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WORKING DOCUMENT

Follow-up of EFSA's re-evaluation of the safety of L(+)-tartaric acid (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354) as food additives

Background

In 2020, the safety of the permitted food additives tartaric acid-tartrates (E 334-337, 354) was re-evaluated by EFSA¹ in the context of the programme for the re-evaluation of approved food additives required by Regulation No 1333/2008. EFSA established a group Acceptable Daily Intake (ADI) for L(+)-tartaric acid-tartrates (E 334-337 and E 354) of 240 mg/kg bw per day. The exposure estimates for the refined non-brand-loyal exposure scenario did not exceed the group ADI of 240 mg/kg bw per day, expressed as tartaric acid. EFSA made several recommendations to be considered by the European Commission.

Follow-up to the re-evaluation

In line with the approach² agreed for the follow-up of such inconclusive scientific opinions, SANTE E2 organised a call for data (published 19 January 2021) requesting business operators to submit the technical data needed to address the issues identified by EFSA by the specified deadline (19 July 2021), (http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en). The following data were requested:

- Information related to the specifications in order to address the EFSA recommendations.
- Data on uses and use levels: since EFSA has established a numerical ADI for the food additives tartaric acid tartrates (E 334-337, 354), numerical maximum use levels should be defined for all their permitted uses. Therefore, all current authorisations at *quantum satis* should be revised.

Uses in accordance with Annex II, Part E of Regulation (EC) No 1333/2008

¹ EFSA Journal 2020;18(3):6030 (<https://www.efsa.europa.eu/en/efsajournal/pub/6030>)

² https://ec.europa.eu/food/system/files/2022-01/fs_food-improvement-agents_reeval_approach.pdf

The permitted food additives tartaric acid-tartrates (E334-7, E 354) are part of Group I of food additives in Annex II, Part C, of Regulation (EC) No 1333/2008. In accordance with Annex II, Part E, Group I is authorised in 66 different food categories at *quantum satis*. In addition, there are specific authorisations for one or more of these food additives in 15 food categories.

No uses/use levels in accordance with Annex II to Regulation No 1333/2008 were reported for E 354.

Actual use levels were reported by business operators for the following food categories:

- 4.2.4.1 Fruit and vegetable preparations excluding compote
- 5.1. Cocoa and chocolate products as covered by Directive 2000/36/EC
- 5.2 Other confectionery including breath refreshing microsweets
- 5.3 Chewing gum
- 5.4 Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4
- 7.1 Bread and rolls
- 7.2 Fine Bakery Ware
- 8.3.2 Heat-treated processed meat
- 11.4.3 Table-top sweeteners in tablets
- 12.6 Sauces
- 14.1.4 Flavoured drinks
- 14.2.2 Wine and other products defined by Regulation (EEC) No 1234/2007, and alcohol-free counterparts
- 16 Desserts excluding products covered in categories 1, 3 and 4
- 17.1 Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms
- 17.2 Food supplements supplied in a liquid form, excluding food supplements for infants and young children

No actual use levels were reported by business operators for the following food categories:

- 1.3 Unflavoured fermented milk products, heat-treated after fermentation
- 1.4 Flavoured fermented milk products including heat-treated products
- 1.6.3 Other creams
- 1.7.1 Unripened cheese excluding products falling in category 16
- 1.7.5 Processed cheese
- 1.7.6 Cheese products (excluding products falling in category 16)
- 1.8 Dairy analogues, including beverage whiteners
- 2.2.2 Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions
- 2.3 Vegetable oil pan spray
- 3. Edible ices
- 4.2.1 Dried fruit and vegetables
- 4.2.2. Fruit and vegetables in vinegar, oil, or brine

- 4.2.3. Canned or bottled fruits and vegetables
- 4.2.5.1. Extra jam and extra jelly as defined by Directive 2001/113/EC
- 4.2.5.2. Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC
- 4.2.5.3 Other similar fruit or vegetable spreads
- 4.2.5.4 Nut butters and nut spreads
- 4.2.6 Processed potato products
- 6.2.2 Starches
- 6.3 Breakfast cereals
- 6.4.1. Fresh pasta
- 6.4.2 Dry pasta
- 6.4.3. Fresh pre-cooked pasta
- 6.4.4. Gnocchi
- 6.4.5 Fillings of stuffed pasta (ravioli and similar)
- 6.5 Noodles
- 6.6 Batters
- 6.7 Pre-cooked or processed cereals
- 8.3.1 Non-heat-treated processed meat
- 8.3.3 Casings and coatings and decorations for meat
- 9.2 Processed fish and fishery products including mollusks and crustaceans
- 9.3 Fish roe
- 10.2 Processed eggs and egg products
- 11.2 Other sugars and syrups
- 11.4.2. Table-top sweeteners in powder form
- 12.1.2 Salt substitutes
- 12.2.2 Seasonings and condiments
- 12.3 Vinegars and diluted acetic acid (diluted with water to 4-30 % by volume)
- 12.4 Mustard
- 12.5 Soups and broths
- 12.7 Salads and savoury-based sandwich spreads
- 12.8 Yeast and yeast products
- 12.9 Protein products, excluding products covered in category 1.8
- 13.1.3 Processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC
- 13.1.5.2 Dietary foods for infants and young children for special medical purposes as defined by Directive 1999/21/EC and special formulae for infants
- 13.2 Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
- 13.3 Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)
- 13.4 Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009
- 14.1.2. Fruit juices as defined by Directive 2001/112/EC and vegetable juices

- 14.1.3 Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products
- 14.1.5.2 Other non-alcoholic beverages
- 14.2.3 Cider and perry
- 14.2.4 Fruit wine and made wine
- 14.2.5 Mead
- 14.2.6 Spirit drinks as defined in Regulation (EC) No 110/2008
 - 14.2.7.1 Aromatised wines
 - 14.2.7.2 Aromatised wine-based drinks
 - 14.2.7.3 Aromatised wine-product cocktails
- 14.2.8 Other alcoholic drinks including mixtures of alcoholic drinks with non alcoholic drinks and spirits with less than 15 % of alcohol
- 15.1 Potato-, cereal-, flour- or starch-based snacks
- 15.2 Processed nuts
- 18. Processed foods not covered by categories 1 to 17, excluding foods for infants and young children

It is considered that there is no interest that the use of E 334-337 and E 354 as food additives remains authorised in the food categories for which no actual use levels have been submitted. Consequently, the authorisation for the use of E 334-337 and E 354 as food additives in these food categories will be withdrawn.

Uses in accordance with Annex III, Part 2, 3, 4 and Section A of Part 5 of Regulation (EC) No 1333/2008

Tartaric acid and tartrates (E 334-337, E 354) are authorised according to Annex III of Regulation (EC) No 1333/2008 as follows:

- as food additives in food additives having a function other than a carrier with a maximum level in the products (beverages or not) at *quantum satis* (Annex III, Part 2).
- as food additives in food enzymes with a maximum level in the products (beverages or not) at *quantum satis* (Annex III, Part 3).
- as food additives including carriers in all food flavourings with a maximum level in the products (beverages or not) at *quantum satis* (Annex III, Part 4).
- as food additives in all nutrients except nutrients intended to be used in foodstuffs for infants and young children, with a maximum level in the nutrient at *quantum satis* (Annex III, Part 5, Section A).

Actual use levels have been submitted for:

- Annex III, Part 2
- Annex III, Part 4
- Annex III Part 5, Section A

No actual use levels were received for:

- Annex III, Part 3

It is considered that there is no interest that the use of E 334-337 and E 354 as food additives remains authorised in accordance with Annex III, Part 3. Consequently, the authorisation for the use of E 334-337 and E 354 as food additives in accordance with Annex III, Part 3 will be withdrawn.

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