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[...](2017) **XXX** draft

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

**of **XXX****

**amending Annexes II and III 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 removal of calcium sorbate (E 203)**

(Text with EEA relevance)

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(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 10(3) and 14 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) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (3) Commission Regulation (EU) No 231/2012<sup>2</sup> (2) lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (4) Calcium sorbate (E 203) is a substance authorised as a preservative in a variety of foods, as well as in food colour preparations and food flavourings, in accordance with Annexes II and III to Regulation (EC) No 1333/2008.
- (5) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority').
- (6) For that purpose, a program for the re-evaluation of food additives is laid down in the Commission Regulation (EU) No 257/2010<sup>3</sup>. Pursuant to Regulation (EU) No 257/2010 the re-evaluation of preservatives had to be completed by 31 December 2015.
- (7) On 30 June 2015 the Authority delivered a Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food

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

<sup>2</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>3</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

additives<sup>4</sup>. The opinion stated that there was a lack of genotoxicity data on calcium sorbate. Consequently the authority was not able to confirm the safety of calcium sorbate as a food additive and concluded that this substance should be excluded from the group Acceptable Daily Intake (ADI) defined for sorbic acid (E 200) and potassium sorbate (E 202). The opinion stated that genotoxicity studies on calcium sorbate need to be performed in order to consider including calcium sorbate in that group ADI.

- (8) On 10 June 2016 the Commission launched a public call for scientific and technological data on the permitted food additives sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203)<sup>5</sup>, targeting the data needs identified by the Authority in the Scientific Opinion on the re-evaluation of these substances. The call invited business operators interested in the continuity of approval of calcium sorbate as a food additive to inform the Commission by 25 November 2016 whether they would formally commit to providing the requested genotoxicity data and when those data would be available for their evaluation by the Authority. However, no business operator committed to providing the requested genotoxicity data for calcium sorbate (E 203). Without those data the Authority cannot complete the re-evaluation of the safety of calcium sorbate as a food additive and consequently it cannot be determined whether this substance still fulfils the conditions pursuant to Article 6(1) of Regulation (EC) No 1333/2008 for inclusion in the Union list of approved food additives.
- (9) It is therefore appropriate to remove calcium sorbate (E 203) from the Union list of approved food additives.
- (10) Pursuant to Article 10(3) of Regulation (EC) No 1333/2008, the Union list of approved food additives shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council<sup>6</sup>.
- (11) Article 3(1) of Regulation (EC) No 1331/2008 provides that the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (12) Therefore, Annexes II and III to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 should be amended by removing calcium sorbate (E 203) from the Union list of authorised food additives since due to the absence of appropriate genotoxicity data its inclusion in the list can no longer be justified.
- (13) It is appropriate to allow for an arrangement for foods containing calcium sorbate (E 203) that have been lawfully placed on the market before the entry in force of this Regulation.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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<sup>4</sup> EFSA Journal 2015;13(6):4144

<sup>5</sup> [http://ec.europa.eu/food/safety/food\\_improvement\\_agents/additives/re-evaluation\\_en](http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en)

<sup>6</sup> 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 (OJ L 354, 31.12.2008, p. 1).

HAS ADOPTED THIS REGULATION:

*Article 1*

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with the 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*.

*Article 4*

Foods containing calcium sorbate (E 203) that have been lawfully placed on the market before the entry into force of this Regulation, may continue to be marketed until stocks are exhausted.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, xx xxxx xxxx

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