



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 8 (a)

CX/FA 13/45/16

January 2013

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fifth Session

Beijing, China 18-22 March 2013

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

(Replies to CL 2012/8-FA)

The following comments have been received from the following Codex members and observers

European Union, Iran, Japan, United States of America, CEFIC and ISDI

EUROPEAN UNION

I.) The European Union is proposing to add the following compounds to the priority list of compounds to be proposed for evaluation by JECFA:

- 1) Beta-glucanase and xylanase from *Disporotrichum dimorphosporum*
- 2) Beta-glucanase, cellulase and xylanase from *Talaromyces emersonii*
- 3) Tagetes extract
- 4) Poyvinyl alcohol (PVA)-poyethylene glycol (PEG) graft co-polymer.

The forms containing information on the compounds to be evaluated by JECFA are attached.

II.) Furthermore, the European Union would like to propose an amendment to the JECFA specifications of "gellan gum" (INS 418) to reflect the current practices relating to the use of ethanol in the manufacturing process of INS 418.

The European Union would like to kindly request JECFA to update the specifications for INS 418 gellan gum to permit the use of ethanol in the manufacturing process as an alternative to isopropyl alcohol. Ethanol is already in use for this purpose in the EU and the EU's specifications were updated accordingly. Moreover, ethanol is considered to be of less safety concern.

Please see the proposed amendment in track changes below:

DEFINITION Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by *Pseudomonas elodea*, purified by recovery with isopropyl alcohol or ethanol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucose units, and is substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically-linked esters. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. It usually contains a small amount of nitrogen containing compounds resulting from the fermentation procedures.

Appendix I GSC CODEX MESSAGE CCFA 45/2013/29

FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Compound(s):	Beta-glucanase and xylanase from <i>Disporotrichum dimorphosporum</i>
Question(s) to be answered by JECFA <i>(kindly provide a brief justification of the request in case of re-evaluations)</i>	Safety evaluation when used as processing aid.

1. Proposal for inclusion submitted by:**Ministry of Health, Welfare and Sport**

Nutrition, Health Protection and Prevention Department
Parnassusplein 5
2511 VX The Hague
P.O. box 20350
2500 EJ The Hague
The Netherlands
Tel: +31 703407132

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

Name of compound : Beta-glucanase and xylanase from *Disporotrichum dimorphosporum*
Trade names : FILTRASE BR and BREWERS FLOW
Chemical names : endo-1,3(4)- β -glucanase (EC 3.2.1.6)
endo-1,4- β -xylanase (EC 3.2.1.8)

3. Names and addresses of basic producers:

DSM Food Specialties
15 Rue des Comtesses
PO Box 239
59472 Seclin Cédex
France
Tel: 33 320964545
Fax: 33 320964500

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 Jack Reuvers
Regulatory Affairs
DSM Food Specialties
PO Box 1
2600 MA Delft
The Netherlands
Tel: 31 15279
Fax: 31 152793614
E-mail: J.Reuvers@dsm.com

6. Justification for use:

The enzyme preparation is used in beer brewing and other fermented beverages to hydrolyse beta-glucans, pentosans, and other gums. This reduces the viscosity of the solution and thereby increases the filtration rate of both wort and beer, and haze is avoided.

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 enzyme preparation is used as processing aid in beer brewing and other fermented beverages in accordance with current Good Manufacturing Practice (cGMP). The dosage of the enzyme varies between 3 and 25 mg Total Organic Solids (TOS)/kg malted barley, depending on the specific application.

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 enzyme preparation containing beta-glucanase and xylanase derived from *Disporotrichum dimorphosporum* is authorized in the following countries:

- Australia : Food Standard 1.3.3 on Processing Aids
- Brazil : Dairio Oficial 2009
- China : Hygiene Standard for Uses of Food Additives, GB 2760-2011

- France : Order 5.9.89, Annex, (Arrete September 5, 1989, Annex 1C)

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

The production organism is from a safe strain as described in the decision tree in Pariza and Johnson, 2001¹. However, to accommodate various registration requirements in different countries world-wide, a full toxicity program for food enzymes has been performed according to the SCF guidelines for the evaluation of food enzymes².

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

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)
- Human lymphocyte cytogenetic assay (*in vitro* micronucleus test)
- 13 weeks oral toxicity study in rats

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

The enzyme from *Disporotrichum dimorphosporum* shows no mutagenic and clastogenic activity.

13 weeks oral administration of the enzyme to rats did not cause in dose related findings. Therefore, the highest dose administered, 199 mg TOS/kg body weight/day, is considered as the NOAEL.

(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)

The product conforms to the General Specifications and Considerations for Enzyme Preparations Used in Food Processing as prepared by the Joint FAO/WHO Expert Committee on Food Additives at its sixty-seventh meeting for publication in FAO JECFA Monographs 3 (2006) and to the acceptance criteria, impurity limits, other test and other requirements for enzyme preparations listed in the Food Chemicals Codex, 7th edition.

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

The enzyme preparation from *Disporotrichum dimorphosporum* will be used as processing aid in the manufacture of beer and other fermented beverages. The function of the enzymes present in the preparation takes place in the malting process step during the early stage of brewing. During the wort boiling step in the beer production process, the enzyme activity is lost. No residual enzyme activity remains in the final product after brewing. The use of the enzyme preparation as processing aid has no influence on the nutritional properties of the final product.

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

Based on the dose of 3-35 mg TOS/kg barley, and the fact that 1 kg barley results in 5 L beer, the amount of TOS in the final product will be 0.6-7 mg TOS/L beer.

¹ Pariza MW, Johnson EA; Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century; Regul Toxicol Pharmacol 2001 Apr;33(2):173-86.

² Opinion expressed by the Scientific Committee for Food on 11 April 1991, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_27.pdf.

- (ii) Estimation of dietary intakes 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 beer and/or fermented beverage is comparable with the amount of soft drinks, i.e. 0.025 L/kg bw/day, the daily intake will be 0.015 – 0.175 mg TOS/kg bw/day.

Other information as necessary

None

10. Date on which data could be submitted to JECFA

As soon as necessary.

Appendix II GSC CODEX MESSAGE CCFA45/2013/29

FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Compound(s):	Beta-glucanase, cellulase and xylanase from <i>Talaromyces emersonii</i>
Question(s) to be answered by JECFA <i>(kindly provide a brief justification of the request in case of re-evaluations)</i>	Safety evaluation when used as processing aid.

1. Proposal for inclusion submitted by:

Ministry of Health, Welfare and Sport

Nutrition, Health Protection and Prevention Department
Parnassusplein 5
2511 VX The Hague
P.O. ox 20350
2500 EJ The Hague
The Netherlands
Tel: +31 703407132

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

Name of compound : Beta-glucanase, cellulase and xylanase from *Talaromyces emersonii*
Trade names : FILTRASE NL, FILTRASE BR-X, FILTRASE NLC, FILTRASE BXC and BREWERS COMPASS
Chemical names : endo-1,3(4)- β -glucanase (EC 3.2.1.6)
cellulase (EC 3.2.1.4)
endo-1,4- β -xylanase (EC 3.2.1.8)

3. Names and addresses of basic producers:

DSM Food Specialties
15 Rue des Comtesses
PO Box 239
59472 Seclin Cédex
France
Tel: 33 320964545
Fax: 33 320964500

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 Jack Reuvers
Regulatory Affairs
DSM Food Specialties
PO Box 1
2600 MA Delft
The Netherlands
Tel: 31 15279
Fax: 31 152793614
E-mail: J.Reuvers@dsm.com

6. Justification for use:

The enzyme preparation is used in beer brewing and in other fermented beverages to hydrolyse beta-glucans, pentosans, and other gums. This reduces the viscosity of the solution and thereby increases the filtration rate of both wort and beer, and haze is avoided.

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 enzyme preparation is used as processing aid in beer brewing and other fermented beverages in accordance with current Good Manufacturing Practice (cGMP). The dosage of the enzyme varies between 0.58 and 23 mg Total Organic Solids (TOS)/kg malted barley, depending on the specific application.

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 enzyme preparation containing beta-glucanases and xylanase derived from *Talaromyces emersonii* is authorized in the following countries:

- France : Arrete 2006
- United Kingdom : Ministry Agriculture, Fisheries and Food FAC/REP/35, 1982
- Australia : Food Standard 1.3.3 on Processing Aids
- Brazil : Dairio Oficial 2009
- China : Hygiene Standard for Uses of Food Additives, GB 2760-2011

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

The production organism is from a safe strain as described in the decision tree in Pariza and Johnson, 2001³. However, to accommodate various registration requirements in different countries world-wide, a full toxicity program for food enzymes has been performed according to the SCF guidelines for the evaluation of food enzymes⁴.

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

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)
- Human lymphocyte cytogenetic assay (*in vitro* micronucleus test)
- 13 weeks oral toxicity study in rats

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

³ Pariza MW, Johnson EA; Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century; Regul Toxicol Pharmacol 2001 Apr;33(2):173-86.

⁴ Opinion expressed by the Scientific Committee for Food on 11 April 1991, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_27.pdf.

The enzyme from *Talaromyces emersonii* shows no mutagenic and clastogenic activity.

13 weeks oral administration of the enzyme to rats did not cause in dose related findings. Therefore, the highest dose administered, 85 mg TOS/kg body weight/day, is considered as the NOAEL.

(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)

The product conforms to the General Specifications and Considerations for Enzyme Preparations Used in Food Processing as prepared by the Joint FAO/WHO Expert Committee on Food Additives at its sixty-seventh meeting for publication in FAO JECFA Monographs 3 (2006) and to the acceptance criteria, impurity limits, other test and other requirements for enzyme preparations listed in the Food Chemicals Codex, 7th edition.

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

The enzyme preparation from *Talaromyces emersonii* will be used as processing aid in the manufacture of beer and other fermented beverages. The action of the enzymes present in the preparation takes place in the malting process step in the early stage of brewing. During the wort boiling step in the beer production process, the enzyme activity is lost. No residual enzyme activity remains in the final product after brewing. The use of the enzyme preparation as processing aid has no influence on the nutritional properties of the final product.

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

Based on the dose of 0.58 – 23 mg TOS/kg barley, and the fact that 1 kg barley results in 5 L beer, the amount of TOS in the final product will be 0.12 – 4.6 mg TOS/L beer.

(ii) Estimation of dietary intakes 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 beer and/or fermented beverage is comparable with the amount of soft drinks, i.e. 0.025 L/kg bw/day, the daily intake will be 0.003 – 0.12 mg TOS/kg bw/day.

Other information as necessary

None

10. Date on which data could be submitted to JECFA

As soon as necessary.

Appendix III GSC CODEX MESSAGE CCFA45/2013/29

FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Compound(s):	Tagetes extract
Question(s) to be answered by JECFA (kindly provide a brief justification of the request in case of re-evaluations)	Safety assessment including establishing of an ADI and revision of specification

1. Proposal for inclusion submitted by:

Germany

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

Tagetes extract; Xangold®; Lutein ester; Xanthophylls; Mixed carotenoids; INS 161b(ii)

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):**Brigitte Grothe**

Senior Manager Global Regulatory Affairs / Human Nutrition, BASF SE

Phone: +49 621 60-44322

Fax: +49 621 60-6644322

E-Mail: brigitte.grothe@basf.com

6. Justification for use:

Alternative source of lutein for colouring purposes.

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):

Same categories as lutein INS 161b(i).

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))

Permitted as food colour in the EU (Dir. 94/36/EC and Reg. (EC) No. 1333/2008)

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

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

Available

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

Available

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

Comparable to Lutein INS 161b(i)

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

Comparable to Lutein INS 161b(i)

Other information as necessary**10. Date on which data could be submitted to JECFA:**

Immediately

Appendix IV GSC CODEX MESSAGE CCFA45/2013/29**FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED**

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Compound(s):	Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer
Question(s) to be answered by JECFA <i>(kindly provide a brief justification of the request in case of re-evaluations)</i>	Safety assessment and establishing of specification and INS number

1. Proposal for inclusion submitted by:

Germany

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

Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer; Kollicoat® IR; Polyvinyl alcohol-polyethylene glycol-graft-co-polymer

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):**Brigitte Grothe**

Senior Manager Global Regulatory Affairs / Human Nutrition, BASF SE

Phone: +49 621 60-44322

Fax: +49 621 60-6644322

E-Mail: brigitte.grothe@basf.com

6. Justification for use:

PVA-PEG graft co-polymer is used mainly for the production of instant-release coatings for food supplements tablets/capsules. The special advantages of PVA-PEG graft co-polymer lies in its enormous flexibility, low viscosity and rapid rate of dissolution.

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):

PVA-PEG graft co-polymer-based film coating formulations are applied to food supplement tablets/capsules. PVA-PEG graft co-polymer may constitute up to 5.0% of the weight of the tablet/capsule.

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))

PVA-PEG graft co-polymer is applied for use in food supplements in the European Union; decision is pending. Furthermore PVA-PEG graft co-polymer is world-wide used in several pharmaceutical applications at comparable use concentrations.

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

(i) Metabolic and pharmacokinetic studies

Study of the Bioavailability after Oral Administration in Rats (BASF 2001)

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

Prenatal Development Toxicity Study in Wistar Rats Oral Administration (Gavage) (BASF 2002),
Salmonella Typhimurium / Escherichia Coli Reverse Mutation Assay (Standard Plate Test and Preincubation Test) (BASF 2000),

In Vitro Gene Mutation Test in L5178Y Mouse Lymphoma Cells (TK+/- Locus Assay, Microwell Version) (BASF 2000),

Cytogenetic Study in Vivo in the Mouse Micronucleus Test After Two Intraperitoneal Administrations (BASF 2001),

Chronic Oral Toxicity in Beagle Dogs Administration in the Diet for 9 Months (BASF 2002),

Subchronic Toxicity in Wistar Rats Administration in Drinking Water for 3 Months (BASF 2001)

Prenatal Developmental Toxicity Study in Himalayan Rabbits Oral Administration (Gavage) (BASF 2002),

Fertility and Pre-/ Postnatal Developmental Toxicity Study in Wistar Rats Oral Administration (Gavage) (BASF 2003),

Acute Oral Toxicity in Rats (BASF 2000),

Acute Dermal Irritation / Corrosion in Rabbits (BASF 2000),

Acute Eye Irritation in Rabbits (BASF 2000)

- (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

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

Available

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

Application levels in food supplements available

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

Available

Other information as necessary

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

Immediately

IRAN

Regarding the document CL 2012/8-FA, we have the following comments. Please note that we have already submitted comments and discussed on Priority list of compounds proposed for evaluation by JECFA in last year. Please kindly submit the following comments to Codex Secretariat. If anyone needs background information about this document or have question please do not hesitate to ask us.

We request the following items to be discussed in the 45th CCFA committee and if they are endorsed by the committee to be added to the form on page 3.

1. Is the compound currently banned for use in food in any country or recognized advisory body? Is there any scientific justification for this ban or in other words significant of health risk can be substantiated from any country?

In continuation to question 8 of the document- How long the product has been used?

- The method of production is relevant. Is there any other methods of production which produce the same product but the analysis require different test methods. Does one monograph can cover all of the methods?
- In continuation to Intake assessment data question (ii) if it is appropriate to add: Is there any new data available from intake assessment that suggest that this additive would significantly change the diet pattern of a country or a region?

JAPAN**FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED**

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Compound(s):	Polyoxyethylene (20) Sorbitan Monostearate, Polysorbate60
Question(s) to be answered by JECFA <i>(Kindly provide a brief justification of the request in case of re-evaluations)</i>	Revision of Specifications (Change of Saponification value and Hydroxyl value)

1. Proposal for inclusion submitted by:

JAPAN

2. Name of compound; Trade name(s); Chemical name(s):

Polyoxyethylene (20) Sorbitan Monostearate, Polysorbate60

3. Names and addresses of basic producers:

NOF Corporation
Yebisu Garden Place Tower
20-3, Ebisu 4-Chome, Shibuya-ku, Tokyo 150-6019 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):

Manufacturer: NOF Corporation

(Contact person: Toyohisa Kobayashi, General Manager, Planning & Administration Department, Oleo & Specialty Division, TEL +81-3-5795-3644, E-mail toyohisa_kobayashi@nof.co.jp)

6. Justification for use:

Emulsifier(widely used in dairy products and bakery products shown in Appendix 1)

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):

Consult Appendix 1.

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 / Polysorbate 60 is permitted and used in European Union, USA, Japan, China, Korea, etc.

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

(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):

Revision of Specifications (Change of Saponification value and Hydroxyl value)

In the specification of the Polyoxyethylene (20) Sorbitan Monostearate regulated by JECFA, the ranges of 'Hydroxyl value' and a 'Saponification value' are not harmonized with many other countries (regions) like EU, USA, Japan etc., (see Appendix 2). We would like to propose revising these specifications.

- (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, 2013

Appendix I GSFA Online Food Additive Group Details PolysorbatesAppendix II

	JECFA	JAPAN	USA	EU
Regulation No.	INS435		§172.836	E435
Assay	97.0-103.0%	-	—	≧ 97%
Oxyethylene content	65.0-69.5%	65.0-69.5%	65-69.5%	≧ 65%
Water	≧ 3%	≧ 3.0%	—	≧ 3%
Sulfated ash	≧ 0.25%	≧ 0.25%	—	-
Acid value	≧ 2	≧ 2.0	0-2	≧ 2
Saponification value	41-52	45-55	45-55	45-55
Hydroxyl value	90-107	81-96	81-96	81-96
1,4-Dioxane	≧ 10 mg/kg	≧ 10 µg/g	—	≧ 5 mg/kg
Lead	≧ 2 mg/kg	≧ 2.0 µg/g	—	≧ 2 mg/kg

GSFA Online

Updated up to the 25th Session of the Codex Alimentarius Commission (2012)

FOOD ADDITIVE GROUP DETAILS

1% POLYSORBATES

The provisions that follow are defined at the additive group level, and thus apply to the total content of the additives participating in this group. Additives that make up this group are provided for reference only.

Participating Additive(s)

INS No.	Additive Name
E122	Polyoxyethylene (20) sorbitan monooleate
E123	Polyoxyethylene (20) sorbitan monostearate
E124	Polyoxyethylene (20) sorbitan monooleate
E125	Polyoxyethylene (20) sorbitan monostearate
E126	Polyoxyethylene (20) sorbitan tristearate

GSFA Provisions for POLYSORBATES

Number	Food Category	Max Level (mg/kg)	Notes
01-0-7	Aerated alcoholic beverages (e.g., beer, wine and sparkling water-type beverages, low alcoholic infusions)	120 mg/kg	
08-0	Butters (e.g., for bread-making or butters for fish or poultry)	3,000 mg/kg	Note 2
01-3-1	Beverage whitening	4,000 mg/kg	
02-4-4	Bread-type products, including bread stuffing and bread crumbs	3,000 mg/kg	Note 11
02-1-1	Breads and rolls	3,000 mg/kg	
08-3	Cereal and starch based desserts (e.g., rice pudding, banana pudding)	3,000 mg/kg	
08-9	Chewing gum	5,000 mg/kg	
12-0-4	Clear sauces (e.g., fish sauce)	3,000 mg/kg	
03-4-3	Clotted cream (plate)	1,000 mg/kg	
05-1-4	Cocoa and chocolate products	5,000 mg/kg	Note 101
04-1-3	Cocoa mixes (spray)	500 mg/kg	
05-1-3	Cocoa-based spreads, including fillings	1,000 mg/kg	
09-3	Confectionery including hard and soft candy, wafer, etc. other than food categories 09-1, 09-2 and 09-4 (candy, excluding moist crackers)	1,000 mg/kg	
02-4-2	Cream analogues	5,000 mg/kg	Note 11
01-4	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	3,000 mg/kg	
01-1-2	Dairy-based drinks, flavoured and/or fermented (e.g., sterilized milk, curd, cottage, drinking yoghurt, whey-based drinks)	3,000 mg/kg	
03-4	Desserts (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	3,000 mg/kg	
13-3	Dietetic foods intended for special medical purposes (excluding products of food category 13-1)	4,000 mg/kg	
13-4	Dietetic formulas for slimming purposes and weight reduction	3,000 mg/kg	
14-3-0	Diluted alcoholic beverages containing more than 12% alcohol	120 mg/kg	

GSFA Online Food Additive Group Details for POLYSORBATES

08-4-2	Fried pastes and noodles and their products	3,000 mg/kg	
08-4	Edible coatings (e.g., sausage casing)	1,500 mg/kg	
03-0	Edible ice, including sherbet and sorbet	1,000 mg/kg	
10-4	Egg-based desserts (e.g., custard)	3,000 mg/kg	
12-0-1	Emulsified sauces and dips (e.g., mayonnaise, salad dressing, onion dip)	3,000 mg/kg	
02-3	Emulsions of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	3,000 mg/kg	Note 101
02-2-2	Fat spreads, dairy fat spreads and blended spreads	5,000 mg/kg	Note 102
02-4	Fat-based desserts excluding dairy-based dessert products of food category 01-7	3,000 mg/kg	Note 102
02-3	Fine bakery wares (sweet, salty, savoury) and others	3,000 mg/kg	
13-0	Food supplements	25,000 mg/kg	
04-1,2,11	Fruit fillings for pastries	3,000 mg/kg	
04-1,2,0	Fruit preparations, including pulp, puree, fruit toppings and coconut mix	1,000 mg/kg	Note 104
04-1,2,9	Fruit-based desserts, including fruit-flavoured water-based desserts	3,000 mg/kg	
13-3,1	Herbs and spices	3,000 mg/kg	
05-1,9	Imitation chocolate, chocolate substitute products	5,000 mg/kg	
02-3,3	Lard, tallow, fish oil, and other animal fats	5,000 mg/kg	Note 105
04-5,5	Milk and cream powder analogues	4,000 mg/kg	
02-1,0	Mixes for bread and ordinary bakery wares	3,000 mg/kg	Note 11
12-0,3	Mixes for sauces and gravies	5,000 mg/kg	Note 112
12-0,2	Non-emulsified sauces (e.g., hotchup, cheese sauce, cream sauce, brown gravy)	3,000 mg/kg	
02-1,3	Other ordinary bakery products (e.g., buns, pizza, English muffins)	3,000 mg/kg	Note 11
04-4,3	Pasteurized cream (plate)	1,000 mg/kg	
06-4,3	Pre-cooked pastes and noodles and their products	5,000 mg/kg	Note 109
08-3	Processed comminuted meat, poultry, and game products	5,000 mg/kg	
08-3	Processed meat, poultry, and game products in whole pieces or cuts	5,000 mg/kg	
12-7	Sauces (e.g., macaroni sauce, potato sauce) and sandwich spreads excluding cocoa- and milk-based spreads of food categories 04-2,3,9 and 02-1,3	3,000 mg/kg	
13-1,1	Salt	10 mg/kg	
12-2,2	Sauces and condiments	5,000 mg/kg	
13-0	Soups and broths	1,000 mg/kg	
02-1,0	Steamed breads and buns	3,000 mg/kg	Note 11
02-4,3	Sterilized and UHT creams, whipping and whipped creams, and cultured fat creams (plate)	1,000 mg/kg	
04-0,1	Unflavoured cream	10 mg/kg	Note 108
04-2,3,0	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and also worts, seaweed, and nuts and seed pods and preparations (e.g., vegetable flours and soups, seedbed vegetables), other than food category 04-3,3,3	3,000 mg/kg	
03-1,3	Vegetable oils and fats	5,000 mg/kg	Note 103
14-1,4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and pardalised drinks	500 mg/kg	Note 122

Note: Unless otherwise specified, food additive provisions apply to the food category indicated (e.g. Dairy), as well as to all

UNITED STATES OF AMERICA

The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 45th Session of the Codex Committee on Food Additives (CCFA).

Addition to the JECFA Priority List

The United States proposes the inclusion of 114 flavors on the JECFA Priority List, which include 39 new flavors and 75 flavors that were included on the JECFA Priority List at the 43rd CCFA. The required information for the flavors (as prescribed in Annex 2 of CL 2012/8-FA) is attached as the Appendix to this letter. The full list of 114 flavors is also attached as the Annex to this letter. The flavors in the Annex are sorted by Chemical Group, and are identified as to whether they are new submissions or were submitted at the 43rd CCFA.

Appendix - Required Information based on Annex 2 of CL 2010/10-FA**List of 114 flavors (comprising 39 new proposals and 75 flavors previously submitted for inclusion on the JECFA Priority List)****1. Proposal for inclusion submitted by:**

The United States of America

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

List of 114 flavors (See Annex A for list of chemical names)

3. Names and addresses of basic producers:

Producer contact information to be submitted. 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)
1620 I Street NW
Suite 925
Washington, DC 20006
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 (USA, EU, 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, 2013

Annex A. List of 114 flavors for inclusion on the JECFA Priority List

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	ALLYL ESTERS				J03	TRS868
	<i>Structural Class II</i>					
Submitted at 43 rd CCFA	4074		6321-45-5	Allyl valerate		
Submitted at 43 rd CCFA	4072		20474-93-5	Allyl crotonate		
	SATURATED ALIPHATIC ACYCLIC LINEAR PRIMARY ALCOHOLS, ALDEHYDES, AND ACIDS				J04	TRS884
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4432		25334-93-4	(+/-) Acetaldehyde ethyl isopropyl acetal		
Submitted at 43 rd CCFA	4335		10486-19-8	Tridecanal		
Submitted at 43 rd CCFA	4528		6986-51-2	Acetaldehyde ethyl isobutyl acetal		
Submitted at 43 rd CCFA	4336		638-53-9	Tridecanoic acid		
Submitted at 43 rd CCFA	4527		5669-09-0	Acetaldehyde di-isobutylacetal		
Submitted at 43 rd CCFA	4688		105-82-8	1-Dipropoxyethane		
Submitted at 43 rd CCFA	4334		1002-84-2	Pentadecanoic acid		
	<i>Structural Class III</i>					
Submitted at 43 rd CCFA	4010		123-63-7	Paraldehyde		

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	ALIPHATIC LACTONES				J06	TRS884 TRS960
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4673		7370-44-7	delta-Hexadecalactone		
Submitted at 43 rd CCFA	4685		7370-92-5	(±)-6-Octyltetrahydro-2H-pyran-2-one		
	ESTERS OF ALIPHATIC ACYCLIC PRIMARY ALCOHOLS WITH BRANCHED-CHAIN ALIPHATIC ACYCLIC ACIDS				J08	TRS884
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4347		850309-45-4	4-Methylpentyl isovalerate		
Submitted at 43 rd CCFA	4346		180348-60-1	5-Methylhexyl acetate		
Submitted at 43 rd CCFA	4343		25415-67-2	Ethyl 4-methylpentanoate		
Submitted at 43 rd CCFA	4344		2983-38-2	Ethyl 2-ethylbutyrate		
Submitted at 43 rd CCFA	4345		2983-37-1	Ethyl 2-ethylhexanoate		
New Submission	4749		35852-42-7	4-Methylpentyl 4-methylvalerate		
	LINEAR AND BRANCHED-CHAIN ALIPHATIC, UNSATURATED, UNCONJUGATED ALCOHOLS, ALDEHYDES, ACIDS AND RELATED ESTERS				J14	TRS891 TRS922 TRS947
	<i>Structural Class I</i>					
New Submission	4768		141-13-9	2,6,10-Trimethyl-9-undecenal		
New Submission	4735		13552-95-9	(4Z,7Z)-Trideca-4,7-dienal		
	ALIPHATIC ACYCLIC AND ALICYCLIC TERPENOID TERTIARY ALCOHOLS AND STRUCTURALLY RELATED SUBSTANCES				J15	TRS891 TRS947 TRS960
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4682		23333-91-7	Octahydro-4,8A-dimethyl-4A(2H)-naphthol		
	CARVONE AND STRUCTURALLY RELATED SUBSTANCES				J16	TRS891
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4525		929116-08-5	Pinocarvyl isobutyrate		
Submitted at 43 rd CCFA	4515		929222-96-8	Carvyl palmitate		
	<i>Structural Class II</i>					
Submitted at 43 rd CCFA	4523		51200-86-3	6-Hydroxycarvone		
	INONES AND STRUCTURALLY RELATED SUBSTANCES				J17	TRS891
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4151		79-89-0	beta-Isomethylionone		
Submitted at 43 rd CCFA	4299		141-10-6	Pseudoionone		
	<i>Structural Class II</i>					
Submitted at 43 rd CCFA	4088		24720-09-0	trans-alpha-Damascone		

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	ALIPHATIC ACYCLIC AND ALICYCLIC ALPHA-DIKETONES AND RELATED ALPHA-HYDROXYKETONES				J18	TRS891 TRS960
					<i>Structural Class II</i>	
Submitted at 43 rd CCFA	4687		544409-58-7	(±)-3-Hydroxy-3-methyl-2,4-nonanedione		
	MENTHOL AND STRUCTURALLY RELATED SUBSTANCES				J19	TRS891 TRS952
					<i>Structural Class I</i>	
Submitted at 43 rd CCFA	4509		2230-90-2	Menthyl formate		
Submitted at 43 rd CCFA	4510		86014-82-6	Menthyl propionate		
Submitted at 43 rd CCFA	4524		68366-64-3	l-Menthyl butyrate		
New Submission	4729		3623-52-7	dl-Isomentol		
					<i>Structural Class II</i>	
Submitted at 43 rd CCFA	4604		406179-71-3	Dimethyl glutarate		
					<i>Structural Class III</i>	
Submitted at 43 rd CCFA	4718		28804-53-7	(±)2-[(2-p-Menthoxy)ethoxy]ethanol		
	SIMPLE ALIPHATIC AND AROMATIC SULFIDES AND THIOLS				J20	TRS896
					<i>Structural Class I</i>	
New Submission	4760		53626-94-1	Prenyl thioisobutyrate		
New Submission	4761		75631-91-3	Prenyl thioisovalerate		
New Submission	4769		851768-51-9	5-Mercapto-5-methyl-3-hexanone		
New Submission	4734		1256932-15-6	3-(Methylthio)-decanal		
					<i>Structural Class II</i>	
New Submission	4733		1006684-20-3	(±) 2-Mercaptoheptan-4-ol		
					<i>Structural Class III</i>	
New Submission	4730		1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate		
	ALIPHATIC PRIMARY ALCOHOLS, ALDEHYDES, CARBOXYLIC ACIDS, ACETALS, AND ESTERS CONTAINING ADDITIONAL OXYGENATED FUNCTIONAL GROUPS				J21	TRS896 TRS960
					<i>Structural Class I</i>	
New Submission	4745		62439-41-2	(±)-6-Methoxy-2,6-dimethylheptanal		
Submitted at 43 rd CCFA	4719		110-15-6	Succinic acid		
New Submission	4765		1367348-37-5	Ethyl 5-formyloxydecanoate		
	CINNAMYL ALCOHOL AND RELATED SUBSTANCES				J22	TRS901
					<i>Structural Class I</i>	
Submitted at 43 rd CCFA	4597		620-80-4	Ethyl alpha-acetylcinnamate		
Submitted at 43 rd CCFA	4599		1205-17-0	3-(3,4-Methylenedioxyphenyl)-2-methylpropanal		
Submitted at 43 rd CCFA	4598		15399-05-0	Ethyl 2-hydroxy-3-phenylpropionate		
					<i>Structural Class III</i>	
Submitted at 43 rd CCFA	4596		4353-01-9	Cinnamaldehyde propyleneglycol acetal		

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
Submitted at 43 rd CCFA	4595		67634-23-5	2-Phenylpropanal propyleneglycol acetal		
PHENOL AND PHENOL DERIVATIVES					J24	TRS901 TRS960
				<i>Structural Class II</i>		
New Submission	4491		17912-87-7	Myricitrin		
				<i>Structural Class III</i>		
New Submission	4495		18916-17-1	Naringin dihydrochalcone		
New Submission	4764		50297-39-7	1-(2,4-Dihydroxyphenyl)-3-(3-hydroxy-4-methoxyphenyl)propan-1-one		
New Submission	4762		580-72-3	(-)-Matairesinol		
HYDROXY-AND ALKOXY-SUBSTITUTED BENZYL DERIVATIVES					J29	TRS909 TRS952
				<i>Structural Class I</i>		
Submitted at 43 rd CCFA	4431		99-06-9	3-Hydroxybenzoic acid		
Submitted at 43 rd CCFA	4430		99-50-3	3,4-Dihydroxybenzoic acid		
Submitted at 43 rd CCFA	4435		673-22-3	2-Hydroxy-4-methoxybenzaldehyde		
New Submission	4750		65405-77-8	cis-3-Hexenyl salicylate		
Submitted at 43 rd CCFA	4606		930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate		
Submitted at 43 rd CCFA	4700		614-60-8	o-trans-Coumaric acid		
				<i>Structural Class III</i>		
Submitted at 43 rd CCFA	4622		61683-99-6	Piperonal propyleneglycol acetal		
Submitted at 43 rd CCFA	4627		6414-32-0	Anisaldehyde propyleneglycol acetal		
ALICYCLIC PRIMARY ALCOHOLS, ALDEHYDES, ACIDS, AND RELATED ESTERS					J32	TRS913
				<i>Structural Class II</i>		
New Submission	4776		198404-98-7	(1-Methyl-2-(1,2,2-trimethylbicyclo[3.1.0]hex-3-ylmethyl)cyclopropyl)methanol		
PHENYLETHYL ALCOHOL, ALDEHYDE, ACID AND RELATED ACETALS AND ESTERS AND RELATED SUBSTANCES					J33	TRS913
				<i>Structural Class I</i>		
Submitted at 43 rd CCFA	4314		61810-55-7	Phenethyl decanoate		
Submitted at 43 rd CCFA	2860		94-47-3	Phenethyl benzoate		
Submitted at 43 rd CCFA	4625		6314-97-2	Phenylacetaldehyde diethyl acetal		
Submitted at 43 rd CCFA	4619		92729-55-0	Propyl 4-tert-butylphenylacetate		
				<i>Structural Class III</i>		
Submitted at 43 rd CCFA	4629		5468-05-3	Phenylacetaldehyde propyleneglycol acetal		
Submitted at 43 rd CCFA	4620		122-99-6	2-Phenoxyethanol		
Submitted at 43 rd CCFA	4618		23495-12-7	2-Phenoxyethyl propinate		

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	SULFUR-CONTAINING HETEROCYCLIC COMPOUNDS				J34	TRS913 TRS947
					<i>Structural Class II</i>	
New Submission	4748		54717-17-8	Triethylthialdine		
					<i>Structural Class III</i>	
New Submission	4767		67936-13-4	2-Isopropyl-4-methyl-3-thiazoline		
	ALICYCLIC KETONES, SECONDARY ALCOHOLS AND RELATED ESTERS				J36	TRS913 TRS960
					<i>Structural Class I</i>	
Submitted at 43 rd CCFA	4724		21862-63-5	trans-4-tert-Butylcyclohexanol		
New Submission	4742		917750-72-2	1-(2-Hydroxy-4-methylcyclohexyl)ethanone		
	ALIPHATIC SECONDARY ALCOHOLS, KETONES AND RELATED ESTERS				J37	TRS913 TRS952 TRS960
					<i>Structural Class II</i>	
Submitted at 43 rd CCFA	4706		35194-30-0	9-Decen-2-one		
Submitted at 43 rd CCFA	4691		1009814-14-5	Yuzunone		
New Submission	4732		83861-74-9	1,5-Octadien-3-ol		
New Submission	4746		68973-20-6	3,5-Undecadien-2-one		
New Submission	4775		67801-20-1	3-Methyl-5-(2,2,3-trimethylcyclopent-3-en-1-yl)pent-4-en-2-ol		
	ALICYCLIC, ALICYCLIC-FUSED AND AROMATIC-FUSED RING LACTONES				J38	TRS922
					<i>Structural Class I</i>	
Submitted at 43 rd CCFA	4438		591-11-7	beta-Angelicalactone		
					<i>Structural Class III</i>	
Submitted at 43 rd CCFA	4140		57743-63-2	2-(2-Hydroxy-4-methyl-3-cyclohexenyl)propionic acid gamma-lactone		
Submitted at 43 rd CCFA	4270		5617-64-1	2-(2-Hydroxyphenyl) cyclopropanecarboxylic acid delta-lactone		
	ALIPHATIC, ALICYCLIC, LINEAR, alpha,beta-UNSATURATED, DI-AND TRIENALS AND RELATED ALCOHOLS, ACIDS AND ESTERS				J39	TRS922
					<i>Structural Class II</i>	
New Submission	4747		91212-78-1	(±)-2,5-Undecadien-1-ol		
	ALIPHATIC BRANCHED-CHAIN SATURATED AND UNSATURATED ALCOHOLS, ALDEHYDES, ACIDS, AND RELATED ESTERS				J40	TRS922 TRS952
					<i>Structural Class I</i>	
Submitted at 43 rd CCFA	4486		5694-82-6	Citral glyceryl acetal		
					<i>Structural Class II</i>	
Submitted at 43 rd CCFA	4612		645-62-5	2-Ethyl-2-hexenal		
Submitted at 43 rd CCFA	4616		13019-16-4	2-Hexylidenehexanal		

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	ALIPHATIC AND AROMATIC ETHERS				J41	TRS922
	<i>Structural Class III</i>					
New Submission	4731		871465-49-5	Cassyrane		
New Submission	4759		16510-27-3	1-Cyclopropanemethyl-4-methoxybenzene		
	ALIPHATIC AND ALICYCLIC HYDROCARBONS				J45	TRS928
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4293		111-66-0	1-Octene		
Submitted at 43 rd CCFA	4292		56700-78-8	2,4-Nonadiene		
Submitted at 43 rd CCFA	4264		475-03-6	alpha-Ionene		
Submitted at 43 rd CCFA	4650		691-38-3	4-Methyl-cis-2-pentene		
Submitted at 43 rd CCFA	4651		124-11-8	1-Nonene		
Submitted at 43 rd CCFA	4652		116963-97-4	1,3,5,7-Undecatetraene		
New Submission	4311		30640-46-1; 1888-90-0	Mixture of methyl cyclohexadiene and methylene cyclohexene		
	MONOCYCLIC AND BICYCLIC SECONDARY ALCOHOLS, KETONES, AND RELATED ESTERS				J48	TRS928 TRS952
	<i>Structural Class I</i>					
Submitted at 43 rd CCFA	4521		97866-86-9	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-ol		
	<i>Structural Class II</i>					
Submitted at 43 rd CCFA	4513		21368-68-3	dl-Camphor		
Submitted at 43 rd CCFA	4519		7787-20-4	l-Fenchone		
Submitted at 43 rd CCFA	4522		97844-16-1	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-one		
	AMINO ACIDS AND RELATED SUBSTANCES				J49	TRS928
	<i>Structural Class I</i>					
New Submission	4752		1188-37-0	N-Acetyl glutamate		
New Submission	4738		16869-42-4	Glutamyl-2-aminobutyric acid		
New Submission	4739		38837-71-7	Glutamyl-norvalyl-glycine		
New Submission	4740		71133-09-0	Glutamyl-norvaline		
	TETRAHYDROFURAN AND FURANONE DERIVATIVES				J50	TRS928
	<i>Structural Class II</i>					
Submitted at 43 rd CCFA	4101		1440-67-0	2,5-Dimethyl-3(2H)-furanone		
Submitted at 43 rd CCFA	4104		65330-49-6	2,5-Dimethyl-4-ethoxy-3(2H)-furanone		
	<i>Structural Class III</i>					
Submitted at 43 rd CCFA	4176		3511-32-8	5-Methyl-3(2H)-furanone		
Submitted at 43 rd CCFA	4546		39156-54-2	Ethyl 2,5-dimethyl-3-oxo-4(2H)-furyl carbonate		
Submitted at 43 rd CCFA	4070		36871-78-0	4-Acetyl-2,5-dimethyl-3(2H)-furanone		

History	FEMA No	JECFA No	CAS	Principle Name	Group No	TRS No
	PHENYL-SUBSTITUTED ALIPHATIC ALCOHOLS AND RELATED ALDEHYDES AND ESTERS				J51	TRS928
	<i>Structural Class II</i>					
New Submission	4758		20921-04-4	Ethyl 3-(2-hydroxyphenyl)propanoate		
New Submission	4194		26643-92-5	(+/-) 2-Phenyl-4-methyl-2-hexenal		
	MALTOL AND RELATED SUBSTANCES				J52	TRS934
	<i>Structural Class II</i>					
Submitted at 43 rd CCFA	4534		852997-28-5	Ethyl maltol isobutyrate		
	MISCELLANEOUS NITROGEN-CONTAINING SUBSTANCES				J56	
	<i>Structural Class III</i>					
New Submission	4766		1160112-20-8	3-[3-(2-Isopropyl-5-methylcyclohexyl)-ureido]-butyric acid ethyl ester		
New Submission	4774		1359963-68-0	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid		
	ALIPHATIC AND AROMATIC AMINES AND AMIDES				J58	TRS934 TRS947 TRS960
	<i>Structural Class III</i>					
New Submission	4741		851670-40-1	N1-(2,3-Dimethoxybenzyl)-N2-(2-(pyridin-2-yl)ethyl) oxalamide		
New Submission	4751		851669-60-8	(R)-N-(1-Methoxy-4-methylpentan-2-yl)-3,4-dimethylbenzamide		
New Submission	4773		125187-30-6	(E)-N-[2-(1,3-benzodioxol-5-yl)ethyl]-3-(3,4-dimethoxyphenyl)prop-2-enamide		

CONSEIL EUROPÉEN DE L'INDUSTRIE CHIMIQUE (CEFC)

FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

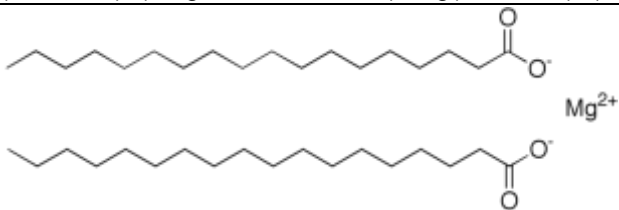
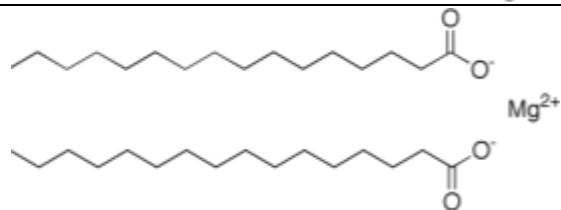
Name of Compound(s):	Magnesium stearate / INS 470(iii)
Question(s) to be answered by JECFA (kindly provide a brief justification of the request in case of re-evaluations)	Safety assessment and establishment of specifications

1. Proposal for inclusion submitted by:

CEFC - The European Oleochemicals and Allied Products Group (APAG)
Av. E. Van Nieuwenhuysse 4 / box 1
B - 1160 Brussels

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

This product is a compound of magnesium with a mixture of solid organic acids obtained from edible sources and consists chiefly of variable proportions of magnesium stearate and magnesium palmitate.

IUPAC name	Magnesium octadecanoate
Common name	Magnesium stearate
CAS number	557-04-0; 91031-63-9
EINECS number	209-150-3; 292-967-2
Other names	Magnesium distearate, Dibasic magnesium stearate, Fatty acids, C16-18 magnesium salts
Molecular mass	591.27 g/mol (magnesium stearate); 535.14 g/mol (magnesium palmitate)
Molecular formula	$Mg(C_{18}H_{35}O_2)_2$ (magnesium stearate); $Mg(C_{16}H_{31}O_2)_2$ (magnesium palmitate)
Molecular structure (magnesium stearate)	
Molecular structure (magnesium palmitate)	

3. Names and addresses of basic producers:

European Oleochemicals and Allied Products Group (APAG), representing the basic producers
 Cédric Delveaux
 Av. E. van Nieuwenhuysse, 4, 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

5. Identification of the manufacturer that will be providing data:

APAG on behalf of the basic producers:
 Baerlocher GmbH / Germany
 Faci SpA / Italy
 Peter Greven GmbH & Co. KG / Germany
 S.o.g.i.s Industria Chimica SpA / Italy
 Unión Deriván SA / Spain

6. Justification for use:

Magnesium stearate has for over 80 years been an essential technological additive for the production of food supplement and confectionery compressed tablets.

The magnesium stearate is commonly used in tablet technology as, when added to the powder before compression, it acts as a lubricant and assists in the ejection of the tablet from the punch and die. It prevents parts of the tablet sticking to the punches. This function is essential with today's high speed tablet presses as debris build-up on the punches and dies can cause serious and expensive damage. The magnesium stearate also provides a smooth surface to the tablet.

Magnesium stearate has become the additive of choice by tablet manufacturers worldwide and it has been estimated that it is used in around 70% of all food supplement tablets produced and in a similarly high percentage of confectionery tablets. Over the years, a number of alternative substances have been tried but none appears to function as effectively as magnesium stearate.

Magnesium stearate is also used as an emulsifier in rusks and baking powder. Furthermore it improves the flowability and continuity with its anti-caking effect in certain hydrophobic powdered foods (e.g. spices and herbs) to extend the shelf life of these powders.

Lubricant for tableting:	0.5-1.0 wt%
Anti cacking:	0.05-1.0 wt%
Hydrophobation:	0.05-1.0 wt%
Emulsifier:	0.05-1.0 wt%

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):

Magnesium stearate is mainly used as a food additive in the following categories:

General Standard on Food Additives / Food Category	Proposed food uses	Use level (mg/kg)
05.3: Chewing gum (05.3)	Chewing gums	5000-10'000
13.6: Food supplements (13.6)	Food supplements in the shape of tablets	500-10'000
05.2: Confectionery including hard and soft candy, nougats, etc.	Hard candies, dragees	5000-10'000
12.2.1: Herbs and spices	Spice, Herb	500-10'000
07.0: Bakery wares	Rusks, baking powder	500-10'000

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)

- **Europe:** Magnesium stearate, included in E470b – Magnesium salts of Fatty Acids, can be generally used as additive in foodstuffs (except in unprocessed foods and foods for which the use of additives is prohibited) with no specific maximum level (quantum satis) as determined by Regulation (EC) No. 1333/2008 on food additives.
- **USA:** magnesium stearate is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use: (1) The ingredient is used as a lubricant and release agent; a nutrient supplement; and a processing aid as defined (2) The ingredient is used in foods at levels not to exceed current good manufacturing practice (CFR, Title 21 I, B, Sec. 184.1440).
- **Codex Alimentarius:** "Magnesium salts of fatty acids" had been previously included in the INS number 470. An Acceptable Daily Intake for its use in food has not been allocated by the 29th meeting of JECFA since there were no food uses reported to JECFA at that time (WHO TRS 733). Their deletion from the Codex International Numbering System had been proposed at the 42nd Session of the Codex Committee on Food Additives, 2010. The International Alliance of Dietary/Food Supplement Associations (IADSA) offered technological justification for not deleting this additive and the CCFA assigned therefore the INS number 470(iii) at the 43rd Session in 2011.

Magnesium stearate is also listed in the *Inventory of Substances Used as Processing Aids*, specifically as an antifoam agent, an anticaking agent and a lubricant.

9. List of data 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

No

(iv) Other data

Yes

Salts of fatty acids have already been assessed by JECFA as well as magnesium (use limited by laxative effects) and stearate/palmitate (ADI *not specified*) separately.

All available information on magnesium, stearate and palmitate will be submitted.

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

Specifications for magnesium stearate based on Salts of Fatty Acids (33rd JECFA 1988), Magnesium Salts of Fatty Acids (E 470b, Commission Regulation (EU) Nr. 231/2012), Magnesium Stearate (Food Chemicals Codex, seventh edition) and Pharm. Eur. (07/2010:0229 corrected 7.4) will be provided.

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

Yes

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:**

November 2013

FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Compound(s):	Citric Acid / INS 330
Question(s) to be answered by JECFA <i>(kindly provide a brief justification of the request in case of re-evaluations)</i>	Revision of Oxalate test method for citric acid

1. Proposal for inclusion submitted by:

CEFIC - The European Citric Acid Manufacturers Association (ECAMA)
Av. E. Van Nieuwenhuyse 4 / box 1
B - 1160 Brussels

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

Citric Acid (INS 330)

3. Names and addresses of basic producers:

European Citric Acid Manufacturers Association (ECAMA), representing the basic producers
Marc Vermeulen
Av. E. van Nieuwenhuyse, 4, 1160 Brussels
Tel. 32-26767446
Fax. 32-26767359
e-mail: mve@cefic.be / www.cefic.org

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

Yes

5. Identification of the manufacturer that will be providing data:

European Citric Acid Manufacturers Association (ECAMA), representing the basic producers
Marc Vermeulen
Av. E. van Nieuwenhuysse, 4, 1160 Brussels
Tel. 32-26767446
Fax. 32-26767359
e-mail:mve@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

Technological data

Not applicable

Intake assessment data

Not applicable

Other information as necessary

Laboratory data with the test results using the JECFA method for oxalate testing.

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

March 2013

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)**Information on Citric Acid Esters Of Mono- and Diglycerides Of Fatty Acids (Ins 472c) 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 compound; trade name(s); chemical name(s):

Citric acid esters of mono- and diglycerides of fatty acids, citroglycerides, mono- and diglycerides of fatty acids esterified with citric acid, CITREM, CAEM;

Trade name is GRINDSTED® CITREM.

INS No. 472c; CAS# 97593-31-2.; E 472c

3. Names and addresses of basic producers (of the infant formula):

Danone Trading 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:

Citric acid esters of mono- and diglycerides of fatty acids 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 emulsifying capacity than products based on whole protein. Citric acid esters of mono- and diglycerides of fatty acids improves the stability and organoleptic properties of products containing (partially) hydrolysed proteins, peptides or amino acids.

Formulae for special medical purposes for infants may also have other ingredients, characteristics or uses that make it technologically more difficult to maintain a stable product that does not separate after reconstitution such as high medium chain triglyceride content, absence of protein or requirement to feed over a period of time by enteral tube.

A range of emulsifiers is 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 compound is used, 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 0.75 g/100 ml in infant formula powder, as consumed, and 0.9 g/100 ml in ready-to-feed liquid formula. The maximum use level of Citric acid esters of mono- and diglycerides of fatty acids in formula is therefore up to 9 g/litre, as consumed.

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 2 or more countries (please identify the countries)?

Citric acid esters of mono- and diglycerides of fatty acids (INS 472c) is permitted and currently used in infant formula, follow-on formulas and FSMP intended for infants in several countries, as described hereafter. Those countries represent a significant percentage of the infant formula commercialization markets across the globe.

Specifically in Infant Formulas (including exempted-formulas in the US) INS 472c is permitted in the USA and Canada. In the EU, Switzerland, Turkey, Mexico, Russia, Brazil and China, Citric acid esters of mono- and diglycerides of fatty acids is permitted in infant formula, follow-on formula and infant foods for special medical purposes. In Australia, Citric acid esters of mono- and diglycerides of fatty acids is permitted in infant formula products for specific dietary use based on protein substitutes.

Other countries (e.g. Chile, Singapore, Saudi Arabia and other countries in the Middle East) granted permission to commercialize formulas for infants and young children with INS 472c after a careful evaluation of justification of use and safety data.

CODEX STAN 74-1981, rev 2006, gives provisions to the use of INS 472c in processed cereal-based products for infants and young children (6months onwards) up to the limit of 0.5g/100g.

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

- √ (i) Metabolic
- √ (ii) Short-term toxicity

X (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 1, 2013