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#### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 January 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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No. Cion doc.:	D101844/02
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1333/2008 of the European Parliament and the Council and Commission Regulation (EU) No 231/2012 as regards the use of Steviol glycosides produced by fermentation using <i>Yarrowia lipolytica</i>

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Delegations will find attached document D101844/02.

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Encl.: D101844/02



Brussels, **XXX**  
PLAN/2024/1358 Rev2  
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[...] (2024) **XXX** draft

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

**of **XXX****

**amending Regulation (EC) No 1333/2008 of the European Parliament and the Council and Commission Regulation (EU) No 231/2012 as regards the use of Steviol glycosides produced by fermentation using *Yarrowia lipolytica***

(Text with EEA relevance)

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

of **XXX**

**amending Regulation (EC) No 1333/2008 of the European Parliament and the Council and Commission Regulation (EU) No 231/2012 as regards the use of Steviol glycosides produced by fermentation using *Yarrowia lipolytica***

(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<sup>1</sup>, and in particular Article 10(3) and 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 flavourings<sup>2</sup>, 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 231/2012<sup>3</sup> 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) Steviol glycosides obtained by three different manufacturing processes, namely, steviol glycosides from Stevia (E 960a), enzymatically produced steviol glycosides (E 960c) and glucosylated steviol glycosides (E 960d) are authorised as food additives and defined by separate specifications. These additives are regulated combined as defined in Part C of Annex II of Regulation (EC) No 1333/2008 ('the group of steviol glycosides (E 960a-960d)') with maximum limits expressed as steviol equivalents.
- (5) In September 2021, an application was received for amending the specifications for the group of steviol glycosides (E 960a-960d) to include a new method for the production of steviol glycosides, namely, of rebaudioside M produced from fermentation by *Yarrowia lipolytica*. Rebaudioside M from fermentation produced by *Yarrowia lipolytica* consists of not less than 95% rebaudioside M, D, A and B and is obtained by fermentation of a source of simple sugar, using the genetically modified strain VRM

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

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

<sup>3</sup> 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>).

of *Yarrowia lipolytica*. It is intended to be used under the same conditions as those already authorised for the group of steviol glycosides (E 960a-960d). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

- (6) On 24 October 2023, the European Food Safety Authority ('the Authority') adopted its opinion on the evaluation of the safety of rebaudioside M produced by fermentation using *Yarrowia lipolytica*<sup>4</sup>. In its opinion, the Authority concluded that there is no safety concern for rebaudioside M, produced by fermentation using *Yarrowia Lipolytica* to be used as a food additive for the proposed uses and at the proposed use levels, taking into account the existing ADI of 4 mg/kg bw per day (expressed as steviol equivalents). The Authority considered that this production method may result in impurities different from those that may be present in the other steviol glycosides, produced in accordance with the applicable respective specifications for E 960a, E 960c and E 960d. Therefore, the Authority considered that separate specifications are needed for the food additive produced via the manufacturing process described in the current application.
- (7) It is therefore appropriate to authorise the use for the proposed uses and at the proposed use levels of rebaudioside M produced by fermentation using *Yarrowia lipolytica*.
- (8) Taking into account the International Numbering System for food additives of the Codex Alimentarius, it is appropriate to authorise the food additive under the name 'Steviol glycosides from fermentation' (E 960b).
- (9) As the food additive steviol glycosides from fermentation (E 960b) may be used combined with additives from the group of steviol glycosides (E 960a-960d) in the food categories where those additives are currently authorised and at the same maximum levels as them, it should be added to the group of steviol glycosides (E 960a-960d) in Part C of Annex II to Regulation (EC) No 1333/2008.
- (10) The specifications for 'Steviol glycosides from fermentation' should be included in Regulation (EU) No 231/2012 in parallel with its inclusion in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008. Taking into account that other methods of production for steviol glycosides from fermentation (E 960b) could be authorised in the future, it is appropriate to include the specification as 'E 960b(i) rebaudioside M from fermentation produced by *Yarrowia lipolytica*'.
- (11) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (12) 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.

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<sup>4</sup> EFSA Journal. 2023;21:e8387.

*Article 2*

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

*Article 3*

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*