Commission Regulation (EU) 2018/98 of 22 January 2018 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 calcium sorbate (E 203) (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/98

of 22 January 2018

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 calcium sorbate (E 203)

(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[(1)], and in particular Article 10(3) and Article 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[(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[(3)]. 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 additives[(4)]. 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 it should be excluded from the group

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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 sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203)[(5)], targeting the data needs identified in the Scientific Opinion on the re-evaluation of those substances as food additives. 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 that 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[(6)].

(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 deleting 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) In order to enable food business operators to adapt to the new requirements or to find alternatives to calcium sorbate (E 203), this Regulation should apply 6 months after its entry into force.

(14) 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

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

Article 2

In the Annex to Regulation (EU) No 231/2012, the entry for food additive E 203 calcium sorbate is deleted.

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*.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/98. (See end of Document for details)*

It shall apply from 12 August 2018.

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

Done at Brussels, 22 January 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/98. (See end of Document for details)*

ANNEX

(1) Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(a) in Part B, in Table 3: Additives other than colours and sweeteners, the entry for the food additive E 203 calcium sorbate is deleted;

(b) Part C, Table 5: Other additives that may be regulated combined, is amended as follows:

(i) point (a) 'E 200 – 203: Sorbic acid – sorbates (SA)' is replaced by the following:

(a) E 200 – 202: Sorbic acid – potassium sorbate (SA)

E-number	Name
E 200	Sorbic acid
E 202	Potassium sorbate

(ii) in point (c) 'E 200 – 213: Sorbic acid – sorbates; Benzoic acid – benzoates (SA + BA)', the entry for the food additive E 203 calcium sorbate is deleted;

(iii) in point (d) 'E 200 – 219: Sorbic acid – sorbates; Benzoic acid – benzoates; p-hydroxybenzoates (SA + BA + PHB)', the entry for the food additive E 203 calcium sorbate is deleted;

(iv) point (e) 'E 200 – 203; 214 – 219: Sorbic acid – sorbates; p-hydroxybenzoates (SA + PHB)' is replaced by the following:

(e) E 200 – 202; 214 – 219: Sorbic acid – potassium sorbate; p-hydroxybenzoates (SA + PHB)

E-number	Name
E 200	Sorbic acid
E 202	Potassium sorbate
E 214	Ethyl-p-hydroxybenzoate
E 215	Sodium ethyl p-hydroxybenzoate
E 218	Methyl p-hydroxybenzoate
E 219	Sodium methyl p-hydroxybenzoate

(c) Part E is amended as follows:

1. In category 01.3 (Unflavoured fermented milk products, heat-treated after fermentation), the entry concerning food additives E 200 – 203 (Sorbic acid – sorbates) is replaced by the following:

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	E 200 – 202	Sorbic acid – potassium sorbate	1 000	(1) (2)	only curdled milk

2. In category 01.4 (Flavoured fermented milk products including heat-treated products), the entry concerning food additives E 200 – 213 (Sorbic acid – sorbates; Benzoic acid – benzoates) is replaced by the following:

	E 200 – 213	Sorbic acid – potassium sorbate; Benzoic acid – benzoates	300	(1) (2)	only non-heat-treated dairy based desserts

3. In category 01.7.1 (Unripened cheese excluding products falling in category 16), the entry concerning food additives E 200 – 203 (Sorbic acid – sorbates) is replaced by the following:

	E 200 – 202	Sorbic acid – potassium sorbate	1 000	(1) (2)	

4. In category 01.7.2 (Ripened cheese), the entries concerning food additives E 200 – 203 (Sorbic acid – sorbates) are replaced by the following:

	E 200 – 202	Sorbic acid – potassium sorbate	1 000	(1) (2)	only cheese, pre-packed, sliced and cut; layered cheese and cheese with added foods
	E 200 – 202	Sorbic acid – potassium sorbate	*quantum satis*		only ripened products surface treatment