Call for technical data on the permitted food additives L(+)-tartaric acid (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354)

Published: 19 January 2021

Deadline: 19 July 2021

Background

According to Article 32 of Regulation (EC) No 1333/2008[1], food additives permitted in the EU before 20 January 2009 should be subject to a new risk assessment by the European Food Safety Authority (EFSA). The programme for the re-evaluation of these permitted food additives has been set up by Commission Regulation (EU) No 257/2010[2].

So far EFSA has not identified a major safety concern (such as a proven carcinogenic or genotoxic activity) for any of the re-evaluated food additives. In fact, in most cases EFSA confirms the safety of those food additives at their currently reported uses and use levels. However, for some additives EFSA has identified issues that require a follow-up. Additional specific data is needed to address those issues.

The additives whose safety re-evaluation by EFSA was hindered by limited data availability, but which are not expected to pose an immediate food safety concern, are not going to be immediately removed from the Union list of permitted additives, or their uses and/or use levels revised. Instead, business operators are requested to indicate to the Commission their interest in the continuity of approval of the additive(s) under re-evaluation and in providing, by a certain deadline, the data needed by EFSA to complete its risk assessment. In general, new toxicological studies will be needed to generate these missing data.

Once EFSA has assessed the new data, the current authorisation of the additive(s) may be revised, if needed.

If business operators do not provide the requested data (by the predefined deadline) the present authorisation will be revised based on EFSA's current scientific opinion and the additive(s) may be removed from the Union list of permitted additives. The same applies if the new data submitted is not sufficient for EFSA to conclude the risk assessment, since there will be no successive requests for additional data.

Food additives for which EFSA has identified concerns in terms of exposure or specifications will be subject to the same follow-up approach, but EFSA's assessment of the new data may not always be needed.

The Commission will undertake that the time assigned for addressing issues identified by EFSA is as short as possible and dependent on the time needed to generate and assess the required new data.

EFSA's Scientific Opinion on the re-evaluation 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

The EFSA Panel on Food Additives and Flavourings (FAF) provided on 11 March 2020 a scientific opinion re-evaluating the safety of tartaric acid tartrates (E 334-337, 354) when used as food

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.

additives[3]. In 1990 the Scientific Committee on Food (SCF) established an acceptable daily intake (ADI) of 30 mg/kg body weight (bw) per day, for L(+)-tartaric acid and its potassium and sodium salts.

The metabolism of L(+)-tartaric acid and its potassium sodium salt was shown to be species dependent, with a greater absorption in rats than in humans. No toxic effects, including nephrotoxicity, were observed in toxicological studies in which the L(+)-form was tested. There was no indication for a genotoxic potential of tartaric acid and its sodium and potassium salts. In a chronic study in rats, no indication for carcinogenicity of monosodium L(+)-tartrate was reported at the highest dose tested (3,100 mg/kg bw per day).

The available studies for maternal or developmental toxicity did not report any relevant effects; no studies for reproductive toxicity were available; however, no effects on reproductive organs were observed in the chronic toxicity study. EFSA concluded that the data on systemic availability were robust enough to derive a chemical-specific uncertainty factor instead of the usual default uncertainty factor of 100. A total uncertainty factor of 10 was derived by applying a total interspecies uncertainty factor of 1 instead of 10, based on data showing lower internal exposure in humans compared to rats. EFSA established a group ADI for L(+)-tartaric acid-tartrates (E 334-337 and E 354) of 240 mg/kg bw per day, expressed as tartaric acid, by applying the total uncertainty factor of 10 to the reference point of 3,100 mg sodium tartrate/kg bw per day, approximately to 2,440 mg tartaric acid/kg bw per day.

The exposure estimates for the different population groups 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 some recommendations to be considered for possible revision of the EU specifications of these food additives.

Overall purpose of this call for data

To give the opportunity to business operators to submit the technical data needed to address issues identified by EFSA in the 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.

Technical data required

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation 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 by EFSA, information is sought on:

1. **<u>Information related to the specifications</u>**

1.1 For monosodium tartrate (E 335 (i)), disodium tartrate (E 335 (ii)), monopotassium tartrate (E 336 (i)), dipotassium tartrate (E 336 (ii)), potassium sodium tartrate (E 337) and calcium tartrate (E 354):

- Information on all manufacturing processes used for the production of each of these food additives;
- Information on the specific rotation of E 335 (i), E 335 (ii), E 336 (i), E 336 (ii) and E 337, in order to introduce a provision for specific rotation in the “identification” section of their specifications, to ensure the exclusive use of the authorised L(+)-stereoisomer in these food additives;
- In case a chemical/microbiological manufacturing process is used for the production of any of these food additives, information on levels of heavy metals (e.g. vanadium, molybdenum or

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

tungsten) resulting from the use of any catalyst should also be provided (as requested below for E 334);

1.2 For L(+)-tartaric acid (E 334):

- Analytical data, if possible supported by certificate of analysis, in commercial samples of the food additive E 334, on heavy metals (e.g. vanadium, molybdenum or tungsten) resulting from the use of any catalyst for the chemical/microbiological production of E 334 using *Rhodococcus ruber* strain CM001 or *Rhodococcus* sp strain USA-AN012;
- The lowest technologically achievable level for heavy metals (e.g. vanadium, molybdenum or tungsten) resulting from the use of any catalyst for the chemical/microbiological production of E 334 using *Rhodococcus ruber* strain CM001 or *Rhodococcus* sp strain USA-AN012, in order to adequately define maximum limits in the specifications for this food additive;

1.3 For L(+)-tartaric acid (E 334), monosodium tartrate (E 335 (i)), disodium tartrate (E 335 (ii)), monopotassium tartrate (E 336 (i)), dipotassium tartrate (E 336 (ii)), potassium sodium tartrate (E 337) and calcium tartrate (E 354):

- Analytical data, if possible supported by certificate of analysis, on current levels of arsenic, lead and mercury in commercial samples of these food additives;
- The lowest technologically achievable level for arsenic, lead and mercury and cadmium in order to adequately define maximum limits in the specifications for these food additives;

The analyses should be performed with appropriate analytical methods applying state of the art techniques. Specific data on the methods of analysis used should be provided. These include, but are not limited to, e.g. the principle of the method, the scope of the method (i.e. the range of sample types that the method is used for), the concentration units used to express the analytical result(s), validation of the method (in particular limit of detection (LOD) and (LOQ).

2. Data on uses/use levels of the food additives L(+)-tartaric acid (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354)

Since EFSA has established a numerical Acceptable Daily Intake (ADI) for the food additives tartaric acid tartrates (E 334-337, 354), numerical maximum use levels should be defined for all their permited uses. Therefore, all current authorisations at *quantum satis* should be revised.

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

Tartaric acid and tartrates (E 334-337, E 354) are included in the Group I of food additives and they are therefore authorised in the 66 food categories in which the use of Group I of food additives is permitted. In addition, there are specific authorisations for one or more of these food additives in 15 food categories.

For all the food categories in which E 334-337 and E 354 are permitted in accordance with Annex II, Part E of Regulation (EC) No 1333/2008, food business operators are requested to provide:

- data on normal and maximum use levels of E 334-337 and E 354 in each food category, expressed as tartaric acid, indicating whether all additives of the group E 334-337, E 354 tartaric acid-tartrates are used or only some/one of them. If E 334-337 and E 354 are used in combination (as a group) the use level provided should be applicable to the group (and not to each member of the group). A numerical maximum level needs to be provided (the *quantum satis* principle should not be applied for these food additives). For dried and/or concentrated foods which need to be reconstituted, the level provided shall apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor;

- information on whether the reported use and use levels concern all different foodstuffs belonging to a food category or only certain foodstuffs (to potentially allow the definition of appropriate restrictions/exceptions of use in Annex II, Part E of Regulation (EC) No 1333/2008).

Data on use levels of E 334-337 and E 354 in the food categories in which these food additives are currently permitted should be reported using the attached template developed for this purpose (MS Excel® file "Data on use of E 334-337 and E 354 in accordance with Annex II, Part E, of Regulation (EC) No 1333-2008.xls"), following the instructions provided in the template.

Data on use of E 334-337 and E 354 i

If no data are provided for a food category in which the intentional addition of E 334-337 and E 354 as food additives is currently authorised, it will be considered that there is no interest that the use of E 334-337 and E 354 as food additives remains authorised in that food category. Consequently, the authorisation for the use of E 334-337 and E 354 as food additives in that food category will be withdrawn.

Therefore, if an interested party has information that E 334-337 and E 354 are not used in one or several food categories in which they are currently authorised, this information should also be provided. Such information will be of course cross-checked with information sent by all interested parties replying to the call.

2.2 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 also 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).

For all the uses for which E 334-337 and E 354 are permitted in accordance with Annex III of Regulation (EC) No 1333/2008, food business operators are requested to provide:

- data on maximum use levels of E 334-337 and E 354 in the preparation as well as in the final food, expressed as tartaric acid, indicating whether all these additives of the group E 334-337, E 354 tartaric acid-tartrates are used or only some/one of them. If E 334-337 and E 354 are used in combination (as a group) the use level provided should be applicable to the group (and not to each member of the group). A numerical maximum level needs to be provided (the *quantum satis* principle should not be applied for these food additives);
- information on whether the reported use concerns all preparations or only certain preparations (when appropriate).

Data on use levels of E 334-337 and E 354 in accordance with Annex III of Regulation (EC) No 1333-2008 should be reported using the attached template developed for this purpose (MS Excel® file

"Data on use of E 334-337 and E 354 in accordance with Annex III of Regulation (EC) No 1333-2008.xls"), following the instructions provided in the template.

Data on use of E 334-337 and E 354 i

If no data are provided for a currently authorised use of E 334-337 and E 354 as food additives in accordance with Annex III, Part II, III, IV or V, it will be considered that there is no interest that that use remains authorised. Consequently, that authorisation for the use E 334-337 and E 354 as food additives in that food category will be withdrawn.

Therefore, if an interested party has information that E 334-337 and E 354 are not used in accordance with Annex III, Part II, III, IV or V, this information should also be provided. Such information will be of course cross-checked with information sent by all interested parties replying to the call.

Procedure of the call for data

It should be noted that this call concerns only technical data. Therefore, the 2-step procedure used in previous calls for scientific and technical data is not followed, since such procedure is considered to be more appropriate for calls for data requesting scientific data (e.g. toxicological data which require that new toxicological studies are performed). Therefore, the deadline of this call is the final deadline for submission of the requested technical data.

Business operators are requested to submit to the Commission by **19 July 2021** the above-requested data.

In order to streamline the data collection exercise, business operators are invited to liaise with the relevant food business operator associations for the data submission. In particular, data providers shall ensure that the same data are not sent several times to the European Commission (for example, they should not be sent by both the business operator and also by the association to which the business operator belongs to).

Any questions about this call for data should be sent to the email address Sante-E2-Additives@ec.europa.eu.

Submission of the required data

Business operators are requested to submit the above-indicated data by the agreed deadline using the online platform CIRCABC. The "Guidance for online data submission on Food Improvement Agents via CIRCABC Sante-Cad-In Group"[4] provides practical information on how to use the CIRCABC platform for the online submissions.

Common electronic formats (e.g. MS Office®, Adobe Acrobat Reader®) allowing content copying and printing (no content copy protection) should be used for the files to be submitted. The text of the files should be searchable using the search facilities of standard software packages. The submission should include a cover letter stating clearly in the subject line the food additive(s) to which it refers, and describing the data submitted. The cover letter should provide the contact details of the data submitter and should be addressed to:

Bruno Gautrais, Head of Unit E2
European Commission
Directorate-General for Health and Food Safety
Directorate E – Food and feed safety, Innovation

[4] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_circabc_data-sub.pdf

Unit E2 – Food Processing Technologies and Novel Foods
B-1049 Brussels

This cover letter should also be sent separately to the functional mailbox SANTE-E2-Additives@ec.europa.eu.

Once the new data are received, they will be submitted to EFSA for evaluation and preparation of a scientific opinion, if appropriate.

Confidential data

According to article 8 of Regulation (EU) No 257/2010 setting up a re-evaluation programme of approved food additives, confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties.

Therefore, the business operators and/or the interested parties should indicate in detail which of the information provided they wish to be treated as confidential and they should provide verifiable justification supporting this request. It should be noted that the information described in article 8(2) of the Regulation (EU) No 257/2010 shall not, in any circumstances, be regarded as confidential.

In application of Article 8(4) of Regulation (EU) 257/2010, following a proposal from EFSA, the Commission will decide after consulting the interested business operator and/or the other interested parties, which information may remain confidential.

Possibility for EFSA to use the data for the safety assessment of the same substance under other legal or regulatory frameworks

In line with Union policy objectives on animal welfare and testing on vertebrates, EFSA aims to avoid the duplication of testing on vertebrates, and to achieve an optimal use of the relevant financial and human resources by the private sector. Therefore, in anticipation of cases where EFSA may be interested in using or reusing relevant information or data (i.e. technical, toxicological data) for the evaluation of the same substance under a different legal or regulatory framework from the one mentioned above, or for the evaluation of another substance under the same or different legal framework as above, please indicate explicitly in writing, whether by participating in the voluntary submission of relevant data or information, you also give EFSA the permission to use and/or reuse these data for other EFSA safety assessments, and/or for a data sharing exercise with third parties or other international bodies.