

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

CX/FA 18/50/11 Add.1

March 2018

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

PROPOSED DRAFT REVISION TO THE *INTERNATIONAL NUMBERING SYSTEM (INS) FOR FOOD ADDITIVES (CXG 36-1989)*

Comments at Step 3 of Brazil, Columbia, Paraguay, Republic of Korea, United States of America, CCC, EFEMA, EU Specialty Food Ingredients, IACM, ICGMA, IFAC and ISC

Brazil

- (i) **Brazil** Consider the replies to the CL 2017/46-FA requesting proposals for changes and/or additions to the INS list; and prepare a proposal for circulation for comments at Step 3.

Brazil supports the addition of the functional class of “glazing agent” and the technological purposes of “glazing agent” and “surface-finishing agent” to mono and di-glycerides of fatty acids (INS 471).

- (ii) **Addition of sequestrant function to malic acid DL (INS 296)**

As stated previously, Brazil supports the addition of sequestrant function to malic acid (INS 296).

- (iii) **The issue of naming steviol glycosides and INS number**

Brazil supports the proposal.

Colombia

COMENTARIO GENERAL

Colombia agradece al Grupo de Trabajo la actividad realizada y la oportunidad de formular observaciones. En ese sentido desea expresar su apoyo a la actualización de la lista del SIN para algunos aditivos alimentarios como se indica en el Cuadro 1 del Anexo 1 del documento CX/FA 18/50/11.

De otra parte, Colombia considera que se deben esperar las especificaciones de JECFA relativas a los Glicósidos de Esteviol de Fermentación, antes de establecer una clasificación para los mismos en la lista del SIN.

Colombia recomienda que al momento de establecer la clasificación de los Glicósidos de Esteviol se tenga en cuenta el impacto que estos pueden tener en el rotulado de los alimentos, de acuerdo a la extensión en las denominaciones propuestas, en especial para productos que se comercializan en empaques de áreas superficiales pequeñas como los productos de confitería.

Paraguay

ENGLISH

Paraguay believes that INS 960 should not become a parent additive, but manifests the need of assigning another INS number to steviol glycosides obtained by technological processes different from the one in the definition of INS 960 in JECFA Monograph 20, in order to avoid confusion or deceit to the consumer.

In addition, we consider that JECFA should first develop and revise the specifications of steviol glycosides obtained by other processes (such as fermentation and enzymatic modification), before making any decision on INS number involving INS 960. Therefore, we recommend that the Committee postpones the work related to the INS of steviol glycosides.

Finally, we would like to point out that consumers choose stevia as a sweetener due to its natural origin and plant-based characteristics, thus we encourage the CCFA to take into account that although the substances under discussion have a similar ADI, it is extremely important that the INS displays the difference of both the process and the source material utilised to obtain steviol glycosides.

ESPAÑOL

Paraguay cree que el SIN 960 no debe constituirse en un aditivo principal o aditivo padre, y además recomienda la asignación de otro número SIN a los glucósidos de esteviol que se obtienen por procesos tecnológicos diferentes a lo expresado en la definición de aditivo SIN 960 en la Monografía 20 del JECFA, a fin de evitar confusión o engaño al consumidor.

Además considera que el JECFA debe desarrollar y revisar las especificaciones de los glucósidos de esteviol obtenidos por otros procesos (como los de fermentación y modificación enzimática), antes de tomar decisiones sobre los números SIN que involucren al aditivo SIN 960. Por lo tanto, se recomienda que el CCFA posponga los trabajos relacionados al SIN de glucósidos de esteviol.

Por último, recalamos que los consumidores eligen a la estevia como edulcorante por su origen vegetal y natural, por lo que solicitamos al Comité que tenga en cuenta que si bien las sustancias en discusión tienen IDA similar, es sumamente importante indicar a través del SIN la diferencia de los procesos y de materiales fuente empleados en la obtención de glucósidos de esteviol.

Republic of Korea

Tamarind seed polysaccharide

The Republic of Korea supports the assignment of INS number of tamarind seed polysaccharide. We can use the tamarind seed polysaccharide as thickener and stabilizer.

United States of America

Mono- and diglycerides of fatty acids (INS 471)

The United States supports the addition of the functional class of “Glazing agent” and the technological purposes of “Glazing agent” and “Surface-finishing agent” to Mono- and di- glycerides of fatty acids (INS 471). Mono- and di- glycerides of fatty acids are Generally Recognized as Safe (GRAS) in the United States for use in food in general, as well as specifically for use as surface-finishing agents in food (21 CFR 184.1505). In addition, in a recent GRAS notification (GRN 648), the U.S. Food and Drug Administration had no questions regarding the use of INS 471 as a surface-finishing agent to protect freshness and extend shelf-life of agricultural products such as fruits (e.g., berries, grapes, citrus, bananas, mangoes, avocados) and vegetables (e.g., legumes, roots, tubers). The United States can support the proposal put forward by the INS eWG in Annex 1 of CX/FA 18/50/11 regarding Mono- and diglycerides of fatty acids.

Steviol glycosides (INS 960)

One of the tasks considered by the INS eWG was the establishment of new INS numbers and names for Steviol glycosides described in two specifications monographs recently prepared by JECFA: “Steviol glycosides from *Stevia rebaudiana* Bertoni” and “Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*”. Paragraphs 12 to 21 of CX/FA 18/50/11 provide a thorough summary of the issues facing CCFA regarding the assignment of these new INS numbers and names. One of the points made in the summary is that JECFA has not yet completed the review of some of the new technologies used to produce some Steviol glycosides (i.e., fermentation, enzyme treatment, and bio-conversion). This point is even more relevant now, as additional proposals for Steviol glycosides have been put forward for consideration by CCFA50 for inclusion on the JECFA priority list (see CX/FA 18/50/12). As JECFA has not yet completed its work on the evaluation of Steviol glycosides from all currently employed technologies, it seems premature for CCFA to establish new INS names and numbers for these Steviol glycosides. Since JECFA has further work to perform on Steviol glycosides, any INS names or numbers put forward by CCFA at this time may need to be changed in the future once JECFA has completed its work. Such changes could be potentially very disruptive for users of the INS system and the General Standard for Food Additives. As a result, the United States proposes that CCFA postpone establishment of new INS names and numbers for these Steviol glycosides until JECFA has had the opportunity to finish their review on the new technologies.

In addition, the new INS names and numbers that CCFA puts forward for Steviol glycosides from new technologies have the potential to be precedent setting in terms of the use of alphabetical suffixes or numerical subscripts for other additives in the future. It therefore makes sense that CCFA wait to make potentially precedent setting changes for Steviol glycosides until JECFA can present CCFA with all pertinent information that can be used to make the best decisions for the establishment of additional INS names and numbers for Steviol glycosides.

Calorie Control Council (CCC)

The Calorie Control Council (CCC) is an international association of manufacturers and end users of low-, no-, and reduced calorie ingredients, foods and beverages and holds non-governmental observer status with Codex Alimentarius.

With regard to the INS numbering for steviol glycosides, which is proposed for consideration at the upcoming CCFA Session, CCC believes it would be a more effective and efficient approach to delay this activity until the eWG on the JECFA priority list has reviewed and considered additional steviol glycosides that have been added or proposed to be added to the JECFA priority list for evaluation. The International Stevia Council (ISC) has submitted a proposal for JECFA to develop separate monographs for steviol glycosides produced through alternative technologies which are outside of the current specification for steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni and to confirm that the glycosides produced through these alternative technologies are covered by the current ADI. We believe these JECFA evaluations should be completed prior to a discussion on INS labeling for steviol glycosides, which would allow CCFA to consider all of these applications at the same time, ensure the most effective use of JECFA's resources, and set a positive precedent for future additives (e.g. mogrosides – monk fruit) which are produced through multiple technologies and fall under the same ADI.

Further, regarding the INS eWG's first and second circulars, it should be noted that very few Member Countries provided a position on the naming of steviol glycosides. This lack of broad feedback indicates a clear reluctance by most countries to take a strong position, and could suggest that many countries are waiting for CCFA because they do not have the appropriate background on the new technologies to formulate a position. The ISC proposal to develop the additional JECFA monographs will allow countries to become more educated on the various technologies and their consistent safety profile.

In summary, CCC proposes to postpone the INS numbering of steviol glycosides at CCFA until after the JECFA review of all pending and proposed steviol glycosides applications. We appreciate the opportunity to comment on this CL and intend to actively participate in this issue at CCFA. If you have any questions, please contact me.

European Food Emulsifier Manufacturers Association (EFEMA)

EFEMA wishes to express its support to the addition of the "stabilizer" function class to sorbitan monostearate (INS 491). EFEMA initially applied for this addition. We therefore strongly support this inclusion into the INS list, for the following reasons:

- In the European Union, Sorbitan monostearate is used as a stabilizer in yeast (category 12.8)¹, as it helps the stabilization of the yeast during drying. This use corresponds to the Codex definition of a "stabilizer", which is according to the Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989)², a "food additive which makes it possible to maintain a uniform dispersion of two or more components".
- Finally, in the General Standard for Food Additives (GSFA)³, INS 491 is regulated together with INS 492, INS 493, INS 494 and INS 495 under the heading "Sorbitan esters of fatty acids". Sorbitan tristearate (INS 492), Sorbitan monolaurate (INS 493) and Sorbitan monooleate (INS 494) are all listed as stabilizers in the CAC/GL 36-1989 document as well as in the GSFA.

¹ According to [Annex II to Regulation \(EC\) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives](#), Sorbitan esters including Sorbitan monostearate are indeed authorized at quantum satis in dry yeast and yeast for baking.

² See http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BGL%2B36-1989%252FCXG_036e.pdf

³ See http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCODEX%2BSTAN%2B192-1995%252FCXS_192e.pdf

Federation of European Specialty Food Ingredients Industries (EU Specialty Food Ingredients)

EU Specialty Food Ingredients would like to express its support to the following additions of functional classes/technological purposes:

- **Addition of “gelling agent” function class to gellan gum (INS 418):** This proposed addition was initially submitted by EU Specialty Food Ingredients. We therefore strongly support it. We would like to remind and stress that according to the *Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989)⁴, gellan gum is listed as a “Stabilizer” and “Thickener”. However, in addition to these two technological uses, we note that the “gelling agent” functional use is also endorsed in the JECFA Monograph for gellan gum⁵.
- **Addition of “stabilizer” function class to sorbitan monostearate (INS 491):** According to our information, in the EU, Sorbitan monostearate is used as a stabilizer in yeast (category 12.8), as it helps the stabilization of the yeast during drying. This use corresponds to the Codex definition of a “stabilizer”, which is according to CAC/GL 36-1989, a “*food additive which makes it possible to maintain a uniform dispersion of two or more components*”. Besides, in the GSFA⁶, INS 491 is regulated together with INS 492, INS 493, INS 494 and INS 495 under the heading “Sorbitan esters of fatty acids”. Sorbitan tristearate (INS 492), Sorbitan monolaurate (INS 493) and Sorbitan monooleate (INS 494) are all listed as stabilizers in the CAC/GL 36-1989 document as well as in the GSFA.

International Association of Color Manufacturers (IACM)

As is noted in CX/FA 18/50/11, proposed draft amendments to the International Numbering System for food additives (CXG 36-1989), Grape Color requested via IACM is a different material than Grape Skin Extract. It does not meet the INS 163ii JECFA monograph as the color is extracted from the entire grape and sulfur dioxide is not used. In the United States, this color is currently approved under the fruit juice regulations at 21 CFR 73.250, and in the European Union, this color is currently approved as an anthocyanin (E163).

To meet the request for allocation of an INS number, specifications are not required to establish any further identity of the additive. However, it is the intention of IACM to request JECFA review of this substance soon. We ask that the Committee reconsider addition of grape color to the INS list to establish an INS number in advance of a JECFA review. We appreciate your consideration of this matter and are available to answer any additional questions on the necessity of an INS number for grape color.

International Council of Grocery Manufacturers Associations (ICGMA)

The International Council of Grocery Manufacturers Associations (ICGMA) is a nongovernmental organization that represents food, beverage and consumer packaged goods manufacturers globally. ICGMA promotes the harmonization of food standards and policies based on science and is a staunch supporter of Codex Alimentarius. ICGMA also works to facilitate international trade of food products by eliminating barriers to trade and believes that global harmonization of science-based food standards is important to achieve that goal.

We believe the strike 11 document offers a good starting point of discussion for INS issues at the upcoming 50th Codex Committee on Food Additives (CCFA).

ICGMA wishes to offer comments with regard to the eWG proposal for steviol glycosides. With a recently submitted proposal related to steviol glycosides pending for consideration and listing on the JECFA priority list, ICGMA respectfully recommends that CCFA delay a decision on the INS listing for steviol glycosides until such time that the JECFA proposal can be reviewed for addition to the priority list, and a JECFA evaluation is available to inform the INS decision.

⁴ See http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%252FBGL%252B36-1989%252FCXG_036e.pdf

⁵ See http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph16/additive-199-m16.pdf

⁶ See http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCODEX%252BSTAN%252B192-1995%252FCXS_192e.pdf

ICGMA has been advised that the International Stevia Council (ISC) submitted a thorough proposal for JECFA to develop monographs for steviol glycosides produced through alternative technologies, since they are outside of the current specification for steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni. ISC also requested that JECFA confirm that the glycosides produced through these alternative technologies are covered by the current ADI. Given the relevance of this JECFA evaluation to INS eWG consideration of listing steviol glycosides, ICGMA believes it would be more efficient to delay adoption of the proposed INS changes rather than pressing forward at this meeting and potentially having to make changes after the results of the JECFA evaluation are available. Such a delay will provide a more holistic consideration of steviol glycosides while simultaneously setting precedent for additional steviol glycosides (or similar additives, such as mogrosides – monk fruit) with all relevant information available from JECFA.

Conclusion

ICGMA appreciates consideration of our feedback on CX/FA 18/50/11. We are extremely optimistic about the potential for this discussion paper to begin a productive dialogue at the CCFA50 on challenges and opportunities for the committee moving forward. ICGMA intends to be an active contributor to that discussion and looks forward to working with all stakeholders to advance our shared goals, enhance CCFA efficiency, and ensure the Committee continues to achieve its important mandates.

International Food Additives Council (IFAC)

The International Food Additives Council (IFAC) is a global association of manufacturers of food ingredients, including food additives. IFAC holds non-governmental organization (NGO) observer status before Codex.

With regard to the proposals made by eWG members on the first and second circulars, IFAC supports adding “glazing agent” as a functional class and “glazing agent” and “surface-finishing agent” as technological purposes for mono- and di-glycerides of fatty acids (INS 471). IFAC also supports adding “gelling agent” as a functional class for gellan gum (INS 418). These additions will help additive and finished product manufacturers produce foods that continue to meet the needs of their customers and consumers.

In addition, IFAC is commenting on the proposed INS naming of steviol glycosides. IFAC notes the feedback was provided on the eWG’s first and second circulars was modest in nature and lacked significant input from Member Countries, which suggests a lack of understanding of the topic and/or a reluctance to take a strong position. IFAC also notes there are additional steviol glycosides that have been proposed or accepted for prioritization on the JECFA priority list, including a proposal from the International Stevia Council to have JECFA develop separate monographs for steviol glycosides produced through technologies which are outside the current specification for steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni and to confirm that the glycosides produced through these alternative technologies are covered by the current ADI.

Based on the apparent lack of understanding around steviol glycosides and considering the proposals for JECFA to evaluate additional steviol glycosides, IFAC supports delaying any action by CCFA50 regarding the naming of steviol glycosides in the INS until the additional JECFA evaluations are completed. Delaying this process will provide Member Countries additional time to better understand these technologies and take stronger positions on INS listings. Further, allowing JECFA to review all steviol glycoside technologies together will result in a more efficient and effective process, and will make best use of JECFA’s resources. Finally, as IFAC may be impacted by proposed JECFA and INS reviews for similar additives within the same family in the future, IFAC believes delaying the INS listings for steviol glycosides sets a positive precedent for future additive evaluations.

In summary, IFAC supports CCFA50 endorsement of the proposed INS additions for mono- and di-glycerides of fatty acids and gellan gum. We also support delaying the INS naming of steviol glycosides at CCFA50. Thank you for your consideration. Please let me know if you have any questions.

International Stevia Council (ISC)

With regard to the INS numbering for steviol glycosides, which is proposed for consideration at the upcoming CCFA Session, the International Stevia Council (ISC)⁷ believes it would be a more effective and efficient approach to delay discussion and decision on this agenda item until the eWG on the JECFA priority list has reviewed and considered all steviol glycosides that have been added or proposed to be added to the JECFA priority list for evaluation.

⁷The International Stevia Council (ISC) is the authoritative voice of the stevia industry, representing stevia leaf growers and producers, refiners of stevia extracts as well as users of stevia extracts in final consumer products. ISC activities aim at promoting the use of stevia as a naturally-sourced zero-calorie sweetener so as to improve the diets and health of people globally by moderating calories in food. The ISC is a 501 (c) (6) not-for-profit global organization incorporated under the law of the State of Delaware in the United States (US).

As you might know, the ISC has submitted in January 2018 a proposal for JECFA to develop separate monographs for steviol glycosides produced through alternative technologies which are outside of the current specification for steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni to confirm that the steviol glycosides produced through these alternative technologies are covered by the current ADI.

We believe that these JECFA evaluations should be completed prior to the discussion and decision on INS labelling for steviol glycosides takes place. This would allow CCFA to consider all of these applications at the same time, to ensure the most effective use of JECFA's resources, and to set a positive precedent for future additives (e.g. monk fruit) which are produced through multiple technologies and fall under the same ADI.

In addition, the ISC application to develop the additional JECFA monographs will allow countries to become more educated on the various technologies and their consistent safety profile and will provide them with the appropriate background on the new technologies to then formulate a position on the INS numbering for steviol glycosides.

Therefore, **ISC respectfully ask that CCFA postpones the discussion and decision on the recommendation from the eWG on the naming of steviol glycosides in the INS list until JECFA completes the reviews of all pending and proposed steviol glycosides applications.**