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COMMISSION REGULATION (EU) 2025/1112

of 4 June 2025

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of Naringenin and 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl) butan-1-one 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) 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.

(3) On 27 October 2021, an application was submitted to the Commission for the authorisation of Naringenin (FL No 16.132), as a flavouring substance to be used in various foods falling under certain 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.

(4) In its opinion adopted on 20 March 2024 ([3]), the Authority evaluated the safety of substance Naringenin (FL No 16.132) when used as a flavouring substance and concluded that such use does not raise a concern with respect to genotoxicity or with respect to interaction with medicinal products. Based on the intended uses and use levels, the Authority concluded that the use of substance Naringenin (FL No 16.132) does not raise any safety concern.

(5) In light of the opinion of the Authority, since the use of the substance Naringenin (FL No 16.132) as a flavouring substance does not give rise to safety concerns with the specified conditions of use and since it is not expected to mislead the consumer, it is appropriate to authorise such use.

(6) On 30 June 2016, an application was submitted to the Commission for the authorisation of substance 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one (FL No 16.134), as a flavouring substance to be used in foods falling under food category 05.3 'Chewing gum' referred to in the Union list of flavourings and source materials. The application was notified to 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.

([1]) OJ L 354, 31.12.2008, p. 34, ELI: http://data.europa.eu/eli/reg/2008/1334/oj.
([2]) OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/oj.
([3]) *EFSA Journal* 2024;22(5):8747.

(7) In its opinion adopted on 21 March 2024 ([4]), the Authority evaluated the safety of the substance 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one (FL No 16.134) when used as a flavouring substance and concluded that such use raises no safety concern at the estimated level of dietary exposure, based on the intended use and use levels. The Authority further concluded that the combined exposure to 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one (FL No 16.134) from its use as a food flavouring substance and from its presence in toothpaste and mouthwash is also not of safety concern.

(8) In light of the opinion of the Authority, since the uses of substance 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl) piperidin-1-yl)butan-1-one (FL No 16.134) as flavouring substance do not give rise to safety concerns with the specified conditions of use and since they are not expected to mislead the consumer, it is appropriate to authorise such uses.

(9) Annex I, Part A, to Regulation (EC) No 1334/2008 should therefore be amended accordingly to include Naringenin (FL No 16.132) and 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one (FL No 16.134) in the Union list of flavourings.

(10) 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, 4 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

([4]) *EFSA Journal* 2024;22(5):8750.

ANNEX

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

‘16.132	Naringenin	480-41-1			In category 1.4 – not more than 500 mg/Kg In category 1.7 – not more than 200 mg/Kg In category 1.8 (only soy based) – not more than 500 mg/Kg In category 3 – not more than 200 mg/Kg In category 5.1 – not more than 400 mg/Kg In category 5.2 – not more than 400 mg/Kg In category 5.3 – not more than 400 mg/Kg In category 6.3 – not more than 200 mg/Kg In category 8.2 – not more than 200 mg/Kg In category 8.3 – not more than 200 mg/kg In category 11.4 – not more than 200 mg/Kg In category 12.2 – not more than 1 000 mg/Kg In category 12.5 – not more than 200 mg/Kg In category 12.9 – not more than 500 mg/Kg In category 14.1 – not more than 300 mg/Kg In category 14.1.4 (only dairy based and soy based) – not more than 500 mg/Kg		EFSA’

					In category 15.1 – not more than 400 mg/Kg In category 16 (only dairy based and soy based) – Not more than 500 mg/Kg		

2. In Annex I, Part A, Section 2, Table 1 to Regulation (EC) No 1334/2008, the following entry is inserted after the entry concerning FL No 16.133:

‘16.134	2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl) piperidin-1-yl)butan-1-one	2413115-68-9			In category 5.3 – not more than 100 mg/kg		EFSA’

ELI: http://data.europa.eu/eli/reg/2025/1112/oj