Commission Regulation (EU) 2020/356 of 4 March 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polysorbates (E 432-436) in carbonated beverages (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/356

of 4 March 2020

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polysorbates (E 432-436) in carbonated beverages

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(1)], and in particular Article 10(3) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.

(2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council[(2)], either on the initiative of the Commission or following an application.

(3) Pursuant to Annex II to Regulation (EC) No 1333/2008, polyoxyethylene sorbitan tristearate (polysorbate 65) (E 436) is currently authorised for use as a food additive in the group 'polysorbates' (E 432-436) in a wide variety of foods at maximum levels ranging between 500 and 10 000 mg/kg and *quantum satis* in food supplements.

(4) On 4 July 2018, an application was submitted for the authorisation of the use of polysorbate 65 (E 436) as an anti-foaming agent in several types of beverages. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) It results from the application that, the proposed use of polysorbate 65 (E 436) is required at the maximum level of 10 mg/kg for containment and inhibition of foam during the manufacture of carbonated beverages by forming a layer around bubbles and stabilising larger bubbles preventing them to coalesce and break. The application shows that, the inhibition of foam is needed to efficiently operate the production equipment, to reduce product waste, to maintain a safe workplace, and to keep facilities clean and in a hygienic state.

(6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('the Authority') in order to update

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/356. (See end of Document for details)*

the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.

(7) The safety of polysorbates (E 432-436) used as food additives was re-evaluated by the Authority in 2015[(3)]. The Authority concluded that the exposure estimates did not exceed the acceptable daily intake (ADI) of 25 mg/kg body weight/day in the refined non-brand-loyal scenario for all age groups at both the mean exposure level and the high level; although for toddlers at the highest level they were very close to the ADI. The Authority noted that more data were needed to decrease uncertainties in the refined exposure assessment scenario used since no reported uses had been obtained for three food categories and that other dietary sources of exposure to polysorbates could not be considered in the opinion.

(8) In the application the applicant estimated the exposure by using the Food Additives Intake Model[(4)] developed by the Authority. The estimates provided indicate that the additional exposure due to the requested extension of use is negligible (below 1 % of the ADI).

(9) The extended use of polysorbate 65 (E 436) at the maximum level of 10 mg/kg in the food categories 14.1.4 'Flavoured drinks', 14.2.3 'Cider and perry', 14.2.4 'Fruit wine and made wine' and 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol' in Part E of Annex II to Regulation (EC) No 1333/2008 requires an update of the Union list which is not liable to have an effect on human health, since its impact on the overall exposure to polysorbates (E 432-436) is negligible. Consequently, it is not necessary to seek the opinion of the Authority.

(10) For the sake of consistency, it is appropriate to address the requested use of (polysorbate 65) (E 436) by authorising the group polysorbates (E 432-436) in the respective food categories.

(11) Therefore, it is appropriate to authorise the use of polysorbates (E 432-436) at the maximum level of 10 mg/kg in the food categories 14.1.4 'Flavoured drinks', 14.2.3 'Cider and perry', 14.2.4 'Fruit wine and made wine' and 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol'.

(12) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(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

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2020/356. (See end of Document for details)*

Article 2

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, 4 March 2020.

For the Commission

The President

Ursula VON DER LEYEN