CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9a **CX/FA 11/43/18**

January 2011

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-third Session

Xiamen (Fujian Province), China, 14-18 March 2011

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF FOOD ADDITIVE PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2010/10-FA)

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

Denmark, Japan, Sudan, United States of America, CEFIC and ISDI

DENMARK

In response to CL 2010/10-FA, the Danish Veterinary and Food Administration would like to request the 43rd CCFA that two enzymes be included on the "Priority List of Food Additives Proposed for Evaluation by JECFA" , in accordance with agenda item 9a, CX/FA 11/43/18.

For your information The Danish Veterinary and Food Administration has already approved the two enzymes after the SCF guidelines with all the necessary toxicological data.

Annex 2: FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA ISPROVIDED

1. Proposal for inclusion submitted by:

Danish Veterinary and Food Administration.

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

Compound: Serine proteinase from *Nocardiopsis prasina* expressed in *Bacillus licheniformis*.

Trade name: iZyme ® B

Chemical name: microbial chymotrypsin; CAS 37259-58-8, EC 3.4.21.1

3. Names and addresses of basic producers:

Novozymes A/S
Krogshøjvej 36
DK-2880 Bagsværd
Denmark

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

Novozymes A/S commits to provide data to support the proposal for inclusion of the serine proteinase in the list of substances to be evaluated by JECFA.

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

Novozymes A/S
Krogshøjvej 36
DK-2880 Bagsværd
Denmark
Attn.: Christina Westphal

cwch@novozymes.com
+45 4446 2491

6. Justification for use:

The active enzyme is a serine proteinase/chymotrypsin (EC 3.4.21.1), which is used to hydrolyze proteins. It is an endoprotease with preferred cleavage site at Tyr+, Trp+, Phe+, Leu+ residues in proteins and therefore well suited for controlled hydrolysis of proteins.

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 intended to be used as a processing aid for production of partly or extensively hydrolyzed proteins. The resulting protein hydrolyzate may in turn be used for various applications as ingredients in food and/or beverages.

The commercial product, iZyme B is standardized to an enzyme activity of 75 KPROT/g. The recommended dosage of iZyme B is up to 1500 KPROT/g per kg protein dry matter, corresponding to a dosage of up to 20g of iZyme B per kg processed protein. The resulting protein hydrolyzate will typically be used at levels up to 10% in food or 3.5% in beverages.

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))

A US GRAS (Generally Recognized As Safe) self determination for the intended use has been done. iZyme B was approved in Denmark in 2010.

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

The following studies were performed:

- 13 weeks oral toxicity study in rats
- Test for mutagenic activity (Ames Test)
- Human lymphocyte cytogenetic assay

The main conclusions of the safety studies can be summarized as follows:

Oral administration to rats of up to 5 ml/kg body weight/day (equivalent to 287469 PROT/kg body weight/day or 500.1 mg TOS[1]/kg bw/day) for 13 weeks did not reveal any significant toxic effects attributable to the test substance and is considered the No Ob-served Adverse Effect Level (NOAEL).

The protease preparation showed no mutagenic activity in either a bacterial reverse mutation assay (Ames Test) or in investigations for both structural and numerical chromosome aberrations in human lymphocytes in vitro.

The safety studies described above were all performed on a liquid protease enzyme concentrate. This batch was obtained by mixing of 3 sub batches, each produced according to the description given in section 3, omitting stabilization and standardization.

[1] TOS = Total Organic Solids, defined as: 100% - water - ash - diluents

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

The protease enzyme preparation complies with the purity criteria recommended for enzyme preparations in the 6th edition of Food Chemicals Codex, 2008 (Online edition). In addition to this, the enzyme preparation also conforms to the General Specifications and Considerations for Enzyme Preparations Used in Food Processing (2006) as proposed by the Joint FAO/WHO Expert Committee on Food Additives in Combined Compendium of Food Additive Specifications, Online edition.

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.

iZyme B is to be used for production of protein hydrolysates in dosages up to a maximum of 20 g of iZyme B per kg processed protein. iZyme B will be standardized to an activity of 75KPROT/g and has an approximate content of 7.7% TOS (Total Organic Substances from the fermentation, mainly protein and carbohydrate components), giving an overestimate of 1.54 g TOS/kg protein hydrolysate.

Because the resulting protein hydrolysates may be used for a variety of applications as ingredients in food and/or beverages, the estimation of human consumption is based on the Budget method2.

In order to demonstrate a worst case calculation, an exaggerated human intake is estimated using the following assumptions.

(a) It is assumed that all processed foods and beverages contain protein hydrolysates produced using iZyme B as a processing aid, used at the highest recommended dosage.

(b) According to the Budget method, a conservative estimate for the food intake is 25 g per kg body weight per day of which processed food is 50% of the food intake or 12.5 g per kg body weight per day. It is further assumed that all processed food contains 10% protein hydrolysates.

(c) Also according to the Budget method, a conservative estimate for the beverage (non-milk) intake is 100 ml per kg body weight per day of which processed beverages (soft drink) is 25% of the non-milk beverage intake or 25 g per kg body weight per day. It is further assumed that all processed beverages contain 3.5% protein hydrolysates.

(d) The calculation is made assuming that all TOS remains in the final product. iZyme B contains 7.7% TOS.

Based on the estimated intakes for processed food of 12.5 g per kg body weight per day and for processed beverages of 25 g per kg body weight per day, the intake of iZyme B corresponds to 1540 x (0.0125 x 0.1 + 0.025 x 0.035) = 3.27 mg TOS per kg body weight per day.

Other information as necessary

10. Date on which data could be submitted to JECFA: November 2011

Annex 2: FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

1. Proposal for inclusion submitted by:

Danish Veterinary and Food Administration.

[2] ILSI Europe Food Chemical Intake Task Force, April 1997. An Evaluation of the Budget Method for Screening Food Additive Intake

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

Compound: Serine proteinase from *Fusarium oxysporum* expressed in *Fusarium venenatum*.

Trade name: Novozym ® 12001

Chemical name: microbial trypsin; CAS 9002-07-7, EC 3.4.21.4

3. Names and addresses of basic producers:

Novozymes A/S
Krogshøjvej 36
DK-2880 Bagsværd
Denmark

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

Novozymes A/S commits to provide data to support the proposal for inclusion of the serine proteinase in the list of substances to be evaluated by JECFA.

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

Novozymes A/S
Krogshøjvej 36
DK-2880 Bagsværd
Denmark
Attn.: Peter Hvass
phva@novozymes.com
+45 4446 3610

6. Justification for use:

The active enzyme is a serine proteinase/trypsin (EC 3.4.21.4), which is used to hydrolyze proteins. It is an endoprotease with preferred cleavage site at Arginine and Lysine residues in proteins and therefore well suited for controlled hydrolysis of proteins.

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 intended to be used as a processing aid for production of partly or extensively hydrolyzed proteins. The resulting protein hydrolyzate may in turn be used for various applications as ingredients in food and/or beverages.

The commercial product, Novozym 12001 is standardized to an enzyme activity of 60 KMTU/g. The recommended dosage of Novozym 12001 is up to 720 KMTU per kg protein dry matter, corresponding to a dosage of up to 12 g of Novozym 12001 per kg processed protein. The resulting protein hydrolyzate will typically be used at levels up to 10% in food or 3.5% in beverages.

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))

A US GRAS (Generally Recognized As Safe) self determination for the intended use has been done. Novozym 12001 was approved in Denmark in 2008. The enzyme is included in the 2010 amendment to the French positive list.

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

The following studies were performed:

- 13 weeks oral toxicity study in rats
- Test for mutagenic activity (Ames Test)
- Human lymphocyte cytogenetic assay

The main conclusions of the safety studies can be summarized as follows:

Oral administration to rats of up to 5 ml/kg body weight/day (equivalent to 603 KMTU/kg bw/day or 581mg TOS[3]/kg bw/day) for 13 weeks did not reveal any significant toxic effects attributable to the test substance and is considered the No Ob-served Adverse Effect Level (NOAEL).

The protease preparation showed no mutagenic activity in either a bacterial reverse mutation assay (Ames Test) or in investigations for both structural and numerical chromosome aberrations in human lymphocytes in vitro.

The safety studies described above were all performed on a liquid protease enzyme concentrate. This batch was obtained by mixing of 3 sub batches, each produced according to the description given in section 3, omitting stabilization and standardization.

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

The protease enzyme preparation complies with the purity criteria recommended for enzyme preparations in the 6th edition of Food Chemicals Codex, 2008 (Online edition). In addition to this, the enzyme preparation also conforms to the General Specifications and Considerations for Enzyme Preparations Used in Food Processing (2006) as proposed by the Joint FAO/WHO Expert Committee on Food Additives in Combined Compendium of Food Additive Specifications, Online edition.

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.

Novozym 12001 is to be used for production of protein hydrolysates in dosages up to a maximum of 12 g of Novozym 12001 per kg processed protein. Novozym 12001 has an activity of 60 KMTU/g and an approximate content of 4% TOS (Total Organic Substances from the fermentation, mainly protein and carbohydrate components), giving an overestimate of 480 mg TOS/kg protein hydrolysate.

Because the resulting protein hydrolysates may be used for a variety of applications as ingredients in food and/or beverages, the estimation of human consumption is based on the Budget method4.

In order to demonstrate a worst case calculation, an exaggerated human intake is estimated using the following assumptions.

It is assumed that all processed foods and beverages contain protein hydrolysates produced using Novozym 12001 as a processing aid, used at the highest recommended dosage.

According to the Budget method, a conservative estimate for the food intake is 25 g per kg body weight per day of which processed food is 50% of the food intake or 12.5 g per kg body weight per day. It is further assumed that all processed food contains 10% protein hydrolysates.

[3] TOS = Total Organic Solids, defined as: 100% - water - ash - diluents

[4] ILSI Europe Food Chemical Intake Task Force, April 1997. An Evaluation of the Budget Method for Screening Food Additive Intake

Also according to the Budget method, a conservative estimate for the beverage (non-milk) intake is 100 ml per kg body weight per day of which processed beverages (soft drink) is 25% of the non-milk beverage intake or 25 g per kg body weight per day. It is further assumed that all processed beverages contain 3.5% protein hydrolysates.

The calculation is made assuming that all TOS remains in the final product. Novozym 12001 contains 4% TOS.

Based on the estimated intakes for processed food of 12.5 g per kg body weight per day and for processed beverages of 25 g per kg body weight per day, the intake of Novozym 12001 corresponds to 480 x (0.0125 x 0.1 + 0.025 x 0.035) = 1.02 mg TOS per kg body weight per day.

Other information as necessary

10. Date on which data could be submitted to JECFA: November 2011

JAPAN

Annex 2: FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

1. **Proposal for inclusion submitted by**: JAPAN
2. **Name of compound; trade name(s); chemical name(s):** Titanium Dioxide; INS No. 171
3. **Names and addresses of basic producers**: N.A.
4. **Has the manufacturer made a commitment to provide data**: N.A.
5. **Identification of the manufacturer that will be providing data:**

   Dr. Kyoko Sato, Head of the First Laboratory, Department of Food Additives,
   National Institute of Health Sciences, Tokyo Japan
   TEL: +81-3-3700-9403 FAX: +81-3-3700-9403 E-mail: ksato@nihs.go.jp
6. **Justification for use**: A colouring agent of white colour
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):**

   Titanium dioxide (INS No. 171) is a food additive that is included in Table 3 of the GSFA, and as such may be used in the following foods under the conditions of good manufacturing practices (GMP) as outlined in the Preamble of the Codex GSFA. Note that food categories listed in the Annex to Table 3 were excluded accordingly.
8. **Is the compound currently used in food that is legally traded in more than one country:**

   Yes/ Titanium Dioxide is permitted for use in a wide range of countries (the European Union, the United State, and etc.).
9. **List of data available:**

   Technological data

   (i) Revision of specifications

   Changes of purity tests (aluminium oxide and silicon dioxide) and the assay.

   The current purity tests for SiO2 uses a harmful chemical reagent, concentrated hydrofluoric acid and has poorly-reproducible.

   Japan would like to propose an alternative method for the detection of Al_2O_3, SiO_2 and TiO_2 in titanium dioxide using inductively coupled plasma (ICP) atomic emission spectrometry without hydrofluoric acid.

10. **Date on which data could be submitted to JECFA**: February 2011

SUDAN

Annex 2: FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

1. **Proposal for inclusion submitted by**: Republic of Sudan, Sudanese Standards & Metrology Organization (SSMO)
2. **Name of compound; trade name(s); chemical name(s):** *Acacia polyacantha* var. *Campylacantha* , kakamut gum, arabino- galactan protein complex;
3. **Names and addresses of basic producers**: Natural product from Republic of Sudan
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):**

   Data will be provided by Sudanese Standards & Metrology Organization (SSMO) - Contact Person is MAYADA M. E.A.ELKARIUM E.MAIL: maelkareem@hotmail.com
6. **Justification for use:**

   The gum from *Acacia polyacantha* is a natural product which belongs to *Acacia senegal* complex, that has been used in food industry in U.S.A, France, Finland & Italy. Mainly in confectionary.
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):**

   It has got similar functional properties as Gum Arabic *Acacia senegal.* Therefore, it could be used in most of the products in which gum Arabic is used
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())**

   Reference can be made to Leaf international Sweden, Finland, Italy, CNI France, KERRY Ingrediets UK & TIC USA. It has been used locally in Sudan in food and folk medicine for hundreds of years. The compound is currently used in confectionary which is legally traded in the countries mentioned above.
9. **List of data available (please check, if available) :**

   Toxicological data

   (i) Metabolic and pharmacokinetic studies: Not Available

   (ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental Not available

   Toxicity studies in animals and genotoxicity studies: there is cytogenetics toxicological studies

   (iii) Epidemiological and/or clinical studies and special considerations not available

   (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) fully available

   (ii) Technological and nutritional considerations relating to the manufacture and use of the listed compound: natural product used to function as emulsifier, stabilizer, thickener, bulking agent, soluble fiber, and binder.

   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 : Expected to be used at similar levels as gum arabic E414

(ii) Estimation of dietary intakes based on food consumption data for foods in which the compound may be used. Expected to be within the same range of gum arabic

Other information as necessary

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

15 February 2011

Literature regarding:

1/ full botanical description

2/ detailed chemical analysis

3/ proposed specifications

4/ cytogenetic toxicological studies

5/ volume in international trade including importing countries

UNITED STATES OF AMERICA

This responds to CL 2010/10-FA (April 2010), Request for Information and Comments on Priority List of Food Additives Proposed for Evaluation by JECFA. The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 43rd Session of the Codex Committee on Food Additives (CCFA).

Addition to the JECFA Priority List

The United States proposes the addition of 52 flavors to the current listing of 133 flavors currently on the JECFA priority list.[5] The required information (as prescribed in Annex 2 of CL 2010/10-FA) for the flavors is included as an Appendix to this comment. The list of flavors is provided as a single table (Annex A) sorted by Chemical Group consisting of the 133 flavors currently on the Priority List plus the proposed 52 new flavors.

Appendix - Required Information based on Annex 2 of CL 2010/10-FA

List of 185 flavors (comprising 52 new proposals and 133 flavors currently on the Priority List)

1. Proposal for inclusion submitted by: United States of America

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

List of 185 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 Flavour Industry (IOFI)
Brussels, Belgium
Thierry Cachet, Ph.D. (Science Director)
6 Avenue des Arts
B1210 Brussels, Belgium
P: 0113222142052
tcachet@iofiorg.org

[5] Annex 3 of CL 2010/10-FA indicates that 134 flavors are currently on the JECFA Priority List. We propose that one of the flavors (Glucosyl steviol glycosides) currently on the JECFA Priority List be removed from consideration. Thus, only 133 flavors from the current JECFA Priority List are included in the 185 flavors (52 new flavors and 133 from the current JECFA Priority list) put forward for consideration in this proposal.

6. Justification for use:

Flavoring 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 in response to JECFA's call for data.

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 31, 2011

Annex A. List of 185 flavors for inclusion on the JECFA Priority List

Chemical Group	Priority	Order	FEMA No	CAS No	Name
ALIPHATIC AND AROMATIC AMIDES (NEW GROUP)					
	1	1	4668	504-48-3; 2539457-4	(2E,6E/Z,8E)-N-(2-Methylpropyl)-2,6,8-decatrienamide
	1	2	4684	1119711-29-3	(2S,5R)-N-[4-2-Amino-2-oxoethyl)phenyl]-5-methyl-2-(propan-2-yl)cyclohexanecarboxamide
	1	3	4681	68489-09-8	(1R,2S,5R)-N-(4-Methoxyphenyl)-5-methyl-2-(1-methylethyl)cyclohexanecarboxamide
	1	4	4693	73435-61-7	N-Cyclopropyl-5-methyl-2-isopropylcyclohexanecarbonecarboxamide
	1	5	4678	1003050-32-5	N-(2-Methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide
	1	6	4701	1093200-92-0	3[(4-Amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide

Chemical Group	Priority	Order	FEMA No	CAS No	Name
ALIPHATIC THIOLS AND SULFIDES					
20	2	1	4694	616-31-9	3-Pentanethiol
20	2	2	4698	33959-27-2	4-Mercapto-3-methyl-2-butanol
20	2	3	4714	33441-50-8	Ethyl 2-Mercapto-2-methylpropionate
20	2	4	4707	61837-77-2	1-(Methylthio)-3-octanone
20	2	5	4670	88497-17-0	1,1-Propanedithiol
20	2	6	4696	122861-78-3	1-Methyldithio-2-propanone
20	2	7	4677	1064678-08-5	(±)-4-Methyl-2-propyl-1,3-oxathiane
SULFUR-SUBSTITUTED FURAN DERIVATIVES					
35	3	1	4320	333384-99-9	2-Methyl-3-furyl methylthiomethyl disulfide
35	3	2	4545	252736-40-6	2-Methyl-3-furyl 2-methyl-3-tetrahydrofuryl disulfide
35	3	3	4535	99253-91-5	2-Tetrahydrofurfuryl 2-mercaptopropionate
35	3	4	4538	94278-26-9	Methyl 3-(furfurylthio)propionate
35	3	5	4501	915971-43-6	3-[(2-Methyl-3-furyl)thio]butanal
35	3	6	4676	58066-86-7	1-(2-Furfurylthio)-propanone
35	3	7	4683	26486-13-5	2-Methyl-4,5-dihydrofuran-3-thiol
35	3	8	4686	252736-41-7	(±)-2-Methyltetrahydrofuran-3-thiol acetate
35	3	9	4697	59303-05-8	5-Methylfurfurylmercaptan
FURFURYL ALCOHOL AND RELATED SUBSTANCES					
23	4	1	4537	4359-54-0	Furfural propyleneglycol acetal
23	4	2	4542	13493-97-5	Furfuryl formate
23	4	3	4539	39252-05-6	Furfuryl decanoate
23	4	4	4544	3857-25-8	5-Methylfurfuryl alcohol
23	4	5	4541	53282-12-5	(E)-Ethyl 3-(2-furyl)acrylate
23	4	6	4540	1197-40-6	di-2-Furylmethane
35	3	7	4543	4265-25-2	2-Methylbenzofuran
SULFUR-CONTAINING HETEROCYCLIC COMPOUNDS					
34	5	1	4387	4861-58-9	2-Pentylthiophene
34	5	2	4645	632-15-5	3,4-Dimethylthiophene
34	5	3	4642	636-72-6	2-Thienylmethanol
34	5	4	4643	13679-74-8	2-Acetyl-5-methylthiophene
34	5	5	4646	94089-02-8	1-(2-Thienyl)ethanethiol
34	5	6	4641	37645-62-8	2-Pentylthiazole
34	5	7	4388	19961-52-5	5-Ethyl-2-methylthiazole
34	5	8	4695	41803-21-8	2-Ethyl-2,5-dihydro-4-methylthiazole
34	5	9	4647	53498-32-1	4,5-Dimethyl-2-isobutylthiazole
34	5	10	4644	52558-99-3	4-Methyl-3-thiazoline
34	5	11	4667	54717-14-5; 54717-13-4	2(4)-Ethyl-4(2),6-dimethyldihydro-1,3,5-dithiazine (mixture of isomers)
34	5	12	4669	1033366-59-4 (salt); 121746-18-7 (free acid)	4-Amino-5,6-dimethylthieno[2,3-D]pyramidin-2(1H)-one (also covers the salt form 4-Amino-5,6-dimethylthieno[2,3-D]pyramidin-2(1H)-one hydrochloride)
AMINO ACIDS AND RELATED SUBSTANCES					
49	6	1	4675	73-32-5	l-Isoleucine
49	6	2	4710	72-19-5	l-Threonine
49	6	3	4190	3184-13-2	l-Ornithine monochlorohydrate/Ornithine
49	6	4	4712	39537-23-0	L-Alanyl-L-Glutamine
49	6	5	4692	14486-03-4	l-Methionylglycine
49	6	6	4709	38837-70-6	Glutamyl-valyl-glycine
49	6	7	4716	714229-20-6	N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate
PYRAZINE DERIVATIVES					
26	7	1	3296	38713-41-6	Isopropenylpyrazine
26	7	2	4434	15707-34-3	5-Ethyl-2,3-dimethylpyrazine
26	7	3	4100	38888-81-2;	3,5 and 3,6-Dimethyl-2-isobutylpyrazine

Chemical Group	Priority	Order	FEMA No	CAS No	Name
				70303-42-3	
26	7	4	3211	13925-08-1	2-Methyl-5-vinylpyrazine
26	7	5	4702	38917-61-2, 38917-62-3	5-Dimethyl-6,7-dihydro-5H-cyclopentapyrazine
26	7	6	4632	72797-16-1	2-Ethoxy-3-isopropylpyrazine
26	7	7	4633	35243-43-7	2-Ethoxy-3-ethylpyrazine
26	7	8	4631	72987-62-3	2-Ethyl-3-methylthiopyrazine
ALIPHATIC AND AROMATIC ETHERS					
41	8	1	4291	4747-07-3	Methyl hexyl ether
41	8	2	4592	24202-00-4	Myrcenyl methyl ether
41	8	3	4315	70786-44-6	3,6-Dimethyl-2,3,3A,4,5,7A-hexahydrobenzofuran
41	8	4	4591	72845-33-1	Ethyl linalyl ether
41	8	5	4593	14049-11-7	Linalool oxide pyranoid
41	8	6	4680	1120363-98-5	5-Isopropyl-2,6-diethyl-2-methyltetrahydro-2H-pyran
41	8	7	4634	10484-56-7	Butyl beta-naphthyl ether
41	8	8	4635	56011-02-0	Isoamyl phenethyl ether
50	23	9	4536	1424-83-5	Nerolidol oxide
41	8	10	4664	31147-36-1	Digeranyl ether
EPOXIDES					
57	9	1	4653	19464-94-9	Ethyl alpha-ethyl-beta-methyl-beta-phenylglycidate
57	9	2	4654	37161-74-3	Methyl beta-phenylglycidate
57	9	3	4655	1195-92-2	d-8-p-Menthene-1,2-epoxide
57	9	4	4656	203719-53-3	L-8-p-Menthene-1,2-epoxide
57	9	5	4657	42134-50-9	2,3-Epoxyoctanal
57	9	6	4658	58936-30-4	2,3-Epoxyheptanal
57	9	7	4659	102369-06-2	2,3-Epoxydecanal
PYRIDINE, PYRROLE, AND QUINOLINE and Related N-HETEROCYCLIC DERIVATIVES					
44	10	1	4317	2167-14-8	1-Ethyl-2-pyrrolecarboxaldehyde
44	10	2	4332	1192-58-1	1-Methyl-1H-pyrrole-2-carboxaldehyde
44	10	3	4389	108-47-4	2,4-Dimethylpyridine
44	10	4	4636	142896-11-5	2-Acetyl-4-isopropenylpyridine
44	10	5	4637	142896-12-6	4-Acetyl-2-isopropenylpyridine
44	10	6	4638	142896-09-1	2-Acetyl-4-isopropylpyridine
44	10	7	4639	1628-89-3	2-Methoxypyridine
44	10	8	4640	5263-87-6	6-Methoxyquinoline
44	10	9	4721	1186004-10-3	1-(2-Hydroxyphenyl)-3-(pyridine-4-yl)propan-1-one
44	10	10	4722	1190230-47-7	1-(2-Hydroxy-4-isobutoxyphenyl)-3-(pyridine-4-yl)propan-1-one
44	10	11	4723	1190229-37-8	1-(2-Hydroxy-4-methoxyphenyl)-3-(pyridine-4-yl)propan-1-one
44	10	12	4725	1119831-25-2	3-(1-((3,5-Dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)-imidazolidine-2,4-dione
44	10	13	4726	1217341-48-4	3-(1-((3,5-Dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)-5,5-dimethylimidazolidine-2,4-dione
LINEAR αβ-UNSATURATED ALDEHYDES, ACIDS AND RELATED ALCOHOLS, ACETALS AND ESTERS					
47	11	1	4552	30418-89-4	trans-2-Nonenyl acetate
47	11	2	4614	10297-72-0	Propyl sorbate
47	11	3	4615	26001-58-1	cis-2-Octenol
47	11	4	4617	74962-98-4	trans-2-Tridecenol
47	11	5	4613	1552-67-6	Ethyl 2-hexenoate
PHENOL AND PHENOL DERIVATIVES					
24	12	1	4720	63550-99-2	Rebaudioside C

Chemical Group	Priority	Order	FEMA No	CAS No	Name
24	12	2	4708	76426-35-2	3',7-Dihydroxy-4'-methoxyflavan
24	12	3	4674	4192-90-9	Trilobatin
24	12	4	4715	4049-38-1; 552-589; 116301-03-2	2-(3,4-Dihydroxyphenyl)-5,7-dihydroxy-4-chromanon
PHENYLETHYL ALCOHOL, ALDEHYDE, ACID AND RELATED ACETALS AND ESTERS AND RELATED SUBSTANCES					
33			4314	61810-55-7	Phenethyl decanoate
33			2860	94-47-3	Phenethyl benzoate
33			4625	6314-97-2	Phenylacetaldehyde diethyl acetal
33			4629	5468-05-3	Phenylacetaldehyde propyleneglycol acetal
33			4619	92729-55-0	Propyl 4-tert-butylphenylacetate
33			4620	122-99-6	2-Phenoxyethanol
33			4618	23495-12-7	2-Phenoxyethyl propionate
ALIPHATIC BRANCHED-CHAIN SATURATED AND UNSATURATED ALCOHOLS, ALDEHYDES, ACIDS, AND RELATED ESTERS					
40			4486	5694-82-6	Citral glyceryl acetal
40			4612	26266-68-2	2-Ethyl-2-hexenal
40			4616	13019-16-4	2-Hexylidenehexanal
ALIPHATIC AND ALICYCLIC HYDROCARBONS					
45			4293	111-66-0	1-Octene
45			4292	56700-78-8	trans-2,trans-4-Nonadiene
45			4264	475-03-6	alpha-Ionene
45			4650	691-38-3	4-Methyl-cis-2-pentene
45			4651	124-11-8	1-Nonene
45			4652	116963-97-4	1,3,5,7-Undecatetraene
HYDROXY- AND ALKOXY-SUBSTITUTED BENZYL DERIVATIVES					
29			4431	99-06-9	3-Hydroxybenzoic acid
29			4430	99-50-3	3,4-Dihydroxybenzoic acid
29			4435	673-22-3	2-Hydroxy-4-methoxybenzaldehyde
29			4622	61683-99-6	Piperonal propyleneglycol acetal
29			4606	930587-76-1	4-Formyl-2-methoxyphenyl 2-hydroxypropanoate
29			4627	6414-32-0	Anisaldehyde propyleneglycol acetal
29			4700	614-60-8	o-trans-Coumaric acid
MENTHOL AND STRUCTURALLY RELATED SUBSTANCES					
19			4509	2230-90-2	Menthyl formate
19			4510	86014-82-6	Menthyl propionate
19			4524	68366-64-3	l-Menthyl butyrate
19			4604	406179-71-3	Dimenthyl glutarate
19			4718	28804-53-7	(±)2-[(2-p-Menthoxy)ethoxy]ethanol
MALTOL AND RELATED SUBSTANCES					
52			4534	852997-28-5	Ethyl maltol isobutyrate
CARVONE AND STRUCTURALLY RELATED SUBSTANCES					
16			4525	929116-08-5	Pinocarvyl isobutyrate
16			4515	929222-96-8	Carvyl palmitate
16			4523	51200-86-3	6-Hydroxycarvone
IONONES AND STRUCTURALLY RELATED SUBSTANCES					
17			4088	24720-09-0	trans-alpha-Damascone
17			4151	79-89-0	beta-Isomethylionone
17			4299	141-10-6	Pseudoionone
CINNAMYL ALCOHOL AND RELATED SUBSTANCES					
22			4596	4353-01-9	Cinnamaldehyde propyleneglycol acetal
22			4595	67634-23-5	2-Phenylpropanal propyleneglycol acetal
22			4597	620-80-4	Ethyl alpha-acetylcinnamate
22			4599	1205-17-0	3-(3,4-Methylenedioxyphenyl)-2-methylpropanal
22			4598	15399-05-0	Ethyl 2-hydroxy-3-phenylpropionate
SATURATED ALIPHATIC ACYCLIC LINEAR PRIMARY ALCOHOLS, ALDEHYDES, AND ACIDS					
04			4010	123-63-7	Paraldehyde

Chemical Group	Priority	Order	FEMA No	CAS No	Name
04			4432	25334-93-4	(+/-)-Acetaldehyde ethyl isopropyl acetal
04			4335	10486-19-8	Tridecanal
04			4528	6986-51-2	Acetaldehyde ethyl isobutyl acetal
04			4336	638-53-9	Tridecanoic acid
04			4527	5669-09-0	Acetaldehyde di-isobutylacetal
4			4688	105-82-8	1-Dipropoxyethane
04			4334	1002-84-2	Pentadecanoic acid
ESTERS OF ALIPHATIC ACYCLIC PRIMARY ALCOHOLS WITH BRANCHED-CHAIN ALIPHATIC ACYCLIC ACIDS					
08			4347	850309-45-4	4-Methylpentyl isovalerate
08			4346	180348-60-1	5-Methylhexyl acetate
08			4343	25415-67-2	Ethyl 4-methylpentanoate
08			4344	2983-38-2	Ethyl 2-ethylbutyrate
08			4345	2983-37-1	Ethyl 2-ethylhexanoate
MONOCYCLIC AND BICYCLIC SECONDARY ALCOHOLS, KETONES, AND RELATED ESTERS					
48			4513	21368-68-3	dl-Camphor
48			4519	7787-20-4	l-Fenchone
48			4521	97866-86-9	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-ol
48			4522	97844-16-1	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-one
SATURATED ALIPHATIC ACYCLIC BRANCHED-CHAIN PRIMARY ALCOHOLS, ALDEHYDES, AND ACIDS					
05			4261	19269-28-4	3-Methylhexanal
05			4498	63885-09-6	6-Methylheptanal
05			4433	30689-75-9	(+/-)-6-Methyloctanal
05			4348	5988-91-0	3,7-Dimethyloctanal
ALIPHATIC SECONDARY ALCOHOLS, KETONES, AND RELATED ESTERS					
37			4724	21862-63-5	trans-4-tert-Butylcyclohexanol
37			4706	35194-30-0	9-Decen-2-one
37			4691	1009814-14-5	Yuzunone
37			4687	544409-58-7	(±)-3-Hydroxy-3-methyl-2,4-nonanedione
TETRAHYDROFURAN AND FURANONE DERIVATIVES					
50			4176	3511-32-8	5-Methyl-3(2H)-furanone
50			4546	39156-54-2	Ethyl 2,5-dimethyl-3-oxo-4(2H)-furyl carbonate
50			4101	14400-67-0	2,5-Dimethyl-3(2H)-furanone
50			4104	65330-49-6	2,5-Dimethyl-4-ethoxy-3(2H)-furanone
50			4070	36871-78-0	4-Acetyl-2,5-dimethyl-3(2H)-furanone
ALICYCLIC, ALICYCLIC-FUSED AND AROMATIC-FUSED RING LACTONES					
38			4140	57743-63-2	2-(2-Hydroxy-4-methyl-3-cyclohexenyl)propionic acid gamma-lactone
38			4270	5617-64-1	2-(2-Hydroxyphenyl) cyclopropanecarboxylic acid delta-lactone
38			4438	591-11-7	beta-Angelicalactone
38			4673	7370-44-7	delta-Hexadecalactone
38			4685	7370-92-5	(±)-6-Octyltetrahydro-2H-pyran-2-one
38			4195	87-41-2	Phthalide
LINEAR AND BRANCHED-CHAIN ALIPHATIC, UNSATURATED, UNCONJUGATED ALCOHOLS, ALDEHYDES, ACIDS, AND RELATED ESTERS					
14			4412	10340-23-5	cis-3-Nonen-1-ol
14			4605	10339-61-4	trans-3-Nonen-1-ol
14			4551	83334-93-4	cis,cis-3,6-Nonadienyl acetate
14			4413	3681-82-1	trans-3-Hexenyl acetate
14			4493	1775-43-5	cis-3-Hexenoic acid
14			4553	13049-88-2	cis-3-Nonenyl acetate
14			4554	76238-22-7	cis-6-Nonenyl acetate
14			4671	71978-00-2	Z-5-Octenyl acetate
14			4672	68820-35-9	(E)-4-Undecenal

Chemical Group	Priority	Order	FEMA No	CAS No	Name
ALLYL ESTERS					
03			4074	6321-45-5	Allyl valerate
03			4072	20474-93-5	Allyl crotonate
TERTIARY ALCOHOLS AND RELATED ESTERS					
15			4682	23333-91-7	Octahydro-4,8A-dimethyl-4A(2H)-naphthol
PRIMARY ALCOHOLS, ALDEHYDES, CARBOXYLIC ACIDS, AND RELATED ESTERS WITH A SECOND OXYGENATED FUNCTIONAL GROUP					
47			4699	85993-25-5	Ferrous l-lactate
47			4719	110-15-6	Succinic acid

CEFIC

Annex 2: FORM ON WHICH INFORMATION ON THE COMPOUND TO BE EVALUATED BY JECFA IS PROVIDED

1. Proposal for inclusion submitted by: CEFIC

2. Name of compound; trade name(s); chemical name(s): Magnesium dihydrogen diphosphate (MgH2P2O7) – proposed INS number: INS 450ix

3. Names and addresses of basic producers: Chemische Fabrik Budenheim KG

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):

Thomas Janssen: thomas.janssen@budenheim.com

6. Justification for use:

Flexible leavening agent with ability to enhance the nutrition profile of baked goods

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):

Food category: 06.6, 07

Use level: <20g/kg (as P2O5; likewise for "fine bakery wares" from EC directive 95/2)

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)): NO

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

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

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 2010

ISDI

The International Special Dietary Foods Industries (ISDI) represents at Codex Alimentarius the manufacturers of special dietary foods and hence is highly involved and interested in contributing to any work that will relate to nutrition products.

ISDI would like to support the inclusion of the following additives in the priority list of substances for JECFA review:

- Xantham gum – INS 415
- Pectin – INS 440
- OSA-modified starch (Starch sodium octenyl succinate) – INS 1450

You will find attached the relevant information supporting that request, based on CL 2010/10-FA. These nominations are being submitted at CCFA in anticipation that the recommendations in Document CX/FA 11/43/5 will be accepted.

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

1. Proposal for inclusion submitted by: International Special Dietary Foods Industries (ISDI)

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

Xanthan Gum; trade name is NovaXan 200™; IUPAC Name is 9H-xanthene.

INS No. 415; CAS#: 11138-66-2; E415

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

Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA

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

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

Lisa Craig, Ph.D.
Director, Regulatory Affairs
Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA
Phone: 614-624-3696
Fax: 614-727-3696
E-mail: lisa.craig@abbott.com

6. Justification for use:

Xanthan gum increases the thickness (viscosity) of infant formula, which improves the physical characteristics of the formula. The thickening of infant formula can result in improvements in infant feeding tolerance.

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

Proposed for use as a thickener up to 1 g/kg, as consumed, in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants.

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)?

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

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

Toxicological data

√ (i) Metabolic and pharmacokinetic studies

√ (ii) Short-term toxicity

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

√ (iv) Other data

• absence of allergens data

Technological data

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

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

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

Intake assessment data

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

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

Other information as necessary

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

December 1, 2011

INFORMATION ON PECTIN (INS 440) 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):

Pectin (no other commonly used chemical names or synonyms)

Chemical Identification: INS 440

CAS Number 9000-69-5

JECFA evaluation: 25th JECFA (1981);

ADI not specified

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

Mead Johnson Nutrition
2400 West Lloyd Expressway
Evansville, IN. 47721-0001
USA

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

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

Peter Van Dael, PhD
Vice President, Global Regulatory and Nutrition Sciences
Mead Johnson Nutrition
2400 West Lloyd Expressway
Evansville, IN. 47721-0001
USA
peter.vandael@mjn.com
Phone: +1 812 429-5185
Mobile: +1 812 568-1253

6. Justification for use:

Pectin is used as a gelling agent, thickener, stabilizer, and emulsifier. In FSMP formulations may lack the natural emulsification properties of whole protein, which provides stability. Stabilizers are therefore a technological requirement for these products 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 up to a maximum of 1 g per 100 mL of product ready for consumption (consistent with current EU maximum level and product category of use).

GSFA Food Products and Food Categories in which the compound is currently used:

Food Category No.	Food Category	Max Level	Year Adopted
14.1.2.1	Fruit juice	GMP	2005
14.1.2.3	Concentrates for fruit juice	GMP	2005
14.3.1	Fruit nectar	GMP	2005
14.1.3.3	Concentrates for fruit nectar	GMP	2005

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)?

The additive pectin is currently permitted in special medical purpose infant formula products in the EU and affiliated countries, and in the USA the FDA has no objection to its use in exempt formula products.

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

Toxicological data

√ (i) Metabolic

√ (ii) Short-term toxicity, long-term toxicity, reproductive toxicity, developmental toxicity studies in animals

√ (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 2011

INFORMATION ON OSA-MODIFIED STARCH (INS 1450) 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):

Octenyl succinic anhydride (OSA) modified starch; starch sodium octenyl succinate;

Trade name is N-Creamer 46.

INS No. 1450; CAS# 66829-29-6; E1450

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

Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA
Mead Johnson Nutrition
2400 West Lloyd Expressway
Evansville, IN USA
47721-0001
PBM Products
204 N. Main St.
Gordonsville, VA 22942

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):

Lisa Craig, Ph.D.
Director, Regulatory Affairs
Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA
Phone: 614-624-3696
Fax: 614-727-3696
E-mail: lisa.craig@abbott.com

6. Justification for use:

OSA modified starch can be used as an emulsifier in infant formula manufactured with a hydrolyzed protein source. Hydrolyzed proteins have different hydrophobic/hydrophilic characteristics than intact

proteins; OSA modified starch stabilizes the hydrolyzed protein to create a more homogeneous mixture (stable emulsion), thus improving the delivery of nutrients to infants.

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 9 g/100 g in infant formula powder or ~12 g/liter, as consumed, and 2 g/100 ml or 20 g/liter in ready-to-feed formula. The maximum use level of OSA modified starch in formula is therefore up to 20 g/liter, 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)?

OSA Modified Starch is permitted in infant formula in the USA and Russia, and is permitted for use in formula for special medical purposes in the EU.

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

Toxicological data

√ (i) Metabolic

√ (ii) Short-term toxicity

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

√ (iv) Other data

- analytical methodology

Technological data

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

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

Intake assessment data

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

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

Other information as necessary

10. Date on which data could be submitted to JECFA: December 1, 2011