Commission Regulation (EU) 2020/1681 of 12 November 2020 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/1681

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(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),

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(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 872/2012[(3)] adopted the 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) 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 but on the condition that safety data addressing the concerns expressed by the Authority was submitted before the expiry of

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1681. (See end of Document for details)*

specific deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008. These substances and their deadlines were identified by footnotes numbered from 1 to 4.

(5) Among the substances included in the Union list of flavourings and source materials but identified by way of a footnote reference requiring additional scientific data to be submitted by 31 December 2012, there were the following five substances alpha-Damascone (Fl No 07.134) (representative substance of the group), delta-Damascone (Fl No 07.130), cis-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)but-2-en-1-one (Fl No 07.225), trans-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)but-2-en-1-one (Fl No 07.226) and alpha-Damascenone (Fl No 07.231) ('the concerned substances'). These substances are part of the subgroup 2.4 of substances from Flavouring Group FGE.19, and were included in the Flavouring Group FGE 210. As regards these substances, the Authority had indicated in its opinion on the Flavouring Group Evaluation 210 of 2009[4] that they contain a structural alert for genotoxicity in their molecular structure as they are alpha, beta-unsaturated ketones, and that additional genotoxicity data was needed to rule out the concern on their genotoxicity in accordance with the Authority's document on the 'Genotoxicity test strategy for substances belonging to subgroups of the Flavouring Group FGE.19'[5].

(6) On 28 December 2012, data was submitted concerning subgroup 2.4 of substances from Flavouring Group FGE.19.

(7) The Authority evaluated the submitted data in revision 1 of the Opinion on the genotoxic potential of the substances of Flavouring Group FGE 210 from chemical group 2.4 of Flavouring Group FGE 19 published on 19 February 2014[6]. However, the Authority considered the submitted data was still insufficient to rule out the genotoxic potential of the concerned substances and it requested further additional data on genotoxicity on the substances representative for this subgroup.

(8) New data was submitted in 2014. The Authority evaluated the new data in revision 2 of its Opinion, published on 10 July 2015[7]. However, the Authority considered that the new data was insufficient to rule out the genotoxic potential of the concerned substances and requested once more further scientific data to be submitted on the genotoxicity of the concerned substances.

(9) Further data was submitted in 2016 on the concerned substances. Following this submission, the Authority requested further information and specific studies to be performed by letters of 8 November 2016, 9 February 2017, 29 June 2017 and 8 February 2019. However, the new data provided did not always correspond to the studies requested by the Authority and were not suitable to answer properly the Authority's concerns. Taking into account all that additional data submitted, the Authority evaluated again the genotoxic potential of the concerned substances in revision 3 of the Opinion on FGE.210[8] published on 22 May 2019. The Authority concluded that the concern for genotoxicity cannot be ruled out for the five concerned substances.

(10) In view of the fact that neither the data submitted within the initial deadline nor the data submitted following the Authority's successive requests after that deadline had allowed the Authority in 2019 to rule out the concerns expressed in its Opinion of 2009, the

Commission considers that it is not established that the concerned substances do not pose a safety risk to the health of the consumer. Therefore, on the basis of the scientific evidence submitted within the framework set out in Part A of Annex I to Regulation (EC) No 1334/2008 for the substances pending the completion of their evaluation, the use of the concerned substances does not comply with the general conditions of use for flavourings set out in Article 4 of Regulation (EC) No 1334/2008.

(11) Consequently, the concerned substances should be removed from the Union list in order to protect human health.

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

(13) Due to technical reasons, transitional periods should be provided for concerning food to which any of the five flavouring substances have been added and which have been placed on the market or dispatched from third countries to the Union and were en route prior to the entry into force of this Regulation. The transitional period should not apply to preparations to which any of these five flavouring substances have been added and which are not intended to be consumed as such as the composition of these preparations are known by their manufacturers when they prepare them.

(14) 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

1 Foods to which any of the flavouring substances listed in the Annex to this Regulation have been added and which were lawfully placed on the market prior to the date of 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 one of the flavouring substances listed in the Annex to this Regulation have been added may be marketed until their date of minimum durability or ‘use by’ date where the importer of such food can demonstrate that they were dispatched from the third country concerned and were en route to the Union before the date of entry into force of this Regulation.

3 The transitional periods provided in paragraphs 1 and 2 shall not apply to preparations not intended to be consumed as such to which any of these five flavouring substances have 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.