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COMMISSION

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

**of XXX**

**amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additives tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354)**

(Text with EEA relevance)

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

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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) 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) 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. Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives including carriers approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (2) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (3) Tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354) are substances authorised in accordance with Regulation (EC) No 1333/2008. Those food additives are currently authorised for use at *quantum satis* and included in Group I, in Annex II, Part C of that Regulation, which covers food additives, other than colours and sweeteners, with an ‘acceptable daily intake not specified’ or for which the most recent risk assessment concluded that ‘there is no need for a numerical acceptable daily intake’. In addition, tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354) are authorised for use in specific food categories with a numerical maximum level or at *quantum satis*.
- (4) On 11 March 2020, the European Food Safety Authority (‘the Authority’) issued a scientific opinion on the re-evaluation of tartaric acid (L(+)-) (E 334), sodium tartrates

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/oj>.

(E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354) as food additives<sup>3</sup>. A group acceptable daily intake (ADI) was established for tartaric acid-tartrates (E 334 - 337 and E 354) of 240 mg/kg bw per day, expressed as tartaric acid. The exposure estimates for the different population groups for the most relevant exposure scenario did not exceed the group ADI of 240 mg/kg bw per day, expressed as tartaric acid. The Authority recommended to harmonise the name for the food additive E 337 in Commission Regulation (EU) No 231/2012<sup>4</sup> and in Regulation (EC) No 1333/2008 by using the name 'potassium sodium tartrate' in both Regulations.

- (5) On 19 January 2021, the Commission launched a public call for technical data on the permitted food additives tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354), requesting food business operators to submit, among other things, data on the uses of those food additives in accordance with Annex II, Part E and Annex III, Parts 2, 3 and 4 and Section A of Part 5 of Regulation (EC) No 1333/2008. The call specified that in the absence of data for a food category in which the intentional use of those food additives is currently authorised, the Commission would consider that there is no interest that the food additives remain authorised in that food category and that consequently the respective authorisation would be withdrawn.
- (6) Business operators provided data on the uses of those food additives in accordance with Annex II, Part E of Regulation (EC) No 1333/2008 for several, but not all, food categories.
- (7) Business operators provided data on the uses of those food additives in accordance with Annex III, Parts 2 and 4 and Section A of Part 5 of Regulation (EC) No 1333/2008. However, no data were provided for uses in accordance with Annex III, Part 3.
- (8) Taking into account the re-evaluation by the Authority, in particular, the establishment of a group ADI for tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354), it is appropriate to remove those food additives from Group I, create a new group for them and review their conditions of use. Furthermore, given the provided data on the uses of those food additives in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008, it is appropriate to amend the current conditions of use of those food additives by withdrawing the authorisations in food categories for which no data were provided in response to the call for data. Moreover, given those provided data on the uses and the dietary exposure calculated by the Authority, it is appropriate to establish numerical maximum use levels for food categories for which data were provided. It is also appropriate to remove some inconsistencies as regards the conditions of use of tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336) in different categories.
- (9) Given the recommendation from the Authority, it is also appropriate to change in Regulation (EC) No 1333/2008 the name of the food additive 'sodium potassium tartrate' (E 337) to 'potassium sodium tartrate'.

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<sup>3</sup> EFSA Journal 2020;18(3):6030.

<sup>4</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, ELI: <http://data.europa.eu/eli/reg/2012/231/oj>).

- (10) The application of new maximum levels should be deferred, and a transitional period should be provided for products placed on the market before the date of application of the respective maximum levels to allow the food business operators, including small and medium enterprises, to adapt to the new conditions of use laid down in this Regulation.
- (11) Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (12) 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*

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with Annex II to this Regulation.

*Article 3*

Foods containing tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) or calcium tartrate (E 354) that do not comply with this Regulation and have been lawfully placed on the market before ... [*6 months after the date of entry into force of this Regulation*] may remain on the market until their date of minimum durability or 'use-by date'.

*Article 4*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [*6 months after the date of entry into force of this Regulation*].

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*