstrated that tamarind seed polysaccharide is not carcinogenic with long-term dietary exposure.

- Chromosomal aberration tests using Chinese hamster lung-derived fibroblast cells

- Ames assay using Salmonella typhimurium strains TA98, TA100, TA1535 and TA1537, and

Escherichia coli strain WP2 uvrA

- A DNA repair test (Rec assay) Bacillus subtilis strains H17 and M45 – unpublished

Tamarind seed polysaccharide is neither mutagenic nor genotoxic.

(iii) Epidemiological and/or clinical studies and special considerations Not applicable

(iv) Other data

None

Technological data;

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

Heavy metals	Not more than 10 µg/g as Pb
Lead	Not more than 10 µg/g as Pb
Arsenic	Not more than 4.0 µg/g as As2O3
Protein	Not more than 3.0%
Loss on Drying	Not more than 14.0%
Ash	Not more than 5.0%
Total bacterial count	Not more than 10,000/g
Escherichia coli	Negative

(8th Edition The Japan's Specifications and Standards for Food Additives)

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

If lumps are formed after adding tamarind seed polysaccharide to water or aqueous solutions, it will not fulfill its function. Tamarind seed polysaccharide should be fully dispersed or dissolved by adding it bit by bit to as large a volume of water as possible while agitating at high speed. If tamarind seed polysaccharide is mixed, beforehand, with about 5 times its volume of sugar, dextrin, alcohol, or oil and add the mixture to water or aqueous solutions, it will be dispersed or dissolved more smoothly.

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

1. Ice cream – up to 0.3%

2. Sauces and condiments – up to 1.0% (especially, up to 1.5% for thicken sauce)

3. Mayonnaise and dressings – up to 1.0%

4. Fruit preserves – up to 1.0%

5. Desserts – up to 0.2%

6. Beverages – up to 0.2%

7. Pickles – up to 1.0%

8. Tsukudani – up to 1.0%

9. Spreads and fillings – up to 0.5%

10. Flour products – up to 0.5%

11. Soups – up to 0.2%

12. All other food categories – up to 0.5%

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

Based on data from the food consumption records section of the National Health and Examination Surveys conducted between 2003 and 2006, the dietary exposure to tamarind seed polysaccharide from all intended food uses for persons older than 2 years was estimated. The estimated mean and 90th percentile daily exposures to tamarind seed polysaccharide are 2,600 and 4,400 mg, respectively. Expressed in terms of bodyweight, the estimated mean and 90th percentile daily exposures are 45 and 91 mg/kg body weight (bw), respectively.

Other information as necessary:

None

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

Until December 2015

NORWAY

Norway would like to provide information on Codex Circular Letter CL 2014/13-FA with regard to dietary exposure from benzoates as requested in Annex 3 of the CL 2014/13-FA:

«The Norwegian Scientific Committee for Food Safety (VKM) has on request from the Norwegian Food Safety Authority conducted a risk assessment of various intense sweeteners and the preservative benzoic acid from soft drinks, "saft", nectar and flavoured water in Norway. In this risk assessment, the intake of intense sweeteners and benzoic acid is evaluated from beverages divided in the categories soft drinks, “saft”, nectar and flavoured water, based on data from 2012 received from the Norwegian industry in October 2013. The calculated exposures of sweeteners from beverages are based on data from the national food consumption surveys Småbarnskost 2007 (Kristiansen et al., 2009) and Norkost 3 (Totland et al., 2012). Due to lack of new dietary surveys, the other age groups of children and adolescents were excluded. The calculated exposures were compared to the acceptable daily intake (ADI) for the respective sweeteners and benzoic acid.”

VKM concludes that the benzoic acid intake in 2-year-old-children is of concern as it reaches ADI for high consumers of soft drinks, “saft” and flavoured water, although the ADI is not a threshold for toxicity. For the other age groups, there is no concern related to the intake of benzoic acid from beverages. However, it should be noted that a considerable intake of benzoic acid also is expected from other sources such as food and cosmetics. High consumers of soft drinks, “saft” or flavoured water in all age groups could be at risk for approaching or exceeding ADI if the exposures from foods are taken into account.

PARAGUAY

In response to Circular Letter CL 2014/13-FA, Request for information and comments on priority list of substances proposed for evaluation by JECFA Annex 3 (Appendix XV of REP14 / FA), Paraguay welcomes the opportunity to submit comments, specifically in relation to the request made to review the JECFA specification for steviol glycosides to include rebaudioside M and rebaudioside E and to delete the requirement for stevioside and/or rebaudioside A as the primary steviol glycosides in stevia preparations.

In this regard, it is stated as follows:

Item 1. Include both, rebaudioside M and rebaudioside E in the list of nine steviol glycosides already allowed and which can contain the test value not lower than 95%

While the inclusion of these minority glycosides does not alter the profile of the extracts currently marketed, it is requested that the analytical methodology be reviewed by the Committee on Methods of Analysis and Sampling.

It is further requested that at the same time an analytical methodology be included to differentiate between glycosides from the plant and glycosides produced by enzymatic modification or synthesis by genetically modified organisms.

Item 2. Remove all parameters which implicitly indicate stevioside and rebaudioside A as the primary steviol glycosides in stevia preparations.

We do not agree to elimination of this requirement, for the following reasons:

1. There is a worldwide industrial effort to produce glycosides by sinthetic means. These glycosides are different from the expectations of consumers and food safety in the control of the final product and processing of steviol glycosides or stevia extracts originating from the *Stevia rebaudiana* Bertoni plant.

2. Steviol glycosides obtained from the leaves of *Stevia rebaudiana* Bertoni reflect the levels of steviol glycosides present in plants, especially those obtained from cultivars from breeding programmes considered Non GMO, without genetic modification, and by means of processes that do not modify the native structure of glycosides.

3. Even though it is not thought that the existent glycosides mentioned in minority percentages affect the profile of the currently marketed extracts, extracts marketed with major percentages of rebaudioside D, rebaudioside M or rebaudioside E can be obtained from synthesis processes or by enzymatic modification which differ from processes approved under the 2008 and 2010 JECFA.

Thus, it is considered that the inclusion of the percentage of these glycosides over existing native percentages in the commercial varieties of leaves, must be accompanied by a detailed analysis of the processes used for obtaining them, as well as analysing a possible new additives category, whereas it is appropriate to differentiate, towards consumers and industries, stevia extracts of natural origin from extracts originating from processes of synthesis or enzymatic modification, both by the nature of the way they are obtained and the safety risks inherent to the two different ways of obtaining them.

4. A commercial product might contain high percentages of stevioside and rebaudiosides A, because they are obtained from leaves with respectively 10% and 3% stevioside and rebaudiosides A. Likewise, in the improved varieties higher percentages of rebaudioside A can be obtained, because they are their main components.

5. In the leaves of stevia minor amounts are present in the order of 0.03% and 0.4% rebauside E and 0.01% and 0.08% rebaudioside M; therefore, the commercial products with 95% rebaudioside M could only be commercially obtained by synthesis methods, which cannot be regarded as natural products.

Finally, and taking into consideration the above arguments it is essential to establish the following proposal for classification and definition of the products, in order to clearly distinguish their nature:

a. Steviol glycosides extracted and purified from Stevia rebaudiana Bertoni, Natural Category: Product obtained from the extraction and purification, without any chemical modification, of steviol glycosides from Stevia rebaudiana Bertoni leaves.

b. Steviol glycosides chemically modified or by synthesis, Natural Identical category: Actives completely or partially synthesized from enzymatic modification of native compounds or integral synthesis in genetically modified organisms. The possibility of considering a different category for this product type should be analysed, in order to fully differentiate it from the natural extracts and to avoid misleading consumers.

References

1. Recombinant production of steviol glycosides World Patent WO 2013022989 A2.

2. Glucosylated steviol glycoside composition as a taste and flavor enhancer. World Patent WO2012128775

3. Glucosyl stevia composition. European Patent EP 2675294 A1

4. Stevia First: http://ir.steviafirst.com/press-releases/detail/544/stevia-first-corp-achieves-milestone-towards-gras

5. DSM: http://www.dsm.com/markets/foodandbeverages/en_US/informationcenter-press/2014/06/2014-06-22-dsm-announces-fermentation-based-sweetener-platform.html

6. Evolva: http://www.cargill.com/news/releases/2014/NA31656205.jsp

SOUTH AFRICA

Name of Substance(s):	Carbohydrate-Derived Fulvic Acid (CHD-FA®)
Question to be answered by JECFA	Evaluation as a food additive (preservative and anti-oxidant)

1. Proposal for inclusion submitted by:

FulviCare (PTY) Ltd
Topshell Park,
Baden Powell drive,
Stellenbosch
South Africa

2. Name of compound; trade name; chemical name

Carbohydrate-Derived Fulvic Acid - CHD-FA®

3. Name and address of basic producers:

Fulvimed SA (PTY)Ltd
Topshell 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?

Yes

5. Identification of the manufacturer that will be providing data

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 of use

Preservatives are food additives, which prevent decomposition by microbial growth and reduce the risk of foodborne infections, decrease microbial spoilage and preserve fresh attributes and nutritional quality.

Carbohydrate-Derived Fulvic Acid (CHD-FA®) is a novel, pure biologically active organic acid, is free of 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, juices, pickles, 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 compound is used as a food additive or as an ingredient, including use level(s)

The relevant GSFA food categories identified for CHD-FA® are listed in table 7.1

Table 7.1: GSFA food categories relevant for the use of CHD-FA

GSFA Main Group	GSFA Foods Codes	Description	CHD-FA® Maximum level mg/kg or L beverage/food	Fulvic Acid intake mg/ day
Alcoholic beverages	14.2.3 14.2.4 14.2.7	Wines Fruit wines Aromatized beverages	137.12mg/L	26.33mg
Soft drinks	14.1.2 14.1.3 14.1.4	Fruit and vegetable juices Fruit and Vegetable nectars Water-based flavoured drinks, eg sport, energy or electrolyte drinks	137.12mg/L 137.12mg/L	19.3mg 34.8mg
Processed fruit Processed vegetables	04.1.2.5 04.1.2.6 04.2.2.5	Jams, jellies, marmalade Fruit-based spreads Vegetable purees and spreads (peanut butter)	137.12mg/L	10.6mg 7.54mg
Cereals	06.3	Breakfast cereals; Maize	102.8mg/kg	38.7mg
Food supplement	13.4 13.4	Dietetic formulae and Meal Replacements	102.8mg/kg	5.14

8. Is the compound currently used in food that is legally traded in more than one country?

No, only in food supplements and health products.

9. List of data available:

9.1 Toxicological data

Toxicity of CHD-FA is well researched and proofed to be non-toxic and safe for oral and dermal dosage. Some of the work is noted below:

Type of Study	Conclusions
30-day Topical Trial with Balb C Mice	The data suggests that CHD-FA, when applied topically, does not produce any hypersensitivity reactions and is non-toxic with regards to liver and kidney function in mice over a one-month period.
Six-month Oral Trial with Sprague Dawley rats	The data suggests, that the product is non-toxic with regards to liver and kidney function in rats over a period of six months, when administered orally (gavage). It could be concluded therefore that the product is safe, at the dosage tested, for oral usage as indicated by the animal trials.
Three-month Oral Trial with Sprague Dawley Rats	The data suggests that CHD-FA, administered by gavage is non-toxic with regards to liver and kidney function in rats in an acute and chronic toxicity study. The product showed no toxicity effects with regards to liver and kidney functions. Post-mortem analysis of organs shows no morphological abnormalities over the periods tested. It could be concluded therefore that the product is safe, at the dosage tested, for oral usage as indicated by the animal trials.
Bacterial Mutation Assay (Ames test)	The test material was considered to be non-mutagenic under the conditions of this test

Micronucleus	It can be concluded that this study indicated no genotoxicity above normal background levels for both filtered and unfiltered CHD-FA, using concentrations of 50,100 and 150 µg/ml in an in vitro micronucleus assay
Non-Allergenic Studies	The test results outlining the data for erythema, scaling and fissure formation on a per-subject base for the test product are attached in tabulated form.

9.2 Technological data

Fulvic acid is a naturally occurring organic acid, primarily derived from the bacterial breakdown of organic material in nature. Fulvic acid binds readily to metals and toxins in the environment, contaminating natural fulvic acid thereby preventing practical use in human medicine.

Carbohydrate Derived Fulvic Acid (CHD-FA) is produced by a wet oxidation process that yields a uniform and pure product which is devoid of the contaminants that are found in environmentally derived forms. CHD-FA is produced by the oxidation of sucrose dissolved in water and has a final concentration of 4% in aqueous solution. The solution is filtered to a molecular weight of 5 000 Dalton and below.

The manufacturing plant is FSSC 22000 certified and ready for the GMP inspection.

9.3 Intake assessment data

Levels of the listed compound used in food or expected to be used in food based on technological function and the range of foods in which they are used.

Based on the dose of 0.22g/kg/bodyweight for CHD-FA liquid as ADI and 25mg/kg/per day for CHD-FA powder as ADI.

Estimation of dietary intakes are based on food consumption data for foods in which the compound may be used.

Based on the conservative calculation by means of the budget method and assuming that the daily intake of processed foods is 50% of the total food intake i.e. 0.176g/kg beverages and 80mg/kg solid foods.

10. Date on which data could be submitted to JECFA

As soon as necessary.

UNITED STATES OF AMERICA

The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 47th Session of the Codex Committee on Food Additives (CCFA).

Addition to the JECFA Priority List

The United States proposes the inclusion of 63 flavors on the JECFA Priority List, which include 3 new flavors, 21 flavors that were included on the JECFA Priority List at previous CCFA meetings, and 39 flavors for which JECFA had requested additional safety information in order to complete its review. The required information for the flavors (as prescribed in Annex 2 of CL 2014/13-FA) is attached as Appendix I to this letter. The full list of 63 flavors is also attached as Appendix II to this letter. The flavors in Appendix II are sorted by Chemical Group, and are identified as to whether they are new submissions, submissions from previous CCFA meetings, or are substances for which JECFA needed additional data to complete its safety review.

Appendix I - Required Information based on Annex 2 of CL 2014/13-FA

List of 63 flavors (comprising 3 new proposals, 21 flavors previously submitted for inclusion on the JECFA Priority List, and 39 flavors for which JECFA required additional information to complete its safety review)

1. Proposal for inclusion submitted by:

The United States

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

List of 63 flavors (See Appendix II 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 Flavour 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 in foods for human consumption

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

Natural occurrence, Food Categories and Use Levels to be submitted.

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

Yes (United Sates, European Union 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 compounds (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 compound - Yes where relevant

Intake assessment data

(i) Levels of the listed compound 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 intakes based on food consumption data for foods in which the compound may be used - Yes

Other information as necessary

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

December 01, 2015

Appendix II. List of 63 flavors for inclusion on JECFA Priority List

CCFA listing History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	CINNAMYL ALCOHOL AND RELATED SUBSTANCES				J22	TRS901
				Structural Class I		
Submitted at 43rd CCFA	4597		620-80-4	Ethyl alpha-acetylcinnamate		
Submitted at 43rd CCFA	4599		1205-17-0	3-(3,4-Methylenedioxyphenyl)-2-methylpropanal		
Submitted at 43rd CCFA	4598		15399-05-0	Ethyl 2-hydroxy-3-phenylpropionate		
				Structural Class III		
Submitted at 43rd CCFA	4596		4353-01-9	Cinnamaldehyde propyleneglycol acetal		
Submitted at 43rd CCFA	4595		67634-23-5	2-Phenylpropanal propyleneglycol acetal		
	ALIPHATIC SECONDARY ALCOHOLS, KETONES AND RELATED ESTERS				J37	TRS913 TRS952 TRS960
				Structural Class II		
Submitted at 43rd CCFA	4706		35194-30-0	9-Decen-2-one		
Submitted at 43rd CCFA	4691		1009814-14-5	Yuzunone		
Submitted at 45th CCFA	4732		83861-74-9	1,5-Octadien-3-ol		
Submitted at 45th CCFA	4746		68973-20-6	3,5-Undecadien-2-one		
Submitted at 45th CCFA	4775		67801-20-1	3-Methyl-5-(2,2,3-trimethylcyclopent-3-en-1-yl)pent-4-en-2-ol		
New Submission	4794		1193-81-3	(±)-Cyclohexylethanol		
	ALICYCLIC, ALICYCLIC-FUSED AND AROMATIC-FUSED RING LACTONES				J38	TRS922
				Structural Class I		
Submitted at 43rd CCFA	4438		591-11-7	beta-Angelicalactone		
				Structural Class III		
Submitted at 43rd CCFA	4140		57743-63-2	2-(2-Hydroxy-4-methyl-3-cyclohexenyl)propionic acid gamma-lactone		
Submitted at 43rd CCFA	4270		5617-64-1	2-(2-Hydroxyphenyl)cyclopropanecarboxylic acid delta-lactone		
	ALIPHATIC AND AROMATIC AMINES AND AMIDES				J58	TRS934 TRS947 TRS960 TRS 974
				Structural Class III		
Submitted at 45th CCFA	4741		851670-40-1	N1-(2,3-Dimethoxybenzyl)-N2-(2-(pyridin-2-yl)ethyl) oxalamide		

CCFA listing History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
Submitted at 45th CCFA	4751		851669-60-8	(R)-N-(1-Methoxy-4-methylpentan-2-yl)-3,4-dimethylbenzamide		
Submitted at 45th CCFA	4773		125187-30-6	(E)-N-[2-(1,3-benzodioxol-5-yl)ethyl]-3-(3,4-dimethoxyphenyl)prop-2-enamide		
New Submission	4788		1309389-73-8	(E)-3-Benzo[1,3]dioxol-5-yl-N,N-diphenyl-2-propenamide		
New Submission	4808		1582789-90-9	N-Ethyl-5-methyl-2-(methylethenyl)cyclohexanecarboxamide		
	TETRAHYDROFURAN AND FURANONE DERIVATIVES				J50	TRS 928
				Structural Class II		
Submitted at 43rd CCFA	4101		1440-67-0	2,5-Dimethyl-3(2H)-furanone		
Submitted at 43rd CCFA	4104		65330-49-6	2,5-Dimethyl-4-ethoxy-3(2H)-furanone		
				Structural Class III		
Submitted at 43rd CCFA	4176		3511-32-8	5-Methyl-3(2H)-furanone		
Submitted at 43rd CCFA	4546		39156-54-2	Ethyl 2,5-dimethyl-3-oxo-4(2H)-furyl carbonate		
Submitted at 43rd CCFA	4070		36871-78-0	4-Acetyl-2,5-dimethyl-3(2H)-furanone		
	FURAN SUBSTITUTED ALIPHATIC HYDROCARBONS, ALCOHOLS, ALDEHYDES, KETONES, CARBOXYLIC ACIDS AND RELATED ESTERS, SULFIDES, DISULFIDES AND ETHERS.				J53	TRS 934 TRS 952 TRS 974
				Structural Class II		
Old	3317	1491	3777-69-3	2-Pentylfuran		
Old	3401	1492	3777-71-7	2-Heptylfuran		
Old	4090	1493	83469-85-6	2-Decylfuran		
Old	4174	1494	15186-51-3	3-Methyl-2-(3-methylbut-2-enyl)-furan		
Old	2494	1497	623-30-3	3-(2-Furyl)acrolein		
Old	4175	1499	5555-90-8	3-(5-Methyl-2-furyl)prop-2-enal		
Old	3163	1503	1192-62-7	2-Furyl methyl ketone		
Old	3609	1504	1193-79-9	2-Acetyl-5-methylfuran		
Old	4071	1505	22940-86-9	2-Acetyl-3,5-dimethylfuran		
Old	4083	1507	4208-57-5	2-Butyrylfuran		
Old	2496	1508	6975-60-6	(2-Furyl)-2-propanone		
Old	4192	1509	3194-17-0	2-Pentanoylfuran		
Old	4120	1510	699-17-2	1-(2-Furyl)butan-3-one		
Old	2495	1511	623-15-4	4-(2-Furyl)-3-buten-2-one		
Old	2435	1513	10031-90-0	Ethyl 3-(2-furyl)propanoate		

CCFA listing History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
Old	2198	1514	105-01-1	Isobutyl 3-(2-furan)propionate		
Old	2071	1515	7779-67-1	Isoamyl 3-(2-furan)propionate		
Old	2070	1516	7779-66-0	Isoamyl 4-(2-furan)butyrate		
Old	2865	1517	7149-32-8	Phenethyl 2-furoate		
Old	3159	1520	13679-46-4	Furfuryl methyl ether		
Old	4114	1521	6270-56-0	Ethyl furfuryl ether		
Old	3337	1522	4437-22-3	Difurfuryl ether		
Old	4034	1523	55764-22-2	2,5-Dimethyl-3-furanthiol acetate		
Old	4119	1524	109537-55-5	Furfuryl 2-methyl-3-furyl disulfide		
Old	4056	1525	61295-44-1	3-[(2-Methyl-3-furyl)thio]-2-butanone		
Old	4043	1526	376595-42-5	O-Ethyl S-(2-furylmethyl)thiocarbonate		
				Structural Class III		
Old	3535	1495	3782-00-1	2,3-Dimethylbenzofuran		
Old	4095	1496	64280-32-6	2,4-Difurfurylfuran		
Old	2704	1498	874-66-8	2-Methyl-3(2-furyl)acrolein		
Old	3307	1500	31704-80-0	3-(5-Methyl-2-furyl)-butanal		
Old	2492	1501	770-27-4	2-Furfurylidene-butyraldehyde		
Old	3586	1502	65545-81-5	2-Phenyl-3-(2-furyl)prop-2-enal		
Old	3391	1506	10599-70-9	3-Acetyl-2,5-dimethylfuran		
Old	3418	1512	14360-50-0	Pentyl 2-furyl ketone		
Old	2945	1518	623-22-3	Propyl 2-furanacrylate		
Old	3970	1519	114099-96-6	2,5-Dimethyl-3-oxo-(2H)-fur-4-yl butyrate		
Old	4541	2103	53282-12-5	(E)-Ethyl 3-(2-furyl)acrylate		
Old	4540	2104	1197-40-6	di-2-Furylmethane		
Old	4543	2105	4265-25-2	2-Methylbenzofuran		

CONSEIL EUROPÉEN DE L'INDUSTRIE CHIMIQUE (CEFIC)

Name of Compound(s):	INS 339(ii) - Disodium hydrogen phosphate
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Revision of specification: The JECFA specification for disodium hydrogen phosphate requires to meet the following "Loss on Drying" test: dry at 40°C for 3h, followed by drying at 105 °C for 5h.This temperature is a good fit for the anhydrous form, but is evidently a problem for the hydrate forms of Disodium Phosphate (2-, 7- and 12-Hydrate), because not all water is removed. Note: Proposed solution at the bottom of the document.

1. Proposal for inclusion submitted by:

CEFIC - The European Phosphoric Acid & Phosphates Producers Association (PAPA)
Av. E. Van Nieuwenhuyse 4 / box 1
B - 1160 Brussels

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

disodium hydrogen phosphate; CAS#7558-79-4 (INS 339(ii))

3. Names and addresses of basic producers:

PAPA, representing the basic producers (Chemische Fabrik Budenheim KG, Prayon SA, ICL Food Specialties).
Cédric Delveaux
Av. E. van Nieuwenhuyse, 4-6, 1160 Brussels
Tel. 32-26767304
Fax. 32-26767347
e-mail:cde@cefic.be / www.cefic.org

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

Yes, as necessary.

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

PAPA on behalf of the basic producers:

Cédric Delveaux
Cefic (European Chemical Industry Council)
Av. E. van Nieuwenhuyse, 4-6, 1160 Brussels
Tel. 32-26767304
Fax. 32-26767347
e-mail:cde@cefic.be / www.cefic.org

6. Justification for use:

not applicable.

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

not applicable.

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

not applicable.

9. List of data available

Toxicological data: not applicable

(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 compounds (specifications applied during development and toxicological studies; proposed specifications for commerce)

available on request at any time

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

use 120°C instead of 105°C for the Loss on Drying

Intake assessment data: not applicable

(i) Levels of the listed compound 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 compound may be used.

Other information as necessary

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

at any time, immediately.

Applying a temperature of 105 °C, this is insufficient to remove the crystal water and thus, the corresponding assay based on the dried substance will be an out-of-specification result. A formal compliance is impossible using the JECFA method as laid down in the monograph.

In order to remove the crystal water completely, a temperature of min. 120 °C is needed.

Proposed amendments:

- Adjust the method for loss on drying to 4h at 120°C in line with the corresponding Food Chemicals Codex specification while keeping the limits.
- The monograph should indicate the CAS numbers for the hydrate forms as well: 10028-24-7 (2-hydrate); 7782-85-6 (7-hydrate); 10039-32-4 (12-hydrate).

FEDERATION OF EUROPEAN SPECIALTY FOOD INGREDIENTS INDUSTRIES (ELC)

Name of Substance(s):	INS 339(ii) - Disodium hydrogen phosphate
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	revision of specification The JECFA specification for disodium hydrogen phosphate requires to meet the following “Loss on Drying” test: dry at 40°C for 3h, followed by drying at 105 °C for 5h.This temperature is a good fit for the anhydrous form, but is evidently a problem for the hydrate forms of Disodium Phosphate (2-, 7- and 12-Hydrate), because not all water is removed.

1. Proposal for inclusion submitted by:

ELC member: Chemische Fabrik Budenheim KG

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

disodium hydrogen phosphate; CAS#7558-79-4 (INS 339(ii))

3. Names and addresses of basic producers:

Chemische Fabrik Budenheim KG – Rheinstr. 27, 55257 Budenheim (Germany)

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

Yes, as necessary.

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

Dr Thomas Janssen, Thomas.janssen@budenheim.com

6. Justification for use:

not applicable

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

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))

not applicable

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

Toxicological data: Not applicable

(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):

available on request at any time

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

use 120°C instead of 105°C for the Loss on Drying

Intake assessment data : Not applicable

(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

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

At any time, immediately.

Applying a temperature of 105 °C, this is insufficient to remove the crystal water and thus, the corresponding assay based on the dried substance will be an out-of-specification result. A formal compliance is impossible using the JECFA method as laid down in the monograph. In order to remove the crystal water completely, a temperature of min. 120 °C is needed. Proposed solution: Increase the drying temperature from 105°C to 120°C for all hydrate forms of the specification.

The monograph should indicate the CAS numbers for the hydrate forms as well: 10028-24-7 (2-hydrate); 7782-85-6 (7-hydrate); 10039-32-4 (12-hydrate)

Name of Substance(s):	Ferric orthophosphate ($FePO_4$* xH_2O)
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Establishment of specifications; Countries are starting to create their own quality criteria - Codex standards should refer to a JECFA specification with regard to trade burdens. Different ways of production need to be reflected by the specification.

1. Proposal for inclusion submitted by:

ELC member Chemische Fabrik Budenheim KG

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

CAS#10045-86-0; iron(iii)orthophosphate

3. Names and addresses of basic producers:

Chemische Fabrik Budenheim KG, Rheinstr. 27, 55257 Budenheim (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):

Dr Thomas Janssen Thomas.janssen@budenheim.com

6. Justification for use:

recommended substance for fortification of foods (e.g. CAC/GL 10-1979)

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):

Category 13: PCBF according to CAC/GL 10-1979

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 (USA; Codex)

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

Toxicological data:

(i) Metabolic and pharmacokinetic studies:

not necessary for determination of specification, but available

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

not necessary for determination of specification, but available

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

not necessary for determination of specification, but available

(iv) Other data

Technological data: can be provided on request; similar to Food Chemicals Codex specification

(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: not necessary for determination of specification - used as per advise as nutrient only.

(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

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

Immediately.

CAS numbers for the hydrate form should be included in the monograph: CAS 13463-10-0 (2-hydrate; synthetic form); 14567-75-0 (2-hydrate; natural form)

Name of Substance(s):	Ferric pyrophosphate ($Fe_4(P_2O_7)3^* xH_2O$)
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Establishment of specifications; Countries (China, Japan) have created their own quality criteria - should be harmonized with a JECFA specification with regard to trade burdens. Different ways of production need to be reflected by the specification.

1. Proposal for inclusion submitted by:

ELC member Chemische Fabrik Budenheim KG

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

CAS#10058-44-3; tetrairon tris(pyrophosphate)

3. Names and addresses of basic producers:

Chemische Fabrik Budenheim KG, Rheinstr. 27, 55257 Budenheim (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):

Dr Thomas Janssen Thomas.janssen@budenheim.com

6. Justification for use:

recommended substance for fortification of foods (e.g. CAC/GL 10-1979)

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):

Category 13: IF, FUF, PCBF, CBF, FSMP according to CAC/GL 10-1979

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; USA; Codex)

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

Toxicological data:

(i) Metabolic and pharmacokinetic studies:

not necessary for determination of specification, but available

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

not necessary for determination of specification, but available

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

not necessary for determination of specification, but available

(iv) Other data

Technological data: can be provided on request; similar to Food Chemicals Codex specification

(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 : not necessary for determination of specification

(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

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

Immediately.

Name of Substance(s):	INS 339(i) -Sodium dihydrogen phosphate
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	revision of specification The JECFA specification for monosodium dihydrogen phosphate requires to meet the following "Loss on Drying" test: dry at 60°C for 1h, followed by drying at 105 °C for 4h.This temperature is a good fit for the anhydrous form, but is evidently a problem for the hydrate forms of monosodium phosphate (1- and 2-Hydrate), because not all water is removed.

1. Proposal for inclusion submitted by:

ELC member Chemische Fabrik Budenheim KG

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

sodium dihydrogen phosphate; CAS#7558-80-7 (INS 339(i))

3. Names and addresses of basic producers:

Chemische Fabrik Budenheim KG, Rheinstr. 27, 55257 Budenheim (Germany)

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

yes, as necessary.

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

Dr Thomas Janssen, Thomas.janssen@budenheim.com

6. Justification for use:

not applicable

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

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))

not applicable

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

Toxicological data: not applicable

(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)

available on request at any time

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

use 120°C instead of 105°C for the Loss on Drying

Intake assessment data : not applicable

(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

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

Applying a temperature of 105 °C, this is insufficient to remove the crystal water and thus, the corresponding assay based on the dried substance will be an out-of-specification result. A formal compliance is impossible using the JECFA method as laid down in the monograph. In order to remove the crystal water completely, a temperature of min. 120 °C is needed. Proposed solution: Increase the drying temperature from 105°C to 120°C for all hydrate forms of the specification.

The CAS numbers of the hydrate forms should be indicated in the monograph as well: 10049-21-5 (1-hydrate); 13472-35-0 (2-hydrate)

FOODDRINKEUROPE

Name of Substance(s):	Carotenes from *Dunaliella salina*
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Safety assessment including establishment of an ADI and revision of specification.

1. Proposal for inclusion submitted by:

Germany

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

Carotenes from *Dunaliella salina*; Natural beta-carotene; Carotenes-natural; Algal carotenes; CI Food Orange 5; INS No. 160a(iv);

3. Names and addresses of basic producers:

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):

Dr. Bernd Haber
Director Regulatory Affairs / Human Nutrition, BASF SE
Phone: +49 621 60-28787
Fax: +49 621 60-6628787
E-Mail: bernd.haber@basf.com

6. Justification for use:

Alternative source of carotenoids 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 carotenoids INS 160a (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 natural carotene source in the EU and other countries

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

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 160a (i)-(iii)

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

Comparable to INS 160a (i)-(iii)

Other information as necessary

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

December 2015

Name of Substance(s):	Riboflavin from *Ashbya gossypii*
Question(s) to be answered by JECFA *(kindly 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:

Germany

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:

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):

Dr. Bernd Haber
Director Regulatory Affairs / Human Nutrition, BASF SE
Phone: +49 621 60-28787
Fax: +49 621 60-6628787
E-Mail: bernd.haber@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)

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

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

December 2015

INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURES (IACM)

Name of Substance(s):	Gum Ghatti
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	JECFA evaluated gum ghatti in 1986 (26th Meeting) and then again at its 29th Meeting (TRS 733). No ADI due to insufficient data; reason given for lack of toxicological data is that this and similar materials are produced in developing countries where testing is not done or resources for testing are not available; JECFA called for international organizations to assist these countries in generating the information needed. Despite structural similarity to other gums, e.g. Gum arabic, that are used with “ADI not specified” the committee considered available data insufficient to complete an evaluation or a toxicological monograph, but specs were maintained as tentative.

1. Proposal for inclusion submitted by:

International Association of Color Manufacturers

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

Gum Ghatti

3. Names and addresses of basic producers:

A basic producer is:

Krystal Colloids PCT Ltd
Gala no. 9 & 10, Nahur Village Road
Mulund West
Mumbai
400080
India

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

IACM or its member companies can provide the available published data in a submission dossier.

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

IACM contact is Sarah Codrea, Executive Director, IACM, 1101 17th St NW, Suite 700 Washington DC 20036

6. Justification for use:

Used as an emulsifier, in a manner similar to gum arabic

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):

Gum Ghatti is not currently listed within the GSFA.

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))

Gum Ghatti is approved for use in the United States (21 cfr 184.1333) and in Japan, among other countries, and is used in foods in those countries

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

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

In vitro and in vivo genotoxicity studies as well as two OECD-compliant 90-day toxicity studies have been published:

Hobbs CA, Swartz C, Maronpot R, Davis J, Recio L, Hayashi SM. 2012. Evaluation of the genotoxicity of the food additive, gum ghatti. Food Chem Toxicol. 50:854-60.

Maronpot, RR, Davis J, Moser G, Giri DK, Hayashi SM. 2013. Evaluation of 90-day oral rat toxicity studies on the food additive, gum ghatti. Food Chem Toxicol. 51:215-224.

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

(ii) 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)

A tentative specification was maintained at JECFA, but a recent publication provides additional information (Sakai et al., 2012, J. Natural Medicines of the Japanese Society of Pharmacognosy). Some characterization information was also published in 2009 by Kaur et al. (Journal of Food Science)

(i) 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

Data for this will be provided.

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

Data for this will be provided.

Other information as necessary

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

IACM or its member companies can provide this data by December 2015.

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

INFORMATION ON CAROB BEAN GUM (410) REQUESTED FOR JECFA EVALUATION FOR USE IN INFANT FORMULA AND FORMULAE FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

1. Proposal for inclusion submitted by:

International Special Dietary Foods Industries (ISDI)

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

Locust bean gum, carob bean gum, galactomannan polysaccharide

Trade name is Locust bean gum, carob bean gum

INS No. 410; CAS 9000-40-2, Einecs 232-541-5, E 410

3. Names and addresses of basic producers:

Danone Nutricia Early Life Nutrition BV
WTC Schiphol Airport Tower E
Schiphol Boulevard 105
1118 BG Schiphol Airport
The Netherlands

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):

Gavino Pericu
Manager, Global Regulatory Affairs
Danone Nutricia Early Life Nutrition
WTC Schiphol Airport Tower E
Schiphol Boulevard 105
1118 BG Schiphol Airport
The Netherlands
Phone: +31 20 456 9000
Fax: +31 20 456 8000
E-mail: gavino.pericu@danone.com

6. Justification for use:

Locust bean gum (LBG) is a galactomannan polysaccharide used as thickener in infant formulae, follow-on formulae and formulae for special medical purposes (FSMP) for infants with the therapeutic aim to treat uncomplicated gastro-oesophageal reflux (GER). Regurgitation is a characteristic symptom of uncomplicated gastro-oesophageal reflux (GER) occurring in infants and usually starts at 2–3 weeks of age. In the context of persistent GER, dietary interventions employing thickening agents or thickened infant formulas is one of the recommended approaches to decrease the number of troublesome regurgitations. Among those thickening agents, the food additive locust bean gum (LBG) is one of the food additives/ingredients of choice to thicken infant formulas prescribed to treat GER.

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):

Proposed use is as a thickener in food category 13.1 Infant formulae, follow-on formulae and formulae for special medical purposes for infants. Proposed use levels are 1 g/100 ml in ready-to-feed liquid formulae. The maximum use level of locust bean gum in formula is therefore up to 10 g/litre, as consumed.

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))

Locust bean gum (INS 410) is permitted for use in infant formulae, follow-on formulae and FSMP for infants in several countries, as described hereafter. AR formulas with an average LBG level of up to 0.5 g/100 ml and intended for infants from birth onwards are on the market world-wide in at least 60 countries.

In the EU, locust bean gum is permitted up to 1 g/100 mL (10 g/L) in FMSP for infants and processed cereal-based foods and baby foods for infants and young children. In Russia, LBG is allowed as in the EU (CU Regulation 029/2012).

In the US, LBG could be used in infant formulas as a stabilizer and thickener at a level not exceeding 5 g/L.

In China, the food safety standard on additives (GB 2760-2011) allows an LBG level for infant and young children formulae up to 0.7 g/100 ml (7 g/L)

In Australia and New Zealand, LBG is authorized up to 0.1 g/100 mL in infant formula and up to 1 g/100 g in food for infants (FSANZ, 2013).

In Korea, the use of LBG in infant formulae and follow-on formulae is authorized according to the Quantum Satis principle meaning the lowest level to achieve the technological function.

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

Toxicological data

√ (i) Digestibility, ADME

√ (ii) Acute, sub-acute, subchronic and chronic

√ (iii) Reproductive toxicity and teratogenicity

√ (iv) Genotoxicity, carcinogenicity

√ (v) Clinical data and epidemiological

√ (vi) Nutritional studies

√ (vii) Analytical methods

Technological data

√ (i) Specifications for the identity and purity of the listed compounds (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 compound.

Intake assessment data

√ (i) Levels of the listed compound 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 reference consumption data for food categories in which the compound may be used

Other information as necessary

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

December 1st, 2015

INFORMATION ON GELLAN GUM (INS 418) REQUESTED FOR JECFA EVALUATION FOR USE IN INFANT FORMULA AND FORMULAE FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

1. Proposal for inclusion submitted by:

International Special Dietary Foods Industries (ISDI)

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

Gellan Gum; trade name is Keltrol ®,Kelcogel®; IUPAC Name is Gelatin , INS No. 418; CAS#: 71010-52-1; E275-117-5

3. Names and addresses of basic producers:

Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA

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):

Brinda Mahadevan, Ph.D
Manager, Regulatory Affairs
Abbott Nutrition
3300 Stelzer Road
Columbus OH 43219, USA Phone: 614-624-3089
Fax: 614-727-6245
E-mail: brinda.mahadevan@abbott.com

6. Justification for use:

Gellan gum acts as a stabilizer in ready-to-feed infant formula, or concentrated liquid products to improve physical stability through mechanisms such as maintaining homogeneity or minimizing ingredient sedimentation. Gellan gum helps to keep minerals such as calcium and phosphorus in suspension and prevents physical separation of the product.

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):

Proposed for use as a stabilizer up to 100 mg/kg, as consumed, in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants

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))

Gellan gum is an approved food additive in the US. It's an approved additive for specific categories in Canada and is recognized by EU and Codex in other categories.

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

Toxicological data

√ (i) Metabolic and pharmacokinetic studies

√ (ii) Short-term toxicity

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

√ (iv) Other data

Technological data

√ (i) Specifications for the identity and purity of the listed compounds (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 compound

Intake assessment data

√ (i) Levels of the listed compound 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 compound may be used

Other information as necessary

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

December 20, 2016

INFORMATION ON SUCROSE ESTERS OF FATTY ACIDS (INS 473) REQUESTED FOR JECFA EVALUATION FOR USE IN INFANT FORMULA AND FORMULAE FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

1. Proposal for inclusion submitted by:

International Special Dietary Foods Industries (ISDI)

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

Sucrose fatty acid esters, Sucrose esters of fatty acids, Sucrose esters, Sugar Ester, mono-, di-, and tri-ester of sucrose with edible fatty acids

INS No. 473; E 473

3. Names and addresses of basic producers:

Danone Trading Medical BV
WTC Schiphol Airport Tower E
Schiphol Boulevard 105
1118 BG Schiphol Airport
The Netherlands

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):

Aaron O'Sullivan
Manager, Global Regulatory Affairs
Danone Medical Nutrition
WTC Schiphol Airport Tower E
Schiphol Boulevard 105
1118 BG Schiphol Airport
The Netherlands
Phone: +31 20 456 9000
Fax: +31 20 456 8000
E-mail: aaron.osullivan@nutricia.com

6. Justification for use:

Sucrose fatty acid esters can be used as an emulsifier in infant formula, follow on formula and in infant FSMP formula manufactured with amino acids and hydrolyzed proteins. Formulations manufactured with amino acids and hydrolyzed proteins have different hydrophobic/hydrophilic characteristics and lower emuslifying capacity than products based on whole protein. Sucrose fatty acid esters used alone or in combination with other stabilizers and emulsifiers improve the stability and organoleptic properties of products containing (partially) hydrolysed proteins, peptides or amino acids. Emulsifiers are therefore a technological requirement for these formulas to ensure both palatability and prevention of separation of the formula after reconstitution.

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):

Proposed use is as an emulsifier in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants. Proposed use levels are 0.012g/100 ml in infant formula powder, as consumed. The maximum use level of Sucrose fatty acid esters in formula is therefore up to 0.12 g/litre, as consumed.

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))

Sucrose fatty acid esters (INS 473) is permitted and currently has some limited use in infant formula, and FSMP intended for infants in several countries, as described hereafter. The emulsifier has a long history of use. In particular, the Scientific Committee for Food (43rd Series, 1998) concluded that the use of INS 473 was acceptable in FSMPs. Since that time has a safe history of use in infant FSMPs intended for infants with inborn errors of metabolism. In the USA, INS 473 is permitted Infant Formulas (including exempted-formulas). In Russia INS 473 is permitted in infant formulas for special medical purposes. Other countries are understood to have granted permission to commercialize formulas for infants with E473 in a specialized.

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

Toxicological data

√ (i) Metabolic

√ (ii) Short-term toxicity

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

√ (iv) Other data

√ analytical methodology

Technological data

√ (i) Specifications for the identity and purity of the listed compounds (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 compound.

Intake assessment data

√ (i) Levels of the listed compound 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 compound may be used.

Other information as necessary

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

December 1st, 2016

INFORMATION ON XANTHAN GUM (INS 415) REQUESTED FOR JECFA EVALUATION FOR USE IN INFANT FORMULA AND FORMULAE FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

1. Proposal for inclusion submitted by:

International Special Dietary Foods Industries (ISDI)

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

Xanthan Gum; trade name is NovaXan ™, Grinsted ™; IUPAC Name is 9H-xanthene. INS No. 415; CAS#: 11138-66-2; E415

3. Names and addresses of basic producers:

Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA

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):

Brinda Mahadevan, Ph.D
Manager, Regulatory Affairs
Abbott Nutrition

3300 Stelzer Road
Columbus OH 43219, USA Phone: 614-624-3089
Fax: 614-727-6245
E-mail: brinda.mahadevan@abbott.com

6. Justification for use:

Xanthan gum is an ingredient used to increase the thickness (viscosity) of infant formulas that use partially or extensively hydrolyzed protein to improve the physical characteristics of the formula. Xanthan gum serves as an emulsion stabilizer as well as stabilizing mineral suspensions.

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):

Proposed for use as a thickener up to 750 mg/kg, as consumed, in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants

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))

Xanthan gum is permitted in infant formula in the USA, Canada and Russia, and is permitted for use in formula for special medical purposes in the EU.

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

Toxicological data

√ (i) Metabolic and pharmacokinetic studies

√ (ii) Short-term toxicity

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

- (iv) Other data

Technological data

√ (i) Specifications for the identity and purity of the listed compounds (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 compound

Intake assessment data

√ (i) Levels of the listed compound 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 compound may be used

Other information as necessary

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

December 21st, 2015