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Delegations will find attached document D056882/04.

Encl.: D056882/04



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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 substance N-(2-methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide

(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 substance *N*-(2-methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide

(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 the Member State or by an interested party.
- (4) Part A of the Union list contains both evaluated flavouring substances, for which no footnotes are assigned, and flavouring substances under evaluation, which are identified by footnote references 1 to 4.
- (5) The substance *N*-(2-methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide FL No. 16.119 was listed with footnote 4 in accordance with Article 4 of the Commission Implementing Regulation (EU) No 872/2012, which means that

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).

additional scientific data had to be submitted by 31 December 2013 for completion of its evaluation.

- (6) On 18 November 2013, the applicant submitted data on *N*-(2-methylcyclohexyl)-2,3,4,5,6- pentafluoro-benzamide FL No. 16.119.
- (7) On 1 February 2017, the European Food Safety Authority ('the Authority') completed the evaluation of the safety of the substance [FL no: 16.119] when used as a flavouring substance⁴ and concluded that its use does not give rise to safety concerns at the estimated levels of dietary intake. The Authority also noted that this substance is intended to be used as a substance with flavouring modifying properties. The conditions of use of this substance should therefore reflect this fact. Based on this, restrictions of use for certain foods in certain food categories should be introduced.
- (8) The Union list laid down in Regulation (EC) No 1334/2008 is intended to regulate only the use of flavouring substances which are added to food in order to impart or modify odour and/or taste. Substance FL No. 16.119 could be added to food as well for other purposes than flavouring and such uses remain subject to different Union rules. This Regulation lays down conditions of use which relate solely to the use of FL-No. 16.119 as a flavouring substance.
- (9) The Authority also provided in its opinion comments regarding the specifications of the substance and indicated that additional information about the ratio of enantiomers was lacking. The applicant has provided information about these issues to the Commission. The specifications should therefore be adapted accordingly.
- (10) Therefore, this flavouring substance should be listed as an evaluated substance in the Union list of flavouring substances without the footnote reference contained in its current entry of the Union list.
- (11) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (12) 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

Part A of Annex I 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.

⁴ EFSA Journal 2017;15(3):4726.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER