Commission Regulation (EU) 2019/799 of 17 May 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) 2019/799

of 17 May 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)

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(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 872/2012[(3)] 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.

(6) The Authority evaluated the submitted data and concluded in its scientific opinion of 11 December 2018[(4)] 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 May 2019.

For the Commission

The President

Jean-Claude JUNCKER