Commission Regulation (EU) 2020/279 of 27 February 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of soybean hemicellulose (E 426) (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/279

of 27 February 2020

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of soybean hemicellulose (E 426)

(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, soybean hemicellulose (E 426) is currently authorised for use as a food additive in a wide variety of foods at maximum levels ranging between 1 500 and 30 000 mg/kg.

(4) On 16 August 2017, an application was submitted for the extension of use of soybean hemicellulose (E 426) as a stabiliser in flavoured fermented milk products and flavoured drinks. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) Soybean hemicellulose (E 426), when used as a stabiliser in flavoured fermented milk products and flavoured drinks, prevents an agglomeration and precipitation of proteins and phase separation under acidic conditions.

(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 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) On 14 March 2017, the Authority published a scientific opinion re-evaluating the safety of soybean hemicellulose (E 426) as a food additive[(3)]. The Authority concluded that it is very unlikely that there is a safety concern from the current use of soybean hemicellulose (E 426) as a food additive, and that there is no need for a numerical

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acceptable daily intake (ADI). Such conclusion is used for substances of a very low safety concern and only if there is reliable information for both exposure and toxicity and there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals[(4)].

(8) Part C of Annex II to Regulation (EC) No 1333/2008 defines all groups of additives. In general, Group I of Part C lists food additives, except for colours and sweeteners, for which there is no need for a numerical acceptable daily intake and which are authorised for use in many foods in accordance with *quantum satis* principle as defined in Article 3(2)(h) of that Regulation.

(9) The outcome of the safety assessment of soybean hemicellulose (E 426) allows its inclusion in Group I of Part C of Annex II to Regulation (EC) No 1333/2008. Since in accordance with Part E of Annex II to Regulation (EC) No 1333/2008 the use of Group I additives is already permitted in flavoured fermented milk products and flavoured drinks, the inclusion of soybean hemicellulose (E 426) in Group I would address the requested extension of use. The inclusion of soybean hemicellulose (E 426) in Group I would also make redundant the existing entries for soybean hemicellulose (E 426) in Part E of Annex II to Regulation (EC) No 1333/2008 since the use of Group I additives is permitted in all the concerned food categories, and they should be therefore deleted. Similarly, the existing reference to the maximum level of soybean hemicellulose (E 426) in the introduction part for food category 17 (Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(5)]) in Part E of Annex II to Regulation (EC) No 1333/2008 should be deleted, since within Group I soybean hemicellulose (E 426) is to be authorised in accordance with the *quantum satis* principle.

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

(11) 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.

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2020/279. (See end of Document for details)*

Done at Brussels, 27 February 2020.

For the Commission

The President

Ursula VON DER LEYEN