



Council of the
European Union

Brussels, 20 May 2019
(OR. en)

9502/19

AGRI 263
DENLEG 63

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	20 May 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2019) 3688 final
Subject:	COMMISSION REGULATION (EU) .../... of 17.5.2019 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the removal from the Union list of the flavouring substance furan-2(5H)-one

Delegations will find attached document C(2019) 3688 final.

Encl.: C(2019) 3688 final



Brussels, 17.5.2019
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COMMISSION REGULATION (EU) .../...

of 17.5.2019

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the removal from the Union list of the flavouring substance furan-2(5H)-one

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

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amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the removal from the Union list of the flavouring substance furan-2(5H)-one

(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(6) 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 a list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.
- (3) Annex I to Regulation (EC) No 1334/2008 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) Part A of the Union list contains both evaluated flavouring substances and flavouring substances under evaluation.
- (5) The flavouring substance furan-2(5H)-one (FL No. 10.066) is included in Annex I to Regulation (EC) No 1334/2008 as a flavouring substance under evaluation and for which additional scientific data was requested by the European Food Safety Authority (hereinafter “the Authority”). Such data was submitted by the applicant.

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).

- (6) The Authority evaluated the submitted data and concluded in its scientific opinion of 11 December 2018⁴ that furan-2(5H)-one (FL No. 10.066) raises a safety concern with respect to genotoxicity as it is genotoxic *in vivo*.
- (7) The use of furan-2(5H)-one (FL No. 10.066) therefore does not comply with the general conditions of use for flavourings set out in Article 4(a) of Regulation (EC) No 1334/2008. Consequently, that substance should be removed from the list without delay in order to protect human health.
- (8) As regards the identification details of furan-2(5H)-one (FL No. 10.066) the Authority provides in its opinion additional elements regarding the identity and characterisation of this substance which are not included in its current entry in Part A of Annex I of Regulation (EC) No 1334/2008. In order to ensure clarity and certainty regarding the identity of the substance and to help stakeholders to properly identify this substance, it is relevant to note that further identification details of furan-2(5H)-one (FL No. 10.066) provided by the Authority in its Opinion are: the CAS No. is 497-23-4, its JECFA No. is 2000 and the JECFA name is 4-hydroxy-2-butenoic acid gamma lactone.
- (9) As the substance raises a safety concern, The Commission should use the urgency procedure for the removal of furan-2(5H)-one from the Union list. Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (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

Part A of Annex I 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 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, 17.5.2019

For the Commission
The President
Jean-Claude JUNCKER

⁴ EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings). Scientific Opinion on Flavouring Group Evaluation 217 Revision 2 (FGE.217Rev2), consideration of genotoxicity potential for alpha, beta unsaturated ketones and precursors from chemical subgroup 4.1 of FGE.19: lactones; EFSA Journal 2019;17(1):5568.