CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Items 2 and 3a **CRD07**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-second Session

Comments of the Codex Secretariat

Item 2

MATTERS FROM CCNFSDU41: INCLUSION OF XANTHAN GUM (INS 415) AND PECTINS (INS 440) IN FOOD CATEGORY 13.1.3 "FORMULAE FOR SPECIAL MEDICAL PURPOSES FOR INFANTS" OF THE GSFA

Background

1. The 49th Session of Codex Committee on Food Additives (CCFA49, 2017)[1] considered action required as a result of changes in the acceptable daily intake (ADI) status and other recommendations arising from the 82nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and agreed to refer the results of JECFA evaluation to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) for consideration of the inclusion of pectins (INS 440) and xanthan gum (INS 415) in relevant standards.

2. CCNFSDU41(2019)[2] agreed to forward to 43rd Session of the Codex Alimentarius Commission (CAC43) for adoption the provisions for xanthan gum (INS 415) and pectins (INS 440) as thickeners in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).

3. CAC43 (2020)[3] adopted these provisions forwarded by CCNFSDU41.

4. CCNFSDU41 requested CCFA include xanthan gum (INS 415) and pectins (INS 440) in food category 13.1.3 "Formulae for special medical purposes for infants" of the *General Standard for Food Additives* (GSFA, CXS 192-1985).

Recommendations

5. In light of the of the information above, CCFA52 is requested to consider: i) the request of CCNFSDU41 under paragraph 4 (four) above; and ii) forwarding the following provisions in the GSFA for adoption by CAC44:

Under FC 13.1.3 "Formulae for special medical purposes for infants"

Additive	INS	Step	Year	Max Level	Notes
Pectins	440	5/8	2021	2000mg/kg	14, 72
Xanthan gum	415	5/8	2021	1000mg/kg	New Note: in powdered hydrolysed protein and/or amino acid based infant formula only

Note 14: For use in hydrolyzed protein liquid formula only.
Note 72: On the ready-to-eat basis

[1] REP17/FA Appendix II
[2] REP20/NFSDU para 167
[3] REP20/CAC para 83 and Appendix II

Item 3a

ADDITION/REMOVAL OF INDIVIDUAL FOOD ADDITIVES UNDER THE GROUP HEADING STEVIOL GLYCOSIDES IN THE GSFA

Background

General information

1. CCFA51[4] noted that the Procedural Manual provided specific considerations for the inclusion of individual food additives as group food additives. CCFA51 clarified that in the future, a JECFA recommendation to CCFA to include an additive in a group header for food additives in the GSFA, would be discussed under agenda item 3(a), "Matters of interests arising from FAO/WHO and JECFA", and that the decision of the committee would be captured both in the body of the report and its respective appendix.

2. As described in the preamble of the GSFA, only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe by JECFA; and an International Numbering System (INS) designation by Codex will be considered for inclusion in this Standard.

Existing provisions for steviol glycosides

3. Currently in the GSFA, the group header of STEVIOL GLYCOSIDES includes additives assigned with INS 960b(i) and INS 960a.

STEVIOL GLYCOSIDES

The provisions that follow are defined at the additive group level, and thus apply to the *total* content of the a
group. Additives that make up this group are provided for reference only.

Participating Additive(s)

INS No.	Additive Name
960b(i)	**Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica**
960a	**Steviol glycosides from Stevia rebaudiana Bertoni (Steviol glycosides from Stevia)**

4. In the *Class Names and the International Numbering System for Food Additives* (CXG 36-1989), the group header STEVIOL GLYCOSIDES as well as the individual additives (under this group header) are demonstrated as below..

960	**Steviol glycosides**	
960a	Steviol glycosides from *Stevia rebaudiana* Bertoni (Steviol glycosides from Stevia)	Sweetener *sweetener*
960b	**Steviol glycosides from fermentation**	
960b(i)	Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*	Sweetener *sweetener*

Agenda items relating to steviol glycosides in CCFA52

5. CCFA52 will consider matters related to STEVIOL GLYCOSIDES under the following three agenda items.

6. Under agenda item 3a, JECFA explained the framework for developing specifications for steviol glycosides by method of production. JECFA determined that no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% steviol glycosides as per existing specifications. JECFA indicated that the ADI of 0–4 mg/kg bw established at the 69th meeting of JECFA for STEVIOL GLYCOSIDES (expressed as steviol) applies to steviol glycosides produced by the four methods indicated in the annexes of the specifications monograph produced at the current meeting.

7. Under agenda item 3b, JECFA included specifications for steviol glycosides produced by different production methods (annexes) as follows and designated them as full:

- Annex 1: Steviol Glycosides from Stevia rebaudiana Bertoni (revised from the specifications monograph for Steviol glycosides from Stevia rebaudiana Bertoni (INS 960a) prepared at the 84th JECFA)

[4] REP19/FA para 8

- Annex 2: Steviol Glycosides from Fermentation (revised from the specifications for Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica (INS 960b(i)) prepared at the 82nd JECFA to include other steviol glycosides from Saccharomyces cerevisiae)
- Annex 3: Enzyme Modified Steviol Glycosides (new specifications)
- Annex 4: Enzyme Modified Glucosylated Steviol Glycosides (new specifications)

8. Under agenda item 6, the Electronic Working Group (EWG) on INS proposed to assign INS 960c to "enzyme modified steviol glycosides", INS 960d to "enzyme modified glucosylated steviol glycosides" and insert the functional class of "Sweetener" and the technological purpose of "*Sweetener*" to these two food additives as well as to "steviol glycosides from fermentation (960b)". For details, please refer to the table below:

INS No.	Name of food additive	Functional class	Technological purpose
960b	Steviol glycosides from fermentation	**Sweetener**	***Sweetener***
960c	**Enzyme modified steviol glycosides**	**Sweetener**	***Sweetener***
960d	**Enzyme modified glucosylated steviol glycosides**	**Sweetener**	***Sweetener***

Recommendations

9. Based on CCFA51's decision and in view of the fact that the relevant specifications and INS numbers will be considered under agenda item 3b and 6 respectively, it is proposed that CCFA52 consider:

i. Including "steviol glycosides from fermentation", "enzyme modified steviol glycosides" and "enzyme modified glucosylated steviol glycosides" under the group header "steviol glycosides" in the GSFA depending on the endorsement of the corresponding specfications under agenda item 3b as well as the INS numbers and associated functional classes under agenda item 6; and

ii. Removing "rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i))" from the GSFA as it has been covered by "steviol glycosides from fermentation (INS 960b)".

10. Specifically, CCFA52 is invited to consider the proposal on addition/removal of individual food additives under the group heading steviol glycosides in the GSFA contained in Annex I of this CRD.

Annex I

ADDITION/REMOVAL OF INDIVIDUAL FOOD ADDITIVES UNDER THE GROUP HEADER STEVIOL GLYCOSIDES IN THE GSFA

STEVIOL GLYCOSIDES*

Note: All additions are shown in **bold underlined** font; all deletions are shown in strikethrough font.

960a	Steviol glycosides from Stevia rebaudiana Bertoni (Steviol glycosides from Stevia)	Functional class: Sweetener
960b	**Steviol glycosides from fermentation**	**Functional class: Sweetener**
~~960b(i)~~	~~Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica~~	~~Functional class: Sweetener~~
960c	**Enzyme modified steviol glycosides**	**Functional class: Sweetener**
960d	**Enzyme modified glucosylated steviol glycosides**	**Functional class: Sweetener**

**These revisions are subject to the recommendations for adoption by CCFA52 relating to the specifications (under agenda item 3b) and INS numbers and functional classes (under agenda item 6).*

If the specification (under agenda item 3(b)) and INS numbers and functional classes (under agenda item 6) are agreeable, CCFA52 will be invited to confirm the decision and to replace the footnote * with *Depending on the adoption by CAC44 relating to the Specifications, INS numbers and functional classes*.