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Delegations will find attached document D089495/03.

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EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of buffered vinegar as a preservative and acidity regulator

(Text with EEA relevance)

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of buffered vinegar as a preservative and acidity regulator

(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 additives¹, and in particular Articles 10(3) and 14 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(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (1) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives and specifications for food additives may be updated either on the initiative of the Commission or following an application from a Member State or an interested party.
- (3) In March 2021, an application was submitted to the Commission for the authorisation of use of buffered vinegar as a preservative and acidity regulator in a broad variety of food categories. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

- (4) In the opinion published on 1 July 2022⁴, the European Food Safety Authority ('the Authority') evaluated the safety of the proposed use of buffered vinegar as a food additive. As acetic acid and its salts are the primary constituents of buffered vinegar, the Authority referred to its previous assessment of acetic acid as a pesticide active substance in 2013⁵ in which it concluded that the establishment of an acceptable daily intake (ADI) for acetic acid is not considered necessary. Such conclusion is reached 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 animals⁶. Taking into account the assessment of acetic acid in 2013 and that buffered vinegar dissociates into the acetic anion, a natural constituent of the human diet and of the human body for which extensive data on its biological effects exist, the Authority assessed the safety of buffered vinegar without biological or toxicological data obtained with this food additive and concluded that there is no safety concern for the use of buffered vinegar as a food additive at the proposed maximum use levels.
- (5) Part C of Annex II to Regulation (EC) No 1333/2008 defines all groups of additives. 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 the *quantum satis* principle as defined in Article 3(2), point (h) of that Regulation. The outcome of the safety assessment of buffered vinegar allows its inclusion in Part C, Group I, of Annex II to Regulation (EC) No 1333/2008.
- (6) Buffered vinegar is a liquid or dried product prepared by adding sodium/potassium hydroxides (E 524-525) and sodium/potassium carbonates (E 500-501) to vinegar, which is compliant with European Standard EN 13188:2000 and is exclusively obtained from an agricultural source origin (except wood/cellulose) by a double (alcoholic and acetous) fermentation. Buffered vinegar is intended for use as an alternative to other authorised preservatives or acidity regulators, in particular to acetic acid and its salts (E 260-263). Buffering increases pH and allows the use as a preservative or acidity regulator in many food categories without impacting the quality of foods.
- (7) It is therefore appropriate to authorise the use of buffered vinegar as a food additive and to assign E 267 as the E-number to that additive.
- (8) The specifications for buffered vinegar (E 267) should be included in the Annex to Regulation (EU) No 231/2012 as this additive is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 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,

⁴ EFSA Journal 2022;20(7):7351.

⁵ EFSA Journal 2013;11(1):3060.

⁶ EFSA Journal 2014;12(6):3697; Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010.

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

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,

For the Commission
The President
Ursula VON DER LEYEN