COMMISSION REGULATION (EU) 2023/441

of 28 February 2023

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 2-hydroxy-4-methoxybenzaldehyde 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/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 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 17 December 2019, an application was submitted to the Commission for the authorisation of 2-hydroxy-4-methoxybenzaldehyde (FL No: 05.229), 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 29 September 2021 ([4]), the Authority evaluated the safety of the substance FL No 05.229 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 (APET) based on the intended uses and use levels. The Authority clarified that the assessment is only applicable if the food flavouring is isolated from the plant *Periploca sepium* using methodologies giving rise to a final product with the purity and residue levels described in the opinion. The Authority also concluded that the cumulative exposure to FL No 05.229 and the three structurally related substances does not raise a safety concern.

([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).
([4]) *EFSA Journal* 2021;19(11):6883.

(6) According to the information available at the European Chemicals Agency (ECHA) website ([5]), the registrant of 2-hydroxy-4-methoxybenzaldehyde indicated that it may contain 1-methyl-2-pyrrolidone (EC No 212-828-1, CAS No 872-50-4) as a stabiliser. 1-methyl-2-pyrrolidone (also called *N*-methyl-2-pyrrolidone (NMP)) is classified as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([6]). Therefore, the Authority requested the applicant to confirm that 1-methyl-2-pyrrolidone is not used in the manufacture of 2-hydroxy-4-methoxybenzaldehyde proposed for use as a food flavouring. In its response, the applicant confirmed that 1-methyl-2-pyrrolidone is not used in the extraction process as a solvent, processing aid, stabiliser nor in any other way in the production of this substance. Therefore, the Authority considered that 1-methyl-2-pyrrolidone is not expected to be present in the solvents used in the manufacturing process described in the application dossier. In addition, the Authority noted that, according to the Scientific Committee on Consumer Safety (SCCS) Opinion on NMP ([7]), there are no known natural sources of NMP. Therefore, the Authority concluded that there are no indications that 1-methyl-2-pyrrolidone is present in the flavouring substance 2-hydroxy-4-methoxybenzaldehyde produced according to the procedure described in the scientific opinion.

(7) In light of the opinion of the Authority, since the use of the substance FL No 05.229 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.

(8) Annex I, Part A, to Regulation (EC) No 1334/2008 should therefore be amended accordingly to include 2-hydroxy-4-methoxybenzaldehyde in the Union list of flavourings.

(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, 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, 28 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

([5]) https://echa.europa.eu/it/registration-dossier/-/registered-dossier/23928/2/1.

([6]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([7]) SCCS (Scientific Committee on Consumer Safety), 2011, OPINION ON N-Methyl-2-pyrrolidone (NMP), 22 March 2011.

ANNEX

In Annex I, Part A, Section 2, Table 1 to Regulation (EC) No 1334/2008, the following entry is inserted below the entry concerning FL No 05.226:

‘05.229	2-hydroxy-4-methoxybenzaldehyde	673-22-3			Isolated from *Periploca sepium*		EFSA’