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Delegations will find attached document D072115/03.

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COMMISSION REGULATION (EU) …/…

of XXX

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(Text with EEA relevance)

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(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 additives[1], 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 flavourings[2], 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) The Annex to Commission Regulation (EU) No 231/2012[3] lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) The Union list of food additives and the specifications for food additives 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 from a Member State or an interested party.

(4) In February 2018, an application was submitted to the Commission for the amendment of the specifications concerning the food additive steviol glycosides (E 960). The Commission made the application 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) are to contain not less than 95 % of eleven named steviol glycosides: stevioside, rubusoside, dulcoside A, steviolbioside and rebaudiosides A, B, C, D, E, F and M, on a dried basis, in any combination and ratio. The manufacturing process of this food additive 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.

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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 requested an amendment of the specifications of stevia glycosides (E 960) to include a new method for the production of rebaudioside M. 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 new process involves the bioconversion of purified stevia leaf extract (≥95% steviol glycosides) through a multistep enzymatic process with enzymes prepared at the first stage of the process. The resulting rebaudioside M undergoes a series of purification and isolation steps to produce the final rebaudioside M (≥ 95%).

(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 adopted its opinion on 24 September 2019[4]. The Authority considered that the enzymatic step process applied for 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 for rebaudioside M produced with this process are needed. Furthermore, it concluded that the existing Acceptable Daily Intake (ADI) of 4 mg/kg bw per day can also be applied to rebaudioside M produced via enzyme modification of steviol glycosides. The Authority considered 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 the enzymatic step process. The Authority also concluded that rebaudioside M produced by enzyme modification of steviol glycosides, 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 for the same proposed uses and at the same use levels as steviol glycosides (E 960).

(9) Therefore, it is appropriate to authorise the use of rebaudioside M produced via the enzymatic step process as a sweetener in the food categories where steviol glycosides (E 960) are currently authorised.

(10) Taking into account the ongoing process for the amendment of the International Numbering System for food additives of the Codex Alimentarius, it is appropriate to include the new food additive as 'E 960c enzymatically produced steviol glycosides' in Part B of Annex II to Regulation (EC) No 1333/2008 for labelling purposes. In the interest of clarity and coherence, the currently authorised food additive 'steviol glycosides (E 960)' should be renamed to 'steviol glycosides from Stevia (E 960a)'. As those food additives may be regulated combined, a new group for steviol glycosides, including both of them, should be inserted in Part C of Annex II to Regulation (EC) No 1333/2008, and all entries for steviol glycosides (E 960) in Part E of Annex II to that Regulation should be replaced accordingly, while maintaining the currently applicable uses and maximum level for authorised uses and use levels.

(11) The specifications for rebaudioside M produced via enzyme modification of steviol glycosides from Stevia should be included in Regulation (EU) No 231/2012 in parallel with the inclusion of 'E 960c enzymatically produced steviol glycosides' in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008.

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

(12) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

(13) 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 from Stevia (E 960a)’ and foods containing it may continue to be marketed as ‘steviol glycosides (E 960)’.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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 it, which are labelled or placed on the market up to 18 months after the entry into force of this Regulation and which comply with the requirements of this Regulation, 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