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.

<table>
<thead>
<tr>
<th>Name of Compound(s):</th>
<th>Beta-glucanase and xylanase from <em>Disporotrichum dimorphosporum</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Question(s) to be answered by JECFA (kindly provide a brief justification of the request in case of re-evaluations)</td>
<td>Safety evaluation when used as processing aid.</td>
</tr>
</tbody>
</table>
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)
end-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
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, 2001. 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.

(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.

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

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: Diario 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, 2001. 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 enzymes.

**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.

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.

<table>
<thead>
<tr>
<th>Name of Compound(s):</th>
<th>Tagetes extract</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question(s) to be answered by JECFA</strong></td>
<td>Safety assessment including establishing of an ADI and revision of specification</td>
</tr>
<tr>
<td><em>(kindly provide a brief justification of the request in case of re-evaluations)</em></td>
<td></td>
</tr>
</tbody>
</table>

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
       Available
   (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.

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

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?
2. 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?

3. 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.*

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

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

2. **Name of compound; Trade name(s); Chemical name(s):**
   Polyoxylethylene (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 indentify 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 Polysorbates

Appendix II

<table>
<thead>
<tr>
<th>Regulation No.</th>
<th>JECFA</th>
<th>JAPAN</th>
<th>USA</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay</td>
<td>INS435</td>
<td>-</td>
<td>$172.836</td>
<td>E435</td>
</tr>
<tr>
<td>Oxyethylene content</td>
<td>97.0-103.0%</td>
<td>-</td>
<td>-</td>
<td>≥ 97%</td>
</tr>
<tr>
<td>Water</td>
<td>≤ 3%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sulfated ash</td>
<td>≤ 0.25%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Acid value</td>
<td>≤ 2</td>
<td>-</td>
<td>0-2</td>
<td>≤ 2</td>
</tr>
<tr>
<td>Saponification value</td>
<td>41-52</td>
<td>45-55</td>
<td>45-55</td>
<td>45-55</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>90-107</td>
<td>81-96</td>
<td>81-96</td>
<td>81-96</td>
</tr>
<tr>
<td>1,4-Dioxane</td>
<td>≤ 10 mg/kg</td>
<td>≤ 10 µg/g</td>
<td>-</td>
<td>≤ 5 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>≤ 2 mg/kg</td>
<td>≤ 2.0 µg/g</td>
<td>-</td>
<td>≤ 2 mg/kg</td>
</tr>
</tbody>
</table>
## FOOD ADDITIVE GROUP DETAILS
### 1. POLYSORBATES

The provisions that follow are derived from the GSPA online database, which compiles and updates the database of the additive provisions published in the Code, adding items that make minor updates and provided for reference only.

**Participating Additives:**
- Polysorbate 80
- Polysorbate 85
- Polysorbate 90
- Polysorbate 92
- Polysorbate 94
- Polysorbate 95
- Polysorbate 98
- Polysorbat 98

### Table: POLYSORBATES

<table>
<thead>
<tr>
<th>Food Category</th>
<th>Provisions</th>
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<tbody>
<tr>
<td>15.8.5</td>
<td>Foods (e.g., bread, cake, and cookies) containing grain products, flour products, or flour flour products containing flour products or flour flour products containing grain products.</td>
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<tr>
<td>15.8.6</td>
<td>Breads (e.g., breads, rolls, and bagels) containing flour products or flour flour products containing flour products or flour flour products containing grain products.</td>
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<td>15.8.7</td>
<td>Biscuits, wafers, and cookies containing flour products or flour flour products containing flour products or flour flour products containing grain products.</td>
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<td>15.8.8</td>
<td>Cereal and cereal-based desserts (e.g., rice pudding, wheat pudding) containing flour products or flour flour products containing flour products or flour flour products containing grain products.</td>
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<td>15.8.9</td>
<td>Cereals, including flour products or flour flour products containing flour products or flour flour products containing grain products.</td>
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<td>15.8.10</td>
<td>Baked goods containing flour products or flour flour products containing flour products or flour flour products containing grain products.</td>
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<td>15.8.11</td>
<td>Bakery products containing flour products or flour flour products containing flour products or flour flour products containing grain products.</td>
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**Note:** These provisions are derived from the GSPA online database, which compiles and updates the database of the additive provisions published in the Code, adding items that make minor updates and provided for reference only.

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Visit the GSPA online database for more detailed information and updates.
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**

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<th>History</th>
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<th>JECFA No</th>
<th>CAS</th>
<th>Principle Name</th>
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<td>ALIPHATIC ACYCLIC AND ALICYCLIC ALPHA-DIKETONES AND RELATED ALPHA-HYDROXYKETONES</td>
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**CONSEIL EUROPÉEN DE L’INDUSTRIE CHIMIQUE (CEFIC)**

**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:**

CEFIC - The European Oleochemicals and Allied Products Group (APAG)
Av. E. Van Nieuwenhuyse 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(C18H35O2)2 (magnesium stearate); Mg(C16H31O2)2 (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 Nieuwenhuyse, 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 a 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 caking: 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:

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

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
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

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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.

<table>
<thead>
<tr>
<th>Name of Compound(s):</th>
<th>Citric Acid / INS 330</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question(s) to be answered by JECFA</td>
<td>Revision of Oxalate test method for citric acid</td>
</tr>
</tbody>
</table>

(kindly provide a brief justification of the request in case of re-evaluations)

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 Nieuwenhuyse, 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