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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	D099950/02
Subject:	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 removal of the flavouring substance 4-Methyl-2-phenylpent-2-enal (FL No 05.100) from the Union list

Delegations will find attached document D099950/02.

Encl.: D099950/02



EUROPEAN
COMMISSION

Brussels, XXX
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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 removal of the flavouring substance 4-Methyl-2-phenylpent-2-enal (FL No 05.100) from the Union list

(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 removal of the flavouring substance 4-Methyl-2-phenylpent-2-enal (FL No 05.100) from the Union list

(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(4) 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 Union 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) The Union list of flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008 contains, among others, a number of flavouring substances for which, at the time of adoption of the list by Regulation (EU) No 872/2012, the European Food Safety Authority ('the Authority') had not been able to rule out a safety risk to the health of the consumer on the basis of the data available and had, therefore, considered that additional data was necessary to complete their evaluation. Those substances were included in the Union list of flavouring substances on the

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 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, ELI: http://data.europa.eu/eli/reg_impl/2012/872/oj).

condition that safety data addressing the concerns expressed by the Authority was submitted before the expiry of specific deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008. Those substances were identified by way of a footnote reference requiring the Authority to complete the evaluation.

- (5) Among the substances included in the Union list of flavourings and source materials but identified by way of a footnote reference requiring the Authority to complete the evaluation is the substance of the Flavouring Group Evaluation 216 (FGE.216) 4-Methyl-2-phenylpent-2-enal (FL No 05.100). For this substance interested food business operators submitted the additional scientific data requested by the Authority.
- (6) In its scientific opinion of 29 June 2022⁴, the Authority evaluated the submitted data and concluded that the representative substance of the FGE.216 revision 2 (FGE.216Rev2), 2-Phenylcrotonaldehyde (FL No 05.062), induced an aneugenicity mode of action. As the available in vivo micronucleus studies were inconclusive, an in vivo potential aneugenicity cannot be ruled out for any substance within FGE.216Rev2 and, therefore, for substance 4-Methyl-2-phenylpent-2-enal (FL No 05.100). Accordingly, the Authority indicated that further data were needed to complete the assessment.
- (7) Pending the submission of further data by interested food business operators, Commission Regulation (EU) 2024/238⁵ introduced restrictions on the use of 4-Methyl-2-phenylpent-2-enal (FL No 05.100).
- (8) However, interested food business operators did not submit the required data and indicated that there is no further use of this flavouring substance.
- (9) As the concern for aneugenicity cannot be ruled out, 4-Methyl-2-phenylpent-2-enal (FL No 05.100) should be removed from the Union list of flavouring substances.
- (10) Regulation (EC) No 1334/2008 should therefore be amended.
- (11) Foods to which 4-Methyl-2-phenylpent-2-enal (FL No 05.100) has been added and which have been placed on the market in the Union or which are in transit from third countries to the Union before the entry into force of this Regulation should be allowed to be marketed in the Union until their date of minimum durability or use-by date. The transitional measure should not apply to the substance itself and to preparations to which this substance has been added and which are not intended to be consumed as such, as the manufacturers of food products that use those preparations as ingredients know their composition when they use them.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ EFSA Journal, 2022;20(8):7420

⁵ Commission Regulation (EU) 2024/238 of 15 January 2024 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the introduction of restrictions on the use of certain flavouring substances (OJ L, 2024/238, 16.1.2024, ELI: <http://data.europa.eu/eli/reg/2024/238/oj>).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1334/2008

Annex I to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

1. Foods to which 4-Methyl-2-phenylpent-2-enal (FL No 05.100) has been added and which were lawfully placed on the market before the entry into force of this Regulation may continue to be marketed until their date of minimum durability or use-by date.
2. Foods imported into the Union to which 4-Methyl-2-phenylpent-2-enal (FL No 05.100) has been added may be marketed until their date of minimum durability or use-by date, if the importer of such food can demonstrate that they were dispatched from the third country concerned and were in transit to the Union before the entry into force of this Regulation.
3. Paragraphs 1 and 2 shall not apply to 4-Methyl-2-phenylpent-2-enal (FL No 05.100) and to preparations containing this substance not intended to be consumed as such.

For the purposes of this paragraph, ‘preparations’ means mixtures of flavourings or mixtures of one or more flavourings with other food ingredients, such as food additives, enzymes or carriers, to facilitate their storage, sale, standardisation, dilution or dissolution.

Article 3

Entry into force

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,

For the Commission
The President
Ursula VON DER LEYEN