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Subject:	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 carbomer in food supplements

Delegations will find attached document D084677/02.

Encl.: D084677/02



EUROPEAN
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Brussels, XXX
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[...] (2022) XXX draft

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 carbomer in food supplements

(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 carbomer in food supplements

(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 Article 10(3) and Article 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.
- (2) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives including colours and sweeteners that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists 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.
- (4) On 22 April 2020, an application was submitted for authorisation of the use of carbomer as a bulking agent and stabiliser in solid food supplements and as stabiliser and thickener in liquid food supplements. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The European Food Safety Authority evaluated the safety of crosslinked polyacrylic acid polymers (carbomer) when used as food additive⁴ and concluded that its use in liquid food supplements at the maximum use level of 30 000 mg/kg and in solid food supplements at the typical use level of 200 000 mg/kg is of no safety concern.
- (6) Carbomer is intended for use in solid food supplements for the controlled extended release of nutrients, allowing smaller size of tablets that are easier for consumers to

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, 22.03.2012, p. 1).

⁴ EFSA Journal 2021;19(8):6693.

swallow. In liquid food supplements, carbomer is intended for use in formulations with a wide range of flow and rheological properties that are stable with a lower level of polymer.

- (7) It is therefore appropriate to authorise the food additive ‘carbomer’ (E 1210) as a bulking agent and a stabiliser in solid and as a stabiliser and thickener in liquid food supplements.
- (8) The specifications for carbomer (E 1210) should be included in Regulation (EU) No 231/2012 as it 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,

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