

COMMISSION REGULATION (EU) 2021/1916**of 3 November 2021****amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid 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 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 24 February 2015, an application was submitted to the Commission for authorisation of the use of the substance 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid (FL No 16.130) and one of its salts, namely, its hemisulfate monohydrate salt, as flavouring substances in various foods falling, in substance, under a number of the food categories referred to in the Union list of flavourings and source materials. According to the application, only that substance and its hemisulfate monohydrate salt, but not other salts of that substance, are intended to be added to food as flavourings. The Commission notified to the European Food Safety Authority ('the Authority') and requested its 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 ⁽⁴⁾ adopted on 30 November 2016, evaluated the safety of substance and of its hemisulfate monohydrate salt both under the FL No 16.130. It noted that this substance is a substance with flavouring modifying properties and concluded that its use and also that of only its hemisulfate monohydrate salt do not give rise to safety concerns when used at the estimated levels of dietary intake.

⁽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 2017;15(1):4660.

- (6) In light of the opinion of the Authority, it is appropriate to authorise the use of substance FL No 16.130 and its hemisulfate monohydrate salt as flavouring substances under the specified conditions of use since their use under these conditions does not give rise to safety concerns and it is not expected to mislead the consumer. Since only the hemisulfate monohydrate salt of the concerned substance is also intended to be added to food as flavouring, it is also appropriate, for the sake of clarity, to explicitly indicate that Part A, Section 2, Note 1 of Annex I to Regulation (EC) No 1334/2008 does not apply to this substance.
- (7) Annex I, Part A 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, 3 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

In Part A, Section 2, Table 1 of Annex I to Regulation (EC) No 1334/2008, the following entry concerning FL No 16.130 is inserted after entry 16.127:

16.130	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid	1359963-68-0	2204		At least 99 % minimum assay (IR NMR MS)	<p>Note: Part A, Section 2, Note 1 of Annex I to Regulation (EC) No 1334/2008 does not apply to this substance.</p> <p>Restrictions for use as a flavouring substance expressed as a sum of the carboxylic acid and the hemisulfate monohydrate salt, expressed as the acid:</p>		EFSA'
	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid hemisulfate monohydrate salt	1460210-04-1	2204.1		<p>Synonym: 3-quinolinecarboxylic acid, 4-amino-5-[2,2-dimethyl-3-[(1-methylethyl)amino]-3-oxopropoxy]-2-methyl-, sulfate, hydrate (2:1:2). At least 99 % minimum assay (HPLC).</p>	<p>In category 1.4. – not more than 10 mg/kg.</p> <p>In category 1.6.3. – not more than 30 mg/kg.</p> <p>In category 1.8. – not more than 30 mg/kg.</p> <p>In categories 2.2.1. and 2.2.2. – not more than 30 mg/kg.</p> <p>In category 3. – not more than 30 mg/kg.</p> <p>In category 4.2.3. – not more than 10 mg/kg.</p> <p>In category 4.2.4.1. – not more than 30 mg/kg.</p> <p>In category 4.2.4.2. – not more than 10 mg/kg.</p> <p>In categories 4.2.5.1., 4.2.5.2., 4.2.5.3. and 4.2.5.4. – not more than 30 mg/kg.</p> <p>In categories 5.1. and 5.2. – not more than 30 mg/kg.</p> <p>In category 5.3. – not more than 300 mg/kg.</p> <p>In category 5.4. – not more than 30 mg/kg.</p>		

					<p>In category 6.3. – not more than 45 mg/kg.</p> <p>In category 7.2. – not more than 15 mg/kg.</p> <p>In categories 8.3.1, 8.3.2. and 8.3.3. – not more than 15 mg/kg.</p> <p>In categories 8.3.4.1., 8.3.4.2. and 8.3.4.3. – not more than 15 mg/kg.</p> <p>In category 11.2. – not more than 30 mg/kg.</p> <p>In category 12.4. – not more than 30 mg/kg.</p> <p>In category 12.5. – not more than 10 mg/l.</p> <p>In categories 14.1.2., 14.1.3. and 14.1.4. – not more than 7 mg/l.</p> <p>In categories 14.1.5.1. and 14.1.5.2. – not more than 7 mg/kg.</p> <p>In category 14.2.1. – not more than 7 mg/l.</p> <p>In categories 14.2.2. and 14.2.5. – not more than 10 mg/l.</p> <p>In category 15.1. – not more than 30 mg/kg.</p> <p>In category 16 (excluding products covered in categories 1, 3 and 5) – not more than 15 mg/kg.</p>	
--	--	--	--	--	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--