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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	10 October 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D099953/02
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of (E)-3-benzo[1,3]dioxol-5-yl-N,N-diphenyl-2-propenamide in the Union list of flavourings

Delegations will find attached document D099953/02.

Encl.: D099953/02



EUROPEAN
COMMISSION

Brussels, **XXX**
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D099953/02
[...](2024) **XXX** draft

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

of **XXX**

**amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of
(E)-3-benzo[1,3]dioxol-5-yl-N,N-diphenyl-2-propenamide in the Union list of flavourings**

(Text with EEA relevance)

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

of **XXX**

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of (E)- 3- benzo[1,3]dioxol- 5- yl- N,N- diphenyl- 2- propenamide in the Union list of flavourings

(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/EC¹, 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 flavourings², 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 872/2012³ adopted the list of flavouring substances and introduced that list in Annex I, Part A, 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 15 January 2019, an application was submitted to the Commission for the authorisation of (E)- 3- benzo[1,3]dioxol- 5- yl- N,N- diphenyl- 2- propenamide, (FL No. 16.135), 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.

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).

- (5) In its opinion adopted on 18 May 2022⁴, the Authority evaluated the safety of the substance FL No. 16.135 when used as a flavouring substance and concluded that there is no safety concern at the estimated level of dietary exposure calculated using the added portions exposure technique based on the intended uses and use levels. The Authority further concluded that the combined exposure to FL No. 16.135 from its use as a food flavouring substance and from its presence in toothpaste is also not of safety concern.
- (6) In light of the opinion of the Authority, since the use of the substance FL No 16.135 as a flavouring substance does not give rise to safety concerns with the specified conditions of use and it is not expected to mislead the consumer, it is appropriate to authorise such use.
- (7) Annex I, Part A, to Regulation (EC) No 1334/2008 should therefore be amended accordingly to include (E)- 3- benzo[1,3]dioxol- 5- yl- N,N- diphenyl- 2- propanamide in the Union list of flavourings.
- (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

Annex I, Part A, to Regulation (EC) No 1334/2008 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

Ursula VON DER LEYEN

⁴ EFSA Journal 2022;20(7):7355.