



Brussels, **XXX**
SANTE/11793/2016
(POOL/E2/2016/11793/11793-EN.docx)
D073140/03
[...](2021) **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 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione in the Union list of flavouring substances

(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 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione in the Union list of flavouring substances

(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 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 10 August 2012, an application was submitted to the Commission for authorisation of the use of 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione, (FL No 16.127), as a flavouring substance in various foods falling, in substance, under a number of the food categories referred to in the Union list of flavourings and source materials. The Commission notified the application to the European Food Safety Authority ('the Authority') and requested its

¹ OJ L 354, 31.12.2008, p. 34.

² OJ L 354, 31.12.2008, p. 1.

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).

opinion. The Commission also made the application available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

- (5) The Authority in its opinion adopted on 21 June 2016⁴ evaluated the safety of substance FL No 16.127, concluded that its use does not give rise to safety concerns when limited to levels up to those specified for various foods in different food categories. The Authority also noted that it is a substance with flavouring modifying properties.
- (6) Since the use of substance FL No 16.127 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 in the light of the Opinion of the Authority.
- (7) Part A of Annex I to Regulation (EC) No 1334/2008 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

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 2016;14(7):4334.