



2024/1451

27.5.2024

COMMISSION REGULATION (EU) 2024/1451

of 24 May 2024

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), sodium potassium tartrate (E 337) and calcium tartrate (E 354)

(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) 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 ⁽²⁾, 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 (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354) as food additives ⁽³⁾. 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.
- (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.

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

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

⁽³⁾ EFSA Journal 2020;18(3):6030.

- (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) 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.
- (10) Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (11) 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), sodium potassium tartrate (E 337) or calcium tartrate (E 354) that do not comply with this Regulation and have been lawfully placed on the market before 16 December 2024 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 16 December 2024.

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

Done at Brussels, 24 May 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

- (1) PART C is amended as follows:
- (a) in point (1) (Group I), the entries for the food additives E 334 Tartaric acid (L(+)-), E 335 Sodium tartrates, E 336 Potassium tartrates, E 337 Sodium potassium tartrate and E 354 Calcium tartrate are deleted;
 - (b) in point (5) ('Other additives that may be regulated combined'), the following point is added:
'(k.2) E 334 – 337 and E 354: Tartaric acid – tartrates

E-number	Name
E 334	Tartaric acid (L(+)-)
E 335	Sodium tartrates
E 336	Potassium tartrates
E 337	Sodium potassium tartrate
E 354	Calcium tartrate';

- (2) PART E is amended as follows:
- (a) in category 01.3 ('Unflavoured fermented milk products, heat-treated after fermentation'), the following entry is inserted after the entry for E 200-202:

'E 334–337 and E 354	Tartaric acid – tartrates	750	(1) (2)';	
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- (b) in category 01.8 ('Dairy analogues, including beverage whiteners'), the following entry is inserted after the entry for E 280-283:

'E 334–337 and E 354	Tartaric acid – tartrates	240	(1) (2)';	
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- (c) in category 02.2.2 ('Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions'), the following entry is inserted after the entry for E 321:

'E 334–337 and E 354	Tartaric acid – tartrates	1 300	(1) (2)';	
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- (d) category 04.2.3 ('Canned or bottled fruit and vegetables') is amended as follows:

(1) the entry for E 334 Tartaric acid (L(+)-) is replaced by the following:

'E 334	Tartaric acid (L(+)-)	9 000	(98)';	
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(2) the entry for E 335 Sodium tartrates is replaced by the following:

	'E 335	Sodium tartrates	9 000	(51) (98);	
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(3) the entry for E 336 Potassium tartrates is replaced by the following:

	'E 336	Potassium tartrates	9 000	(51) (98);	
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(4) the entry for E 337 Sodium potassium tartrate is replaced by the following:

	'E 337	Sodium potassium tartrate	9 000	(51) (98);	
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(5) the new footnote (98) is inserted after footnote (56):

'(98): Maximum individually or for the combination of E 334–337';

(e) in category 04.2.4.1 ('Fruit and vegetable preparations excluding compote'), the following entry is inserted after the entries for E 220-228:

	'E 334–337 and E 354	Tartaric acid – tartrates	3 000	(1) (2);	
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(f) in category 04.2.5.1 ('Extra jam and extra jelly as defined by Directive 2001/113/EC'), the entries for the food additives E 334 Tartaric acid (L(+)-) and E 335 Sodium tartrates are deleted;

(g) in category 04.2.5.2 ('Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC'), the entries for the food additives E 334 Tartaric acid (L(+)-) and E 335 Sodium tartrates are deleted;

(h) in category 04.2.5.3 ('Other similar fruit or vegetable spreads'), the entries for the food additives E 334 Tartaric acid (L(+)-) and E 335 Sodium tartrates are deleted;

(i) in category 04.2.6 ('Processed potato products'), the following entry is inserted after the entry for E 310-320:

	'E 334–337 and E 354	Tartaric acid – tartrates	240	(1) (2);	
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(j) in category 05.2 ('Other confectionery including breath freshening microsweets'), the following entry is inserted after the entry for E 297:

	'E 334–337 and E 354	Tartaric acid – tartrates	25 000	(1) (2);	
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(k) in category 05.3 ('Chewing gum'), the following entry is inserted after the entry for E 310-321:

E 334-337 and E 354	Tartaric acid – tartrates	25 000	(1) (2);	
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(l) in category 05.4 ('Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4'), the following entry is inserted after the entries for E 297:

E 334-337 and E 354	Tartaric acid – tartrates	11 000	(1) (2);	
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(m) in category 06.4.1 ('Fresh pasta'), the entry for the food additive E 334 Tartaric acid (L(+)-) is deleted;

(n) in category 06.4.3 ('Fresh pre-cooked pasta'), the entry for the food additive E 334 Tartaric acid (L(+)-) is deleted;

(o) in category 06.4.4 ('Potato Gnocchi'), the entry for the food additive E 334 Tartaric acid (L(+)-) is deleted;

(p) in category 06.7 ('Pre-cooked or processed cereals'), the following entry is inserted after the entry for E 310-320:

E 334-337 and E 354	Tartaric acid – tartrates	740	(1) (2);	
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(q) in category 07.1 ('Bread and rolls'), the following entry is inserted after the entries for E 280-283:

E 334-337 and E 354	Tartaric acid – tartrates	15 000	(1) (2)	except products in 7.1.1 and 7.1.2;
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(r) in category 07.2 ('Fine bakery wares'), the following entry is inserted after the entry for E 310-320:

E 334-337 and E 354	Tartaric acid – tartrates	18 000	(1) (2);	
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(s) in category 08.3.2 ('Heat-treated meat products'), the following entry is inserted after the entry for E 310-320:

E 334-337 and E 354	Tartaric acid – tartrates	3 000	(1) (2);	except foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben;
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(t) in category 09.2 ('Processed fish and fishery products including molluscs and crustaceans'), the following entry is inserted after the entry for E 316:

	E 334–337 and E 354	Tartaric acid – tartrates	2 300	(1) (2);	
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(u) in category 11.4.2 ('Table-top sweeteners in powder form'), the entry for the food additive E 336 Potassium tartrates is deleted;

(v) category 11.4.3 ('Table-top sweeteners in tablets') is amended as follows:

(1) the entry for E 334 Tartaric acid (L(+)-) is replaced by the following:

	E 334	Tartaric acid (L(+)-)	270 000	(99);	
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(2) the entry for E 336 Potassium tartrates is replaced by the following:

	E 336	Potassium tartrates	270 000	(51) (99);	
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(3) the new footnote (51) is inserted before footnote (60) and the new footnote (99) is inserted after footnote (60):

'(51): Maximum usable levels are expressed in free acid';

'(99): Maximum individually or for the combination of E 334 and E 336';

(w) in category 12.2.2 ('Seasonings and condiments'), the following entry is inserted after the entry for E 310-321:

	E 334–337 and E 354	Tartaric acid – tartrates	17 000	(1) (2);	
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(x) in category 12.4 ('Mustard'), the following entry is inserted after the entries for E 220-228:

	E 334–337 and E 354	Tartaric acid – tartrates	12 000	(1) (2);	
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(y) in category 12.5 ('Soups and broths'), the following entry is inserted after the entry for E 310-320:

	E 334–337 and E 354	Tartaric acid – tartrates	240	(1) (2);	
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(z) in category 12.6 ('Sauces'), the following entry is inserted after the entry for E 310-320:

'E 334-337 and E 354	Tartaric acid – tartrates	4 000	(1) (2)';	
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(aa) in category 12.7 ('Salads and savoury-based sandwich spreads'), the following entry is inserted after the entry for E 200-213:

'E 334-337 and E 354	Tartaric acid – tartrates	1 800	(1) (2)';	
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(bb) in category 12.9 ('Protein products, excluding products covered in category 1.8'), the following entry is inserted after the entries for E 220-228:

'E 334-337 and E 354	Tartaric acid – tartrates	240	(1) (2)';	
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(cc) category 13.1.3 ('Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC') is amended as follows:

(1) the entry for E 334 Tartaric acid (L(+)-) is replaced by the following:

'E 334	Tartaric acid (L(+)-)	5 000	(100)	only L(+)-form; only biscuits and rusks and baby foods';
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(2) the entry for E 335 Sodium tartrates is replaced by the following:

'E 335	Sodium tartrates	5 000	(51) (100)	only L(+)-form; only biscuits and rusks and baby foods';
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(3) the entry for E 336 Potassium tartrates is replaced by the following:

'E 336	Potassium tartrates	5 000	(51) (100)	only L(+)-form; only biscuits and rusks and baby foods';
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(4) the new footnotes (51) and (100) are inserted after footnote (42):

'(51): Maximum usable levels are expressed in free acid

(100): Maximum individually or for the combination of E 334, E 335 and E 336';

(5) the entry for E 354 Calcium tartrate is deleted;

(dd) in category 14.1.2 ('Fruit juices as defined by Directive 2001/112/EC and vegetable juices'), the entry for the food additive E 336 Potassium tartrates is deleted;

(ee) in category 14.1.4 ('Flavoured drinks'), the following entry is inserted after the entry for E 297:

'E 334-337 and E 354	Tartaric acid – tartrates	4 000	(1) (2)';	
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(ff) category 14.2.6 ('Spirit drinks as defined in Regulation (EU) 2019/787') is amended as follows:

(1) the following entry is inserted after the entry for E 220-228:

	E 334–337 and E 354	Tartaric acid – tartrates	1 000	(1) (2);	
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(2) the new footnote (2) is inserted after footnote (1):

'(2): The maximum level is applicable to the sum and the levels are expressed as the free acid';

(gg) in category 14.2.7.1 ('Aromatised wines'), the following entry is inserted after the entry for E 242:

	E 334–337 and E 354	Tartaric acid – tartrates	8 000	(1) (2);	
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(hh) in category 14.2.7.2 ('Aromatised wine-based drinks'), the following entry is inserted after the entry for E 242:

	E 334–337 and E 354	Tartaric acid – tartrates	8 000	(1) (2);	
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(ii) in category 14.2.7.3 ('Aromatised wine-product cocktails'), the following entry is inserted after the entry for E 242:

	E 334–337 and E 354	Tartaric acid – tartrates	8 000	(1) (2);	
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(jj) in category 14.2.8 ('Other alcoholic beverages including mixtures of alcoholic beverages with non-alcoholic beverages and other alcoholic beverages based on distilled alcohol with alcoholic strength by volume less than 15 %'), the following entry is inserted after the entry for E 242:

	E 334–337 and E 354	Tartaric acid – tartrates	8 000	(1) (2);	
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(kk) in category 15.1 ('Potato-, cereal-, flour- or starch-based snacks'), the following entry is inserted after the entry for E 310-320:

	E 334–337 and E 354	Tartaric acid – tartrates	60 000	(1) (2);	
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(ll) in category 16 ('Desserts excluding products covered in categories 1, 3 and 4'), the following entry is inserted after the entry for E 297:

	E 334–337 and E 354	Tartaric acid – tartrates	3 000	(1) (2);	
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(mm) in category 17 ('Food supplements as defined in Directive 2002/46/EC'), the Introduction part is replaced by the following:

The maximum levels of use indicated for colours, polyols, sweeteners, E 200-213, E 334-337 and E 354, E 338-452, E 405, E 416, E 432-436, E 459, E 468, E 473-475, E 491-495, E 551-553, E 901-904, E 961, E 1201-1204, E 1505 and E 1521 refer to the food supplements ready for consumption prepared following the instructions for use provided by the manufacturer.

The dilution factor for those food supplements that have to be diluted or dissolved has to be communicated together with the instructions for use.;

(nn) in category 17.1 ('Food supplements supplied in a solid form, excluding food supplements for infants and young children'), the following entry is inserted after the entry for E 310-321:

E 334-337 and E 354	Tartaric acid – tartrates	100 000	(1) (2)	except food supplements in chewable form
E 334-337 and E 354	Tartaric acid – tartrates	130 000	(1) (2)	only food supplements in chewable form';

(oo) in category 17.2 ('Food supplements supplied in a liquid form, excluding food supplements for infants and young children'), the following entry is inserted after the entry for E 310-321:

E 334-337 and E 354	Tartaric acid – tartrates	6 000	(1) (2)'	
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Annex III to Regulation (EC) No 1333/2008 is amended as follows:

- (1) in Part 2, the following entry is inserted after the entry for E 321:

E 334–337 and E 354	Tartaric acid – tartrates (Table 8 of Part 6)	220 000 mg/kg singly or in combination in the preparation and 11 000 mg/kg in the final product expressed as the free acid	E 440 Pectins used in food category 05.2 (Other confectionery including breath freshening microsweets) and food category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4);
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- (2) in Part 3, the entries for the food additives E 334 Tartaric acid (L(+)-), E 335 Sodium tartrates, E 336 Potassium tartrates, E 337 Sodium potassium tartrate and E 354 Calcium tartrate are deleted;

- (3) in Part 4, the following entry is inserted after the entry for E 320:

E 334–337 and E 354	Tartaric acid – tartrates (Table 8 of Part 6)	All flavourings	20 000 mg/kg singly or in combination in the flavouring and 400 mg/kg in the final product expressed as the free acid';
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- (4) in Part 5, Section A is amended as follows:

- (a) the entries for the food additives E 334 Tartaric acid (L(+)-), E 335 Sodium tartrates, E 336 Potassium tartrates, E 337 Sodium potassium tartrate and E 354 Calcium tartrate are deleted;
- (b) the following entry is inserted after the entry for E 333:

E 334–337 and E 354	Tartaric acid – tartrates (Table 8 of Part 6)	1 000 mg/kg singly or in combination in the nutrient preparation	All nutrients';
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- (5) Part 6 is amended as follows:

- (a) in Table 1, the entries for the food additives E 334 Tartaric acid (L(+)-), E 335 Sodium tartrates, E 336 Potassium tartrates, E 337 Sodium potassium tartrate and E 354 Calcium tartrate are deleted;

(b) the following table is added:

Table 8
Tartaric acid – tartrates

E-number	Name
E 334	Tartaric acid (L(+)-)
E 335	Sodium tartrates
E 336	Potassium tartrates
E 337	Sodium potassium tartrate
E 354	Calcium tartrate'