



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

Comments of International Stevia Council (ISC)

Recommendation 1: The International Stevia Council (ISC)¹ recommends the addition in the JECFA priority list of the ISC joint application dossier for the development of separate monographs for steviol glycosides produced through alternative technologies.

Background: On 14 January 2018, ISC submitted to Codex Secretariat a notification for the nomination of substances to be evaluated by JECFA in response to the Circular Letter CL 2017/48-FA of April 2017.

ISC is asking JECFA to prepare stand-alone JECFA specification monographs for steviol glycosides that are produced through technologies outside of the current specification for steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni and to confirm that the glycosides produced through these technologies are covered by the current steviol glycoside's ADI.

These technologies include: a) Fermentation²; b) Bioconversion³; and c) Enzyme modified or glucosylated steviol glycosides⁴.

Goals and Benefits of such a joint application:

The ISC – on behalf of the 4 applicants⁵ - proposes to submit one single application covering three buckets, one per technology (fermentation, bioconversion and enzymatic modification) in order to have 3 JECFA specification monographs. The rationale is that the safety paradigm is the same for all steviol glycosides while each production technology will have its own monograph.

This approach has the following benefits:

- 1) it will reduce and expedite the work of JECFA by decreasing the number of future applications and also by decreasing the review time of the applications falling under the three mentioned specifications and based on the safety paradigm;
- 2) it might create a fundamental ground approach to be then reused for other additives that have multiple manufacturing processes derived from plant extracts;
- 3) companies will see their application going through abbreviated review if their product fulfils the specifications criteria to be in one of the three buckets.

Recommendation 2: ISC recommends the adoption of the updated safety assessment and proposed draft specification of steviol glycosides from *Stevia rebaudiana* Bertoni as prepared at the 84th JECFA meeting. (*Agenda item 3b - CX/FA 18/50/4*)

¹The 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).

² Fermentation: involving the use of genetically modified (GM) microorganisms in the production of steviol glycoside preparations with high levels of a specific rebaudioside such as rebaudioside M or for example, the JECFA specification for rebaudioside A produced from gene donors expressed in *Yarrowia lipolytica* (2016);

³ Bio-conversion: whereupon steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni are enzymatically converted to products containing higher percentages of singular steviol glycosides such as rebaudioside D and M, using isolated purified enzymes generated from (GM) sources, and

⁴ Enzyme modified or glucosylated steviol glycosides: whereupon steviol glycosides extracted from the plant *Stevia rebaudiana* Bertoni are enzymatically modified to larger steviol glycosides using an enzyme system from a non-GM or GM source.

⁵ The applicants are Blue California, Cargill, DSM and Pure Circle: all members of the ISC.

Background; The updated safety assessment and revised full specifications monograph for steviol glycosides from *Stevia rebaudiana* Bertoni have been prepared at the 84th JECFA meeting in 2017 (published in FAO - [JECFA Monographs 20 \(2017\)](#)) and proposed for adoption at the CCFA meeting in March.

These specifications aim at removing the parameters which implicitly indicated that Stevioside and Rebaudioside A should be the principal steviol glycosides in such preparations and will pave the way for a product to contain one or any of the authorized steviol glycosides in any combination or ratio. The specifications also proposed a new method of analysis for the measurement at high purity level of all steviol glycosides molecules existing in the plant, including minor steviol glycosides, (whose names are available in the Appendix 1 of the monograph).

The adoption of the updated safety assessment and revised specifications is important as it enhances the opportunity for different combinations of steviol glycosides extracted from the plant to be used in product innovation and reformulation. These stevia-based preparations have an improved sweetness quality that more closely resembles to sucrose. Thus, the proposed changes to the specifications will result in an increased number of great tasting, naturally-derived sweetened stevia based-products able to achieve increased calories reduction levels while ensuring the same high level of safety and purity.