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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending the Annex to Regulation (EU) No 231/2012 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, as regards specifications for enzymatically produced steviol glycosides to include rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extract (E 960c(ii)) using the genetically modified yeast <i>K. phaffii</i> CGMCC 7539
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Delegations will find attached document D114904/02.

Encl.: D114904/02



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2025/2943
[Pool/E2/2025/2943/2943-EN]
D114904/02
[...](2026) **XXX** draft

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

of **XXX**

amending the Annex to Regulation (EU) No 231/2012 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, as regards specifications for enzymatically produced steviol glycosides to include rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extract (E 960c(ii)) using the genetically modified yeast *K. phaffii* CGMCC 7539

(Text with EEA relevance)

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

of **XXX**

amending the Annex to Regulation (EU) No 231/2012 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, as regards specifications for enzymatically produced steviol glycosides to include rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extract (E 960c(ii)) using the genetically modified yeast *K. phaffii* CGMCC 7539

(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 Article 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) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) 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.
- (3) The currently authorised food additive ‘enzymatically produced steviol glycosides’ (E 960c) is included in the group ‘steviol glycosides (E960a-E960c)’ in Part C of Annex II to Regulation (EC) No 1333/2008.
- (4) Regulation (EU) No 231/2012 provides that ‘rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts’ (E 960c(ii)) is produced using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401).
- (5) On 22 December 2022, an application was submitted to the Commission for the amendment of the specifications to include in the specifications for rebaudioside M produced via enzyme modification of steviol glycosides from stevia (E 960c(i))

¹ OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>.

² OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/oj>.

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), ELI: <http://data.europa.eu/eli/reg/2012/231/oj>.

rebaudioside M produced via enzyme-catalysed bioconversion using the genetically modified yeast *K. phaffii* CGMCC 7539. However, in the course of the risk assessment, the applicant revised its original proposal and requested the amendment of the specifications for rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts (E 960c(ii)) instead. The Commission made the application available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

- (6) In the opinion published on 14 May 2025⁴, the European Food Safety Authority ('the Authority') evaluated the safety of the proposed amendment of the specifications for rebaudioside M produced via enzyme-catalysed bioconversion using the genetically modified yeast *K. phaffii* CGMCC 7539. The Authority concluded that there is no safety concern with respect to the proposed amendment to the specifications of E 960c(i) or E 960c(ii) in the Annex to Regulation (EU) No 231/2012 related to the use of the new genetically modified strain *K. phaffii* CGMCC 7539 in the manufacturing process of the food additive Rebaudioside M produced via enzyme-catalysed bioconversion. The Authority considered that it is in the remit of the risk managers to decide whether the proposed changes in the specifications should result in an amendment of the already existing specifications of E 960c(i) or E 960c(ii). In addition, the Authority recommended introducing a specific entry for kaurenoic acid in the proposed specifications.
- (7) The Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (8) 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

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

Article 2

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

⁴ EFSA Panel on Food Additives and Flavourings, (2025). Safety of the proposed amendment of the specifications of the food additive E960c(i) or E960c(ii). *EFSA Journal*, 2025;23:e9396, <https://doi.org/10.2903/j.efsa.2025.9396>.

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