

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

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 Substance(s):	<i>INS 960 steviol glycosides (rebaudioside A and M respectively)</i>
Question(s) to be answered by JECFA <i>(Provide a brief justification of the request in case of re-evaluations)</i>	<i>Request for a revision of specifications for Rebaudioside A from Multiple Gene Donors Expressed in Yarrowia Lipolytica (FAO JECFA Monograph 19 (2016)).</i> <i>The purpose is to revise the specifications (2016 Monograph) on Rebaudioside A from Multiple Gene Donors Expressed in Yarrowia by including data on Rebaudioside M and renaming the specifications as appropriate (e.g. Steviol glycosides produced by Yarrowia lipolytica).</i>

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 substance; trade name(s); chemical name(s):

Steviol glycosides

3. Names and addresses of basic producers:

DSM Food Specialties, PO Box 1, 2600 MA Delft, The Netherlands Tnv Dr J.A.G. van de Wiel, PP 600-0250

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):

DSM Food Specialties contact person: Jeanine van de Wiel, Jeanine.Wiel-van-de@DSM.com

6. Justification for use:

The GSFA includes provisions for steviol glycosides used as sweetener. The proposed revision of the specifications does not alter the justification which had been provided for the adopted GSFA provisions.

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



INS960FoodCategoriesCXS_192eApril2015.

See attachment

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

≥ 95% Rebaudioside A product produced by Yarrowia lipolytica has GRAS status, has got an endorsed JECFA Monograph and is currently under evaluation by EFSA.

The ≥95 Rebaudioside M product produced by Yarrowia lipolytica will be submitted to FDA at the beginning of 2018 as well as to the EU Commission for evaluation by EFSA in the first half of 2018.

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

Toxicological data

- (i) Metabolic and pharmacokinetic studies:

Not by our company but publications in Scientific literature on the same compounds Steviol glycosides available and scientific evaluations by EFSA and JECFA

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

Yes, 90-day study with actual \geq 95% Rebaudioside M material, Ames test and Mouse Nucleus test as in vitro mutagenicity tests were performed.

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

Not by our company but publications in scientific literature on Steviol glycosides available and have been evaluated by EFSA and JECFA

- (iv) Other data: No

Technological data

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

Yes, along the same lines as proposed for the DSM Rebaudioside A product that was evaluated by JECFA earlier

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

Yes, along the same lines as proposed for the DSM Rebaudioside A product that was evaluated by JECFA earlier.

Intake assessment data

- (i) Levels of the listed substance 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 by using the Steviol glycosides regulatory status as a sweetener in several food categories with established limits and conditions for use.

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

Yes, by using the FAIM model for the EU countries.

Other information (as necessary/identified)

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

In June 2018.