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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending the Annex to Regulation (EU) No 231/2012 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 as regards specifications for Microcrystalline cellulose (E460(i))

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Delegations will find attached document D052937/02.

Encl.: D052937/02



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/10766/2017  
(POOL/E2/2017/10766/10766-EN.doc)  
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[...](2017) **XXX** draft

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

of **XXX**

**amending the Annex to Regulation (EU) No 231/2012 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 as regards specifications for Microcrystalline cellulose (E460(i))**

(Text with EEA relevance)

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

of **XXX**

**amending the Annex to Regulation (EU) No 231/2012 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 as regards specifications for Microcrystalline cellulose (E460(i))**

(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<sup>1</sup>, and in particular 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 flavourings<sup>2</sup>, and in particular Article 7(5) thereof,

Whereas:

- (1) Commission Regulation (EU) No 231/2012<sup>3</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) Those specifications 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.
- (3) On 8 February 2016 an application was submitted for the amendment of specifications concerning the food additive microcrystalline cellulose (E 460(i)). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) The current specification as regards the solubility of the food additive microcrystalline cellulose (E 460(i)) states “Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution”.
- (5) The applicant requests that the solubility of this food additive is amended to “Insoluble in water, ethanol, ether and dilute mineral acids. Practically insoluble or insoluble in sodium hydroxide solution”.
- (6) In its opinion of 24 January 2017<sup>4</sup> the European Food Safety Authority ('the Authority') concluded that the amendment to the specifications as regards the

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1.

<sup>3</sup> 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).

<sup>4</sup> EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to food), 2017. Safety of the proposed amendment of the specifications for microcrystalline cellulose (E 460(i)) as a food additive. EFSA Journal 2017;15(2):4699, 7 pp. doi:10.2903/j.efsa.2017.4699

solubility of microcrystalline cellulose (E 460(i)) proposed by the applicant is not of a safety concern. However, the Authority recommended that the concentration of sodium hydroxide solution to be used in the solubility test should be indicated in the EU specifications.

- (7) Consequently, it is appropriate to amend the description of the solubility of the food additive microcrystalline cellulose (E 460(i)) in sodium hydroxide solution (concentration: 50 g NaOH/L) to “practically insoluble or insoluble”.
- (8) Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (9) 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*

The Annex to Regulation (EU) No 231/2012 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 Members States.

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*