Call for technical data on the permitted food additive metatartaric acid (E 353)

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 metatartaric acid (E 353) as a food additive

The EFSA Panel on Food Additives and Flavourings (FAF) provided on 11 March 2020 a scientific opinion re-evaluating the safety of metataric acid (E 353) when used as a food additive[3].

Metatartaric acid (E 353) had been previously evaluated by the Scientific Committee on Food (SCF) and Joint FAO/WHO Expert Committee on Food Additives (JECFA). Based on the presumption that metatartaric acid is fully hydrolysed presystemically to L(+)-tartaric acid, EFSA concluded that

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] EFSA Journal 2020;18(3):6031 (https://www.efsa.europa.eu/en/efsajournal/pub/6031)

metatartaric acid (E 353) should be included in the group acceptable daily intake (ADI) of 240 mg/kg body weight (bw) per day, expressed as tartaric acid, for L(+)-tartaric acid-tartrates (E 334–337, 354) which was established by the EFSA FAF Panel in 2020.

Exposure estimates were calculated for metatartaric acid (E 353) using a maximum level and refined exposure assessment scenario. EFSA also concluded that there is no safety concern for the use of metatartaric acid (E 353) at the reported use and use level.

EFSA made a number of recommendations concerning the specifications for metatartaric acid (E 353) in Commission Regulation (EU) No 231/2012.

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 metatartaric acid (E 353) as a food additive.

Technical data required

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of metatartaric acid (E 353) as a food additive by EFSA, information is sought on:

- Information on all manufacturing processes used for the production of metatartaric acid (E 353);
- In case a chemical/microbiological manufacturing process is used for the production of metatartaric acid (E 353), information on levels of heavy metals (e.g. vanadium, molybdenum or tungsten) resulting from the use of any catalyst should also be provided (as requested in the call for data on L(+)-tartaric acid (E 334) (see https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en);
- Information on the solubility (expressed as g/L) of the food additive metatartaric acid (E 353) in water and ethanol;
- Information on the optical rotation, molecular weight, molecular weight distribution and polydispersity index the food additive metatartaric acid (E 353);
- Analytical data, if possible supported by certificate of analysis, on current levels of free tartaric acid, pyruvic acid and oxaloacetic acid in commercial samples of the food additive metatartaric acid (E 353);
- The lowest technologically achievable level for free tartaric acid, pyruvic acid and oxaloacetic acid in the food additive metatartaric acid (E 353) in order to adequately define maximum limits in the specifications for the food additive metatartaric acid (E 353);
- Analytical data, if possible supported by certificate of analysis, on current levels of arsenic, lead and mercury in commercial samples of the food additive metatartaric acid (E 353);
- The lowest technologically achievable level for arsenic, lead and mercury and cadmium in order to adequately define maximum limits in the specifications for the food additive metatartaric acid (E 353);

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).

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
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

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

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.