Commission Regulation (EU) 2019/36 of 10 January 2019 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) 2019/36

of 10 January 2019

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/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 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 Implementing Regulation (EU) No 872/2012, which means that additional scientific data had to be submitted by 31 December 2013 for completion of its evaluation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/36. (See end of Document for details)*

(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 substance[4] 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*.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2019/36. (See end of Document for details)*

Done at Brussels, 10 January 2019.

For the Commission

The President

Jean-Claude JUNCKER