



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10144/2021 CIS
(POOL/E2/2021/10144/10144-EN
CIS.docx)
[...](2021) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards steviol glycosides (E 960) and rebaudioside M produced via enzyme modification of steviol glycosides from Stevia as a sweetener

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards steviol glycosides (E 960) and rebaudioside M produced via enzyme modification of steviol glycosides from Stevia as a sweetener

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Articles 10(3) and 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) In February 2018 an application was submitted for the amendment of specifications concerning the food additive steviol glycosides (E 960). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The current specifications stipulate that steviol glycosides (E 960) contain not less than 95 % of eleven named steviol glycosides: stevioside, rebaudiosides A, B, C, D, E, F and M, steviolbioside, rubusoside and dulcoside, on a dried basis, in any combination and ratio. The manufacturing process comprises two main phases, the first involving water extraction from the leaves of the *Stevia rebaudiana* Bertoni plant and preliminary purification of the extract, and the second involving recrystallisation of the steviol glycosides.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

- (6) The applicant requests an amendment of the present specifications of stevia glycosides (E 960) to include a new method for the production of higher yield of rebaudioside M via enzymatic bioconversion of purified stevia leaf extract ($\geq 95\%$ steviol glycosides). Rebaudioside M is a minor glycoside present at very low levels ($< 1\%$) in the stevia leaf, which has a taste profile that is more reflective of sucrose when compared to the major glycosides (i.e. stevioside and rebaudioside A).
- (7) The manufacturing process applied to produce higher yield of rebaudioside M involves the bioconversion of purified stevia leaf extract ($\geq 95\%$ steviol glycosides) through a multistep enzymatic process with enzymes prepared at the first stage of the process. Uridine diphosphate (UDP)-glucosyltransferase and sucrose synthase enzymes facilitate the transfer of glucose to steviol glycosides via glycosidic bonds. The resulting rebaudioside M undergoes a series of purification and isolation steps to produce the final rebaudioside M ($\geq 95\%$) determined to be 200 times sweeter than sucrose.
- (8) The European Food Safety Authority ('the Authority') evaluated the safety of the proposed amendment of the specifications of the food additive steviol glycosides (E 960) and expressed its opinion on 24 September 2019⁴. The Authority considered that the enzymatic step process applied to the production of rebaudioside M may result in impurities different from those that may be present in steviol glycosides (E 960) obtained from water extraction of the leaves of the *Stevia rebaudiana* followed by recrystallisation. Therefore, the Authority considered that separate specifications are needed. The existing ADI of 4 mg/kg bw per day can also be applied to Rebaudioside M produced via enzymatic bioconversion of purified stevia leaf extract. The Authority considers that exposure to rebaudioside M (expressed as steviol equivalent) will not be higher than the exposure to steviol glycosides (E 960) if replaced by rebaudioside M produced via enzymatic bioconversion of purified stevia leaf extract. The Authority concluded that rebaudioside M produced via enzymatic bioconversion of purified stevia leaf extract using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffii* UGT-*a* and *K. phaffii* UGT-*b* would not be of safety concern at the same proposed uses and use levels as steviol glycosides (E 960).
- (9) Therefore, it is appropriate to authorise the use of rebaudioside M produced via enzyme modification of steviol glycosides from stevia as a sweetener in the food categories specified in Annex I to this Regulation and to assign E 960c(i) as an E-number to characterise the glycoside compound produced by the enzymatic process. Taking into account the ongoing process for the amendment of the International Numbering System for food additives of the Codex Alimentarius, it is also appropriate to include E 960c(i) in a new food additive class of steviol glycosides 'E 960c enzymatically produced steviol glycosides' as an alternative E-number and name for labelling purposes.
- (10) The specifications for rebaudioside M produced via enzyme modification of steviol glycosides from *Stevia* should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (11) In order to achieve more clarity and coherence, the currently authorised food additive 'steviol glycosides (E 960)' should be renamed to 'steviol glycosides from *Stevia* (E 960a)' and the two new food additive classes of steviol glycosides shall replace the

⁴ EFSA Journal 2019;17(10):5867, 19 pp.

references to ‘steviol glycosides (E 960)’ contained in Annex II to Regulation (EC) No 1333/2008. Namely, the food additive ‘steviol glycosides (E 960)’ should be replaced by ‘steviol glycosides from Stevia (E 960a)’ and ‘enzymatically produced steviol glycosides (E 960c)’ in the Union list of authorised food additives in Part B. In Part C a new group for steviol glycosides, which lists both new additive classes of that additive, shall be inserted so that this group replaces all provisions for steviol glycosides (E 960) in Part E of Annex II to Regulation (EC) No 1333/2008 while maintaining the same authorised uses and use levels.

- (12) The specifications for rebaudioside M produced via enzyme modification of steviol glycosides from Stevia should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (13) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (14) In order to allow economic operators to adapt to the new rules, it is appropriate to provide for a transitional period during which the food additive ‘steviol glycosides’ (E 960) and foods containing those food additives may continue to be marketed under the current name and E-number.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

The food additive ‘steviol glycosides’ (E 960) and foods containing those food additives, labelled or placed on the market up to 18 months after the entry into force of this Regulation and which do not comply with the requirements of ‘stevia glycosides from Stevia (E 960a)’, may be marketed until the stocks are exhausted.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN