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COMMISSION REGULATION (EU) 2026/172

of 26 January 2026

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester in the Union list of flavourings and correcting certain CAS numbers

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ([1]), and in particular Article 11(3) 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 I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.

(2) Commission Implementing Regulation (EU) No 872/2012 ([3]) adopted the Union list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.

(3) That list 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 submitted by a Member State or by an interested party.

(4) On 16 March 2020, an application was submitted to the Commission for the authorisation of 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester (FL No 16.136), as a flavouring substance to be used in various foods falling under a number of food categories referred to in the Union list of flavourings and source materials. The application was notified to the European Food Safety Authority ('the Authority') for its opinion. The Commission also made the application available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) In its opinion adopted on 16 December 2024 ([4]), the Authority evaluated the safety of 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester (FL No 16.136) when used as a flavouring substance and concluded that such use under the proposed conditions of use does not raise a safety concern.

(6) In the light of the opinion of the Authority, since the use of 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester (FL No 16.136) as a flavouring substance does not give rise to safety concerns under the specified conditions of use and it is not expected to mislead the consumer, it is appropriate to authorise such use.

([1]) OJ L 354, 31.12.2008, p. 34, ELI: http://data.europa.eu/eli/reg/2008/1334/oj.
([2]) OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/oj.
([3]) Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2012/872/oj).
([4]) *EFSA Journal* 2025; 23:e9201 (https://doi.org/10.2903/j.efsa.2025.9201) .

(7) In addition, the Chemical Abstracts Service registry numbers (CAS Nos) listed in Annex I to Regulation (EC) No 1334/2008 for the flavouring substances FL Nos 08.017, 08.127, 16.041 and 16.132 are incorrect and should be corrected.

(8) Annex I to Regulation (EC) No 1334/2008 should therefore be amended and corrected accordingly to include 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester (FL No 16.136) in the Union list of flavourings and to correct the CAS Nos for the flavouring substances FL Nos 08.017, 08.127, 16.041 and 16.132.

(9) 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 I to Regulation (EC) No 1334/2008 is amended in accordance with Annex I to this Regulation.

Article 2

Annex I to Regulation (EC) No 1334/2008 is corrected 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, 26 January 2026.

For the Commission
The President
Ursula VON DER LEYEN

In Part A, Section 2, Table 1, of Annex I to Regulation (EC) No 1334/2008, the following entry is inserted after the entry concerning FL No 16.135:

‘16.136	3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester	1160112-20-8	2203			In category 1.7 – not more than 6 mg/kg In category 1.8 (only cheese analogues) – not more than 6 mg/kg In category 2.1 – not more than 8 mg/kg In category 4.2 (only vegetables) – not more than 8 mg/kg In category 8.2 – not more than 8 mg/kg In category 8.3 – not more than 8 mg/kg In category 9.2 – not more than 8 mg/kg In category 10.2 – not more than 10 mg/kg In category 12.2 – not more than 20 mg/kg In category 12.5 – not more than 10 mg/kg In category 12.6 – not more than 10 mg/kg In category 14.1 – not more than 1,7 mg/kg In category 15.1 – not more than 20 mg/kg		EFSA’

ANNEX II

In Part A, Section 2, of Annex I to Regulation (EC) No 1334/2008, Table 1 is corrected as follows:

(1) in the entry for FL No 08.017, the number in the third column is replaced by '97-67-6';

(2) in the entry for FL No 08.127, the number in the third column is replaced by '13794-15-5';

(3) in the entry for FL No 16.041, the number in the third column is replaced by '150436-68-3';

(4) in the entry for FL No 16.132, the number in the third column is replaced by '67604-48-2'.