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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9(a) **CX/FA 09/41/11**

February 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-first Session

Shanghai, China, 16-20 March 2009

Proposals for Additions and Changes to the Priority List of Food Additive proposed for evaluation by JECFA (replies to CL 2008/26-FA)

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

Australia, Japan, Switzerland and IFAC

AUSTRALIA

AUSTRALIA is pleased to respond to Part (i) of CL 2008/26-FA by nominating **Steviol Glycosides (SG)** to the CCFA's "Priority List of Food Additives Proposed for Evaluation by JECFA" during the 41st Session of the CCFA (Shanghai, China on 16-20 March 2009), for revision of specifications.

AUSTRALIA believes that its nomination meets all the criteria elaborated in Annex 1 of CL 2008/26-FA for inclusion of a food additive in the Priority List for JECFA review. Accordingly, we are attaching a completed Annex 2 ("Form on which Information on the Additive to be Evaluated by JECFA is Provided") as prescribed by the CL.

AUSTRALIA views the nomination of SG to the Priority List for revision of specifications, as noted below, in the light of promoting fair trade and supporting innovation in food technology, while protecting the public health. AUSTRALIA contends that the proposed revision is grounded in sound science and reflects advances in the development of new food ingredients and analytical methodology.

According to the most recently revised specifications for SG (69th JECFA, 2008):

> "**Stevioside** and **rebaudioside A** are the component glycosides of principal interest for their sweetening property. Associated glycosides include **rebaudioside C**, **dulcoside A**, **rubusoside**, **steviolbioside**, and **rebaudioside B** generally present in preparations of steviol glycosides at levels lower than stevioside or rebaudioside A."

The 69th JECFA established a full ADI for SG of 0-4 mg/kg bw, expressed as steviol, the aglycone of each of the component glycosides. This ADI applies to all preparations of SG meeting the current specifications for which the assay is given as: "Not less than 95% of the total of the seven named steviol glycosides, on the dried basis."

AUSTRALIA is requesting a further revision of the JECFA specifications to recognize preparations of SG containing enhanced levels of two minor glycosides of native *Stevia rebaudiana* Bertoni. These glycosides are **rebaudioside D**, and **rebaudioside F**. Both of these glycosides possess sweetening properties similar to the two principal sweet glycosides noted above. SG preparations containing enhanced levels of rebaudioside D and rebaudioside F are now commercially available, but they cannot meet the JECFA assay, because neither rebaudioside D nor rebaudioside F are listed as one of the named steviol glycosides in the newly revised JECFA specification. AUSTRALIA believes that the toxicological evaluation by the 69th JECFA supports the inclusion of rebaudioside D and rebaudioside F in the JECFA monograph for SG as a named glycoside because, at a minimum, these glycosides were present in samples used in the 90-day and reproductive studies reviewed by JECFA. Further, these glycosides, when ingested, behave in the same

manner as the named glycosides, that is, it is metabolized to steviol - the compound on which the permanent ADI is based. Additionally, rebaudioside D and rebaudioside F have been demonstrated by the latest analytical methods to be present at various concentrations in stevia leaves from different geographies.

AUSTRALIA appreciates the opportunity to nominate SG to the CCFA Priority List for further consideration by JECFA, particularly with respect to including rebaudioside D as a named steviol glycoside in the SG specifications monograph.

Annex: Form on Which Information on the Additive to be evaluated by JECFA is Provided

1. Proposal for inclusion submitted by:
   Australia
2. Name of compound; trade name(s); chemical name(s):
   Steviol glycosides
3. Name and addresses of basic producers
   Cargill, Incorporated
   15407 McGinty Rd
   Wayzata, MN 55391
   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)
   Amy Boileau, Cargill Incorporated
6. Justification for use:
   The additive Steviol glycosides is of principal interest for its sweetening properties. It is thermally and hydrolytically stable for use in a variety of foods, including acidic beverages, under normal conditions of processing and storage. As its components undergo no chemical change during production or in its use in formulating commercial products, some consumers may prefer this naturally derived sweetener as an alternative to a synthetic high intensity sweetener.
7. Food products and food categories within the GSFA in which the compound(s) are used, including use level(s):

Category	Typical Max Use Level
Non-alcoholic, water-based flavored drinks	600 ppm
Fruit juice based drinks	600 ppm
Confectionary, with no added sugar	1,000 ppm
Jams or jellies, energy reduced	1,000 ppm
Chewing gum	10,000 ppm
Sauces	1,000 ppm
Yogurt	500 ppm
Pickles	1,000 ppm

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?
   Australia, New Zealand, Japan, Brazil
9. List of data (toxicology, dietary exposure, specification on chemical identity and purity, analytical methods) available:
   Current JECFA specifications exist and proposed revised specifications are available.
   The necessary additional toxicology data to support this proposal are available and can be provided upon request.
10. Date on which data could be submitted to JECFA
    June, 2009

JAPAN

In response to the Codex Circular Letter CL 2008/26-FA (August 2008), Japan would like to provide information to the Codex Committee on Food Additives (here after CCFA) about "Aluminum compounds".

Aluminium compounds

Aluminum-containing compounds were included in the priority list of food additives proposed for JECFA evaluation at the 40th Session of CCFA. Last year, Japan provided information on our plans to conduct bioavailability study, and developmental toxicity and a multi-generation study of aluminium-containing compounds, which were required by JECFA for assessment. Hereunder we provide additional information about these studies.

(a) The following studies are currently in progress.

- Bioavailability study; Aluminium sulfate, Aluminium ammonium sulfate and Aluminium lactate
- Developmental toxicity and multi-generation study; Aluminium sulfate and Aluminium ammonium sulfate.

(b) The data would be available by the end of 2009.

SWITZERLAND

In reply to the Codex Circular Letter CL 2008/26-FA of August 2008, Switzerland is pleased to submit the following request in view of the inclusion of the food additive Pullulan on the Priority List of food additives, contaminants and naturally occurring toxicants proposed for evaluation by JECFA which will be reviewed at the forthcoming 41st session of the Codex Committee on Food Additives due to be held in Shanghai, China, from 16th to 20th March 2009.

Switzerland is convinced that the candidate food additive Pullulan, and its proposed assessment as a dietary fibre / slow digestible carbohydrate, meets the criteria for the inclusion in the Priority List laid down in Annex 1, and thereby provides the requested information in Annex 2 as follows:

INFORMATION ON THE ADDITIVE TO BE EVALUATED BY JECFA

1. Proposal for inclusion submitted by:
   Switzerland
2. Name of compound; trade name(s); chemical name(s):
   Pullulan
   INS No. 1204
3. Names and addresses of basic producers:
   Hayashibara Biochem. Inc.
   2-3 Shimoishii 1-chome
   Okayama 700, Japan
4. Has the manufacturer made a commitment to provide data?
   Yes
5. Identification of the manufacturer that will be providing data (contact details):
   Bioresco Ltd.
   Food Scientific and Regulatory Services
   Bundesstrasse 29
   4054 Basel, Switzerland
6. Justification for use:
   Pullulan is currently used in many Codex Member States
   - as a glazing agent / film-forming agent preventing foodstuffs from oxidation, providing gloss;
   - as a thickener improving texture, providing viscosity and adhesiveness to foodstuffs;
   - as a carrier of herbs, spices, flavourings, food colours; and

- as a dietary fibre / slow digestible carbohydrate, used

  (i) as a capsule shell replacing gelatine;

  (ii) as tablets, wafers replacing other dietary fibres and other carbohydrates.

  As for other dietary fibres / slow digestible carbohydrates, a wider use of Pullulan as a nutritive substance can also be expected.

At the 65th JECFA Meeting which took place in June 2005, Pullulan was evaluated by JECFA as a glazing agent, film-forming agent and thickener.

Pullulan is increasingly being used as a dietary fibre / slow digestible carbohydrate. We therefore propose the extension of the JECFA safety assessment of Pullulan for its use as a dietary fibre / slow digestible carbohydrate.

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

F. C. No.	Food Category	Maximum use level (mg/kg)	Function
04.1.1	Fresh fruit	30'000	glazing agent
04.2.2.1	Frozen vegetables	30'000	glazing agent, thickener
04.2.2.7	Fermented vegetables	30'000	glazing agent
06.2.1	Flours	50'000	thickener
06.4.1	Fresh pastas and noodles and like products	10'000	glazing agent, thickener
06.4.2	Dried pastas and noodles and like products	10'000	glazing agent, thickener
07.2.2	Other fine bakery products	GMP	film-forming agent (wafers)
09.2	Processed fish and fish products	30'000	glazing agent, thickener
10.2.1	Liquid egg products	20'000	glazing agent, thickener
10.2.2	Frozen egg products	20'000	glazing agent, thickener
11.4	Other sugars and syrups	10'000	glazing agent, thickener
12.2.1	Herbs and spices	30'000	glazing agent, thickener (carrier)
13.1.	Infant formulae, follow-up formulae	30'000	thickener
13.2.	Complementary foods for infants & young children	30'000	thickener
13.6	Food supplements	GMP	glazing agent, film-forming agent (capsule shells)
14.1.5	Coffee, coffee substitutes, tea, herbal infusions	4'000	glazing agent, thickener

8. Has the compound been approved for use in 2 or more countries?

   In Japan, Pullulan is used as a food ingredient for a variety of applications since 1976. To date, more than three thousand metric tons of Pullulan have entered the Japanese food chain.

   In the United States of America, the FDA has accepted the petitioner's GRAS notice without further questions (GRAS Notice No. GRN 000099). This notice covers a wide range of applications with an aggregated estimated daily intake (EDI) of 9.4 and 18.8 g for the mean and 90th percentile consumer, respectively.

   In the European Community, Pullulan is authorised for use as a coating of food supplements in capsule and tablet form (GMP), and in breath freshening micro-sweets in the form of wafers, films (GMP).

9. List of data available:

   Appropriate toxicological and other information which support the extension of the safety assessment to include the use of Pullulan as a dietary fibre / slow digestible carbohydrate.

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

    In the course of 2009 upon request from the JECFA Secretary.

We sincerely appreciate this opportunity to submit our comments and we look forward to an interesting exchange of views at the forthcoming session of the Codex Committee on Food Additives.

IFAC (THE INTERNATIONAL FOOD ADDITIVES COUNCIL)

IFAC is pleased to submit the following comments in response to CL 2008/26-FA.

Appendix 3 – Priority List of Food Additives Proposed for Evaluation by JECFA

Aluminium compounds – IFAC has agreed to provide information for Aluminium phosphates. That data is expected to be available in 2010. IFAC, therefore, requests that Aluminium compounds be scheduled for further review by JECFA in 2011.