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European Union

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From:	European Commission
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To:	General Secretariat of the Council
No. Cion doc.:	D055959/03
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 certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate)

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Delegations will find attached document D055959/03.

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Encl.: D055959/03



Brussels, **XXX**  
SANTE/11719/2017  
(POOL/E2/2017/11719/11719-EN.doc)  
D055959/03  
[...](2018) **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 certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmate)**

(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 certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate)**

(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 14 October 2014 an application was submitted for the amendment of specifications concerning the food additives sorbitan monostearate (E491), sorbitan tristearate (E492) and sorbitan monopalmitate (E495). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) The current Union specifications lay down a range of congealing temperatures (an identification parameter) for sorbitan monostearate (E491), sorbitan tristearate (E492) and sorbitan monopalmitate (E495).
- (5) The applicant requests that the reference to the congealing range as an identification method of sorbitan monostearate (E491), sorbitan tristearate (E492) and sorbitan monopalmitate (E495) in the Union specifications be removed as it is not an optimal method for identification due to a lack of a clear and common methodology.
- (6) In its opinion of 5 May 2017<sup>4</sup> the European Food Safety Authority ('the Authority') concluded that the amendment to the specifications as regards the removal of 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).

parameter 'congealing range' for identification of sorbitan monostearate (E491), sorbitan tristearate (E492) and sorbitan monopalmitate (E495) as proposed by the applicant would not give rise to a safety concern.

- (7) The Authority also concluded that the removal of the congealing range from the Union specifications would result in less characterisation of the various sorbitan esters of saturated fatty acids, and that this identification parameter could be replaced by another one. The Authority noted that out of all analytical methods available, gas chromatography analysis appears to deliver the most accurate and reliable results and is fit for purposes of food controls.
- (8) Consequently, it is appropriate to amend the Union specifications regarding the removal of the 'congealing range' as an identification parameter for the food additives sorbitan monostearate (E491), sorbitan tristearate (E492) and sorbitan monopalmitate (E495) and to replace it by 'Identification test - by acid value, iodine value, gas chromatography'.
- (9) The Annex to Regulation (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*

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*

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<sup>4</sup> EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to food), 2017. Scientific Opinion on the re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives. EFSA Journal 2017;15(5):4788, 56 pp. <https://doi.org/10.2903/j.efsa.2017.4788>