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Delegations will find attached document D091974/02.

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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 introduction of restrictions on the use of certain flavouring substances

(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 introduction of restrictions on the use of certain flavouring substances

(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 (EC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13[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) By Commission Implementing Regulation (EU) No 872/2012[3] the list of flavouring substances was adopted and introduced 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,

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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).

therefore, considered that additional data was necessary to complete their evaluation. Those substances were included in the Union list of flavouring substances but on the 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.

(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, there are the following three substances of the Flavouring Group Evaluation 216 (FGE.216): 2-Phenylcrotonaldehyde (FL No 05.062), 5-Methyl-2-phenylhex-2-enal (FL No 05.099) and 4-Methyl-2-phenylpent-2-enal (FL No 05.100). For those substances the Authority requested additional scientific data that were subsequently submitted by the applicants.

(6) In its scientific opinion of 29 June 2022[4], the Authority evaluated the submitted data and concluded that the representative substance of the group, 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 2-Phenylcrotonaldehyde (FL No 05.062), 5-Methyl-2-phenylhex-2-enal (FL No 05.099) and 4-Methyl-2-phenylpent-2-enal (FL No 05.100).

(7) Following this opinion and in order to further evaluate the safety of those three substances the interested business operators committed to provide further data that would allow a thorough assessment of the in vivo aneugenicity for these three substances[5].

(8) It is also appropriate, pending the re-evaluation by the Authority of the additional data from the interested business operators and following on from the scientific opinion of 29 June 2022, to limit the conditions of use of 2-Phenylcrotonaldehyde (FL No 05.062), 5-Methyl-2-phenylhex-2-enal (FL No 05.099) and 4-Methyl-2-phenylpent-2-enal (FL No 05.100) to their current use.

(9) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.

(10) Foods not complying with the new conditions set out, to which any of the substances concerned have been added and which have been placed on the market in the Union or which have been dispatched from third countries and were in transit 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. This transitional measure should not apply to preparations to which any of the substances concerned 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.

(11) For reasons of harmonisation with Regulation (EC) No 1333/2008 of the European Parliament and the Council[6] and in order to account for the restrictions that correspond

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4 Scientific Opinion on Flavouring Group Evaluation 216 Revision 2 (FGE.216Rev2): consideration of the genotoxicity potential of α,β- unsaturated 2- phenyl- 2- alkenals from subgroup 3.3 of FGE.19. EFSA Journal 2022;20(8):7420, doi:10.2903/j.efsa.2022.7420. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/7420

5 IOFI EFFA Letter DG Sante - EFSA Opinion 216 Rev2 (EFSA Journal (2022; 20(8) 7420)) - follow-up IOFI/EFFA letter: confirmation of follow-up testing and anticipated timings. Ares(2022)8489668

6 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

to the food categories used by the Authority during the exposure assessment, the food categories listed in Section 1 of Part A of Annex I to Regulation (EC) No 1334/2008 should be replaced by the food categories listed in Part D of Annex II to Regulation (EC) No 1333/2008.

(12) A new footnote should be added to column 8 in the Union list, under Section 1 of Part A of Annex I to Regulation (EC) No 1334/2008 to indicate the need for additional data where additional data are expected in order to fully complete the assessment of the Authority.

(13) 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

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 any of the flavouring substances listed in the Annex to this Regulation have been added, which do not comply with the conditions set out in that Annex and which have been lawfully placed on the market before the entry into force of this Regulation may be marketed until their date of minimum durability or use by date.

2. Foods to which any of the flavouring substances listed in the Annex to this Regulation have been added, which do not comply with the conditions set out in that Annex and which have been imported into the Union from a third country may be marketed until their date of minimum durability or useby date where the importer of such foods 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. The transitional measures provided for in paragraphs 1 and 2 shall not apply to preparations, not intended to be consumed as such, to which any of the flavouring substances listed in the Annex to this Regulation has been added.

4. For the purposes of this Regulation, preparations shall be understood as mixtures of one or more flavourings to which other food ingredients such as food additives, enzymes or carriers may be also incorporated 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