CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 (a) **CX/FA 12/44/16**

February 2012

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fourth Session

Hangzhou, China 12-16 March 2012

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF FOOD ADDITIVE PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2011/8-FA)

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

Australia, Colombia, European Union and Japan

AUSTRALIA

Australia is pleased to respond to CL 2011/8-FA by requesting **Advantame** be considered for inclusion in the CCFA's priority list of compounds proposed for evaluation by JECFA at the 44th session of CCFA. This request is for the safety assessment and establishment of specifications for **Advantame.**

Australia believes that its nomination meets the criteria elaborated in Annex 1 of CL 2011/8-FA for inclusion in the priority list. Accordingly we have completed Annex 2 ("Form on which information on the compound to be evaluated by JECFA is provided") for **Advantame**, as prescribed in CL 2011/8-FA.

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

Name of Compound	Advantame
Questions to be answered by JECFA	Safety assessment and establishment of specifications

1. Proposal for inclusion submitted by:
   Australia

2. Name of compound; trade name(s); chemical name(s):
   Advantame; {N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate; CAS No. 714229-20-6}

3. Name and address of basic producers:
   Ajinomoto Co. Inc.

   15-1 Kyobashi 1-Chome, Chuo-Ku

   Tokyo 104-8315

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):
   Akira Otabe, Ajinomoto Co. Inc.

6. Justification for use:
   Advantame is used in foods to provide high intensity sweetness while maintaining their flavour integrity. In addition, when used at a low level, Advantame also enhances existing flavour of food.

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

TABLE 2.4: FOOD CATEGORIES AND TYPICAL USE LEVELS OF ADVANTAME AS A SWEETENER

General Standard on Food Additives (GSFA) Food Category	**Australia New Zealand Food Standard Code Food Category**	**Proposed Food Uses**	**Use level (mg/L)**
14.1: Non-alcoholic ("soft") beverages	Non-Alcoholic Beverages*	Powdered Non-Milk Based Meal Replacements and Protein Drinks	2.9
14.1.5: Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	Coffee, coffee substitutes, tea, herbal infusions and similar products*	Instant Teas	3.0
		Instant Coffee Drinks	1.8
01.1.2: Dairy-based drinks, flavoured and/or fermented (eg. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) **01.5:** Milk powder and cream powder and powder analogues	Dairy Products*	Powdered Flavoured Milk and Milk Drinks	2.9-4.4
01.5: Milk powder and cream powder and powder analogues		Powdered Milk-Based Meal Replacements and Protein Drinks	4.4
14.1.4.3: Concentrates (liquid or solid) for water-based flavoured drinks	Fruit and vegetable juice products*	Powdered Fruit Flavoured Drinks	4
11.6: Table-top sweeteners, including those containing high-intensity sweeteners	Sugar Substitutes(mg/kg)	Tabletop Sugar Substitutes (powdered and tablets)	450

*Only powdered and artificially sweetened versions of these foods are proposed for use for Advantame

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)):

It is approved for use in Australia and New Zealand and in the US.

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 *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 for Australian and New Zealand populations*

Other information as necessary

Human studies

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

COLOMBIA

Background: The JECFA Secretariat presented the paper CX/FA 11/43/19 and recalled that the JECFA and the CCFA had repeatedly discussed the need for a more systematic approach to the re-evaluation of food additives that is now being carried out in response to specific requests. Colombia presents to the Codex Committee on Food Additives and JECFA a request for inserting **Polyglycerol polycirinoleate (PGPR)** in the GSFA**.**

A completed form is attached

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

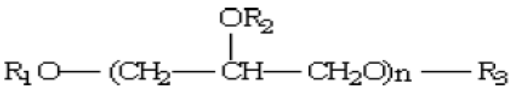
In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained

Name of compound(s):	**Polyglycerol polycirinoleate (PGPR)**
Question(s) to be answered by JECFA	

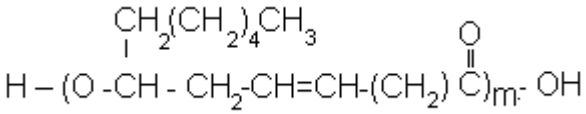
1. Proposal for inclusion submitted by: *COLOMBIA*

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

- Glycerol esters of condensed castor oil of fatty acids (*Ricinus communis L)*
- Polyglycerol esters of interesterified ricinoleic acid.
- 9-octadecenoic acid, 12-hydroxy-, (9Z, 12R)- polymer with 1,2,3-propanetriol.
- CAS 29894-35-7
- INS 476
- The major components have the general structure:



where the average value of n is about 3 and R_1 R_2 and R_3 each may be hydrogen or a linear condensation polymer of ricinoleic acid with itself thus:



Where the average value of m is between 5 and 8

3. Names and addresses of basic producers:

DANISCO COLOMBIA LTDA – Carrera 90 A No. 64C-54 Bogotá COLOMBIA – Tel +57 1 4251510.

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):

- Deltagen Group, manufacturer of PGPR, has the representations for Colombia, Ecuador, Peru and Venezuela.

  Name: Savannah Surfactants

  Phone: +91 832 2395109

  Address: 283A Kundaim Ind Estate

  E mail: a.bajaj@savannahgoa.com

  Contact person: Ani Bajaj

- In Colombia: Dr. GLORIA MARIA VELASCO- SPECIAL PROJECTS DIVISION DELTAGEN SAS. E mail: gloriav@deltagenbiop.com

6. Justification for use:

PGPR is a mixture of partial esters of polyglycerol with linear sterified fatty acids (ricinoleic acid). The polyglycerol fraction is mostly di-, tri- and tetraglycerol.

PGPR is used to modify the fluidity properties of chocolate and because it is an efficient surfactant for stabilizing oil in water emulsions, such as spreads with low fat content. In addition, it acts as a viscosity modifier in chocolate products and cacao based products, and with Lethicin it has a synergistic effect, which has a beneficial influence on the plastic viscosity. The use of PGPR allows reducing the fat levels in the product.

On the other hand, PGPR differs positively from other emulsifiers due to its singular yield value which reduces its capacity and ability to counteract the negative effect of moisture on chocolate covers for ices.

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):

a. Standard f*or Chocolate and Chocolate Products (CODEX STAN 87):* Maximum level: 5 g/kg (Products described under 2.1 and 2.2 in the commodity standard)

b. Standard for Cacao powders (cocoas) and dry mixtures of cocoa and sugars (CODEX STAN 105-1981, REV 1-2001): Maximum level: 5 g/kg

c. Standard for fat spreads and blended spreads (CODEX STAN 256-2007): Maximum level: 4000 mg/kg (4 g/kg)

Table 2 of the GSFA proposed for discussion (foods or food categories where the use of additives is allowed), lists the additive polyglycerol esters of interesterified ricinoleic acid for the food categories: Cocoa mixes (powders) and cocoa mass/cake

05.1.1 Cocoa mixes (powders) and cocoa mass/cake.

05.01.4 Cocoa and chocolate products.

05.1.5 Imitation chocolate, chocolate substitute products.

All of them with a maximum level of 5000 mg/kg.

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 additive PGPR is approved in legislations of several Latin American countries: Colombia, Venezuela, Ecuador, Paraguay, Argentina, México, Peru (see attached file). Additionally it is regulated by EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE No 95/2/EC of 20 February 1995 at a maximum level of 5 g/kg (See PDF directive, page 48/68) and by the FDA Gras Notice 000009 at a maximum level of 3 mg/kg (See PDF GRAS)

The support documents and access links to web pages are available at the following link: ftp://ftp.fao.org/codex/ccfa44/fa44_16_worksheet.pdf

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.

- JECFA monograph (INS 476)

http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-318.pdf

- Manufacturer PGPR technical file with technical/toxicological data available at: (ftp://ftp.fao.org/codex/ccfa44/fa44_16_Polyglycerol polyricinoleate.pdf)
- Toxicological studies (INCHEM) WHO FOOD ADDITIVES SERIES NO. 5

http://www.inchem.org/documents/jecfa/jecmono/v46aje48.htm

- EFEMA index of food emulsifiers - September 2009 5th edition

http://www.emulsifiers.org/files/EFEMA_Index_of_Food_Emulsifiers.pdf

- COMMISSION OF THE EUROPEAN COMMUNITIES - Reports of the Scientific Committee for Food - Eighth series 1979

http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_08.pdf

- FOOD AND DRUG REGULATIONS- June 8, 2009- Published by the Minister of Justice at the following address: http://laws-lois.justice.gc.ca

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.

- The acceptable daily intake (ADI) of PGPR which is widely used in confectionery, especially in chocolate coatings, is 75 mg/Kg of weight.

Other information as necessary:

Document of reference: Directive 95/2/EC on food additives other than colours and sweeteners that establishes a list of allowed food additives, the commodities where they can be used and conditions of their use.

This Directive was adopted in February 1995 and has been amended three times: in 1996, 1998 and 2001. Now it needs to be adapted according to the most recent developments of technical and scientific knowledge. The aim of this proposal is ensuring the functioning of the internal market, a high level of protection of human health and the protection of consumer interests:

- Number 3. Authorization for extending the use of authorised food additives

  Food additives with ADI «not specified». Two viscosity parameters are used in chocolate processing to ensure optimal processing and eating quality. Yield value is the minimum amount of force required to produce a flow. Plastic viscosity describes the flow characteristics once the flow has been initiated. Both yield value and plastic viscosity can be influenced by adding more fat. Since fat, and especially cocoa butter, is the most costly part of chocolate, it is desirable to influence these rheological properties by means of emulsifiers.

- Emulsifiers with an effect on rheological properties of chocolate include E 322 lecithin, E 442 ammonium phosphatides, E 476 polyglycerol polyricinoleate and E 472c citric acid esters of which all but E 472c are currently allowed for chocolate within the EU.

- When affecting both yield value and plastic viscosity, they can be used as the sole alternative to the combined use of lecithin/ammonium phosphatide and polyglycerol polyricinoleate thereby reducing the number of emulsifiers in certain products.

10. **Date on which data could be submitted to JECFA**: February 2012

EUROPEAN UNION

The European Union and its Member States (EUMS) would like to submit the substance "Glucoamylase from *Trichoderma reesei* , TrGA" for addition to the priority list of food additives proposed for evaluation by JECFA:

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):***	Glucoamylase from *Trichoderma reesei* expressed in *Trichoderma reesei*
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	

1. Proposal for inclusion submitted by:

European Union and its Member States

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

Compound: Glucoamylase enzyme produced by a non-pathogenic, non-toxigenic strain of *Trichoderma reesei* (formerly *Trichoderma longibrachiatum*), which is genetically modified to over express a native *T. reesei* glucoamylase enzyme.

[In this document TrGA is used as a code for the specific enzyme, which is an abbreviation for *Trichoderma reesei* GlucoAmylase.]

Trade name: DISTILLASE and DIAZYME (main commercial name)

(various other commercial names will be used, like DISTILLASE CS, DISTILLASE ASP, DISTILLASE SSF, DIAZYME TGA, DIAZYME SG2, DISTILLASE ASP NK, DISTILLASE SSF +, DIAZYME SSF2)

Chemical name: CAS 9075-68-7, EC 3.2.1.3

3. Names and addresses of basic producers:

Danisco US, Inc.

Genencor, a Danisco Division

200 Meridian Centre Blvd.

Rochester, NY 14618-3916

USA

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

Genencor, a Danisco Division, commit to provide data to support the proposal for inclusion of the glucoamylase in the list of substances to be evaluated by JECFA.

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

Danisco US, Inc.

Genencor, a Danisco Division

200 Meridian Centre Blvd.

Rochester, NY 14618-3916

USA

Attn.: Lone Brønd Miller Ph.D., Sr Regulatory Specialist

lone.broend.miller@danisco.com

+45 8943 5354

6. Justification for use:

Glucoamylase (GA) causes hydrolysis of terminal 1,4-linked a-D-glucose residues successively from non-reducing ends of the chains with release of b-D-glucose.

It can also hydrolyze 1,6-a-D-glucosidic bonds when the next bond in the sequence is 1,4.

The glucoamylase enzyme preparation will be used as a processing aid to hydrolyze starch, e.g., for syrup, dextrose or maltose production and in grain processing, brewing, potable alcohol and baking.

In *grain processing/sweeteners production* glucoamylase is used to sacccharify liquefied starch resulting in glucose-rich syrups. The syrups can be purified to meet various specifications: crystallized to produce dextrose, isomerized to produce high fructose corn syrup, or fermented to produce organic acids, alcohol or amino-acids.

In *brewing and potable alcohol* glucoamylase is used to maximize the conversion of starchy substrate to fermentable carbohydrate increasing production yield.

In *baking* glucoamylase gives control over the carbohydrate profile. It will reduce or replace the need to add simple sugars to the formulation and in addition it will reduce firming caused by starch retrogradation.

A more thorough description of the various application processes and fate of the glucoamylase will be presented in final dossier.

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):

Grain processing/sweeteners production, i.e. starch saccharification – glucoamylase is used at a level of 31 – 77 g enzyme protein per metric ton of starch dry substance, in accordance with current Good Manufacturing Practices (cGMPs)

Brewing and Potable Alcohol, i.e. extraction and saccharification of starch and conversion of starchy substrate to fermentable carbohydrate – glucoamylase is used at a level of 387 - 774 g enzyme protein per metric ton of grist (e.g. malted barley) in brewing. For potable alcohol, the dose level is 44 – 77 g enzyme protein per metric ton of equivalent starch dry substance (or approximately 93 - 155 g enzyme protein per metric ton of equivalent grist), in accordance with current Good Manufacturing Practices (cGMPs).

Baking, i.e. hydrolysis of starch and starch-derived carbohydrates into glucose and reduction of retrogradation – glucoamylase is used at a level of 0.0155 – 0.310 mg enzyme protein per g of flour, in accordance with current Good Manufacturing Practices (cGMPs).

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))

Glycoamylase produced with this production organism is approved in:

- Denmark: Ministry of Food, Argriculture and Fisheries, Danish Veterinary and Food Administration, File No 2011-20-5406-00036 (October 13, 2011).
- USA: Department of Health & Human Services, Public Health Service, Food and Drug Administration, GRN 000372 (July 25, 2011). http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?filter=372&sortColumn=&rpt=grasListing

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

The production organism is from a safe strain lineage as described in the decision tree in Pariza and Johnson, 2001[1]; however, to accommodate various registration requirements in different countries world-wide, a full toxicity program for food enzymes has been performed.

The safety of TrGA has been assessed in a battery of toxicology studies investigating its irritation, acute ingestion, genotoxic and systemic toxicity potential.

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

[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.

Genencor has conducted six safety studies on the *T. reesei* glucoamylase enzyme which is the subject of this safety assessment:

- Acute dermal irritation study in rabbits (sequential approach)
- Acute oral toxicity in rats – Fixed dose procedure
- Acute eye irritation/corrosion study in rabbits
- Bacterial Reverse Mutation Assay – Ames assay
- *In vitro* Mammalian Chromosomal Aberration Test Performed with Human Lymphocytes
- A 13-week Oral (Gavage) Toxicity Study in Rats

All safety studies were conducted in accordance with internationally accepted guidelines (OECD) and are in compliance with the principles of Good Laboratory Practices ("GLP") according to the FDA/OECD.

Under the conditions of the toxicology studies conducted at LAB Scantox, TrGA is non hazardous based on acute oral studies according to the classification scenario in the Directive of the Commission 93/21/EEC of April 27, 1993. TrGA is not an eye and skin irritant (Note: these studies were done as part of assessing worker safety). In genotoxicity studies, TrGA is not mutagenic, clastogenic or aneugenic. Daily administration of TrGA by oral gavage for 90 consecutive days did not result in adverse systemic toxicity or adverse effects on clinical chemistry, hematology, functional observation tests and macroscopic and histopathologic examinations.

In addition, Genencor, a Danisco Division, has conducted two safety (pathogencity) studies on *T reesei* itself - one study on a recombinant strain using the same host strain, for the production of endoglucanase I, and another study on a classical strain used to make cellulase, xylanase and beta-glucanase. This strain was also derived from the same host strain but through mutation and selection. Genencor, A Danisco Division, has also conducted many safety studies on *T. reesei* derived enzymes.

(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

Nutritional considerations:

TrGA is a protein and any residual amounts remaining in food consumed would have the same nutritional value accordingly. However, the use levels of TrGA are very low, and will be removed in most instances. As with other enzymes that are currently approved and used as processing aids, use of this product would have an insignificant impact on the nutritional value of the food.

Technological considerations:

The glucoamylase enzyme preparation will be used as a processing aid to hydrolyze starch, e.g., for syrup, dextrose or maltose production and in grain processing, brewing, potable alcohol and baking.

In *grain processing/sweetners production* the hydrolysates obtained from glucoamylase treatment will be subjected to filtration and various additional purification steps (filtration, carbon treatment, ion exchange) effectively removing all of enzyme protein. Negligible carryover of the TrGA is expected.

In *brewing* the liquid containing the fermentable sugars (wort) is separated from the solids (mash) by filtration steps and ultimately boiled for 1-1.5 hrs for sterilization. With Tm value of 74º C, this boiling process will inactivate the TrGA completely.

In *potable alcohol* at the end of fermentation any TrGA protein precipitate will be removed with the solids. In addition the liquids are distilled, which will irreversibly denature the enzyme.

In *baking* the temperature in the center of the bread goes above 90ºC and above 110 ºC at the surface of the bread. Considering the Tm value of TrGA is 74º C, it is expected that TrGA will be inactivated.

A more thorough description of the various application processes and fate of the glucoamylase will be presented in final dossier.

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

1. Grain processing/sweeteners production – 0.047 mg enzyme protein/g

   In this assessment, an application rate of 47 g enzyme protein per metric ton of starch dry substance used to represent a worst

2. Brewing – 0.132 mg enzyme protein/ml of beer

   In this assessment, an application rate of 774 g enzyme protein per metric ton of grist is used to represent a worst case scenario.

3. Potable Alcohol – 0.120 mg enzyme protein/ml of potable alcohol

   In this assessment, an application rate of 77 g enzyme protein
   Product per metric ton of equivalent starch dry is used to represent a worst case scenario.

4. Baking - 0.204 mg enzyme protein/g of bread

   In this assessment, an application rate of 0.310 mg enzyme protein per g of flour used to represent a worst case scenario.

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

Although it is expected that residues of a processing aid in the final products would be inactivated and negligible after processing, a worst-case-scenario approach is used in this risk assessment assuming that:

(1) 100% of the above commodities are treated with TrGA enzyme product
(2) Human's consumption consists of only commodities treated with TrGA
(3) 100% of TrGA is not removed during processing

Maximum Daily Exposure to TrGA =

0.065 mg enzyme protein/kg bw/day from all sweeteners

0.495 mg enzyme protein/kg bw/day from brewing

0.027 mg enzyme protein/kg bw/day from potable alcohol

0.832 mg enzyme protein/kg bw/day from bakery

Total = 1.419 mg enzyme protein /kg bw/day from all commodities

A more in dept presentation and explanation of the calculations, the data and references will be included in the final dossier

Other information as necessary

None.

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

November 2012

JAPAN

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):	Annatto extracts, bixin-based (INS 160b(i)) and Annatto extracts, norbixin-based (INS 160b(ii))
Question(s) to be answered by JECFA *(kindly provide a brief justification of the request in case of re-evaluations)*	Revision of specifications (Change of purity test and revise of specific limits for residual solvents)

1. Proposal for inclusion submitted by: JAPAN

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

Annatto extracts, bixin-based (INS 160b(i)) and Annatto extracts, norbixin-based (INS 160b(ii))

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** (Please indicate contact person):

Dr. Hiroshi Akiyama, Head of Department of Food Additives,

National Institute of Health Sciences, Tokyo Japan

TEL:+81-3-3700-9484 FAX: +81-3-3700-9484 E-mail: akiyama@nihs.go.jp

6. Justification for use: red/orange colorants

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):

GSFA provisions of annatto extracts are as follows.

1) Annatto extracts, bixin-based (INS 160b(i)): food category: 02.2.1 (butter), use level:<20mg/kg

2) Annatto extracts, norbixin-based (INS 160b(ii)): no provision, currently.

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/ Annatto extracts are permitted for use in many countries (the European Union, the United States, Japan, etc.)

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

Technological data

Revision of specifications (Change of purity test and revise of specified limits for residual solvents)

We found that the analytical method for residual solvents in annatto extracts, which is recommended by JECFA, cannot be applied to annatto extracts, since commercial annatto extracts are insoluble in water designated as a diluent for headspace gas chromatography and the residual solvents cannot be precisely determined. Japan would like to propose an alternative analytical method for residual solvents using a polar organic solvent, such as dimethylformamide (DMF). The proposed method can be applied to precisely determine residual solvents such as methanol, acetone, hexane and 2-propanol. The data determined using the proposed analytical method are available upon request. Furthermore, according to our data, we would also like to propose the revision of specified limits for residual solvents in annatto extracts.

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

December 1, 2012