Call for scientific data on L(+)-tartaric acid (E 334) and related food additives authorised in the EU

EFSA-Q-number: EFSA-Q-2016-00353
Published: 31/05/2016
Deadline: 31/12/2016

Background

According to Regulation (EC) No 1333/2008\(^1\), food additives which were permitted for use in the European Union before 20 January 2009 need to be re-evaluated by the European Food Safety Authority (EFSA). The programme for this re-evaluation is defined by Regulation (EU) No 257/2010\(^2\).

In accordance with the above regulations EFSA started a systematic re-evaluation of authorised food additives and is issuing scientific opinions on these food additives, according to the priorities indicated in the Regulation (EU) No 257/2010.

In order to ensure an effective re-evaluation, it is important that EFSA retrieves from interested parties all relevant data for the re-evaluation of the selected food additives. Therefore, in accordance to article 6(3) of the regulation (EU) No 257/2010 EFSA launches a public call for data in order to acquire documented information (published, unpublished or newly generated) on L(+)-tartaric acid (E 334) and related food additives.

EFSA will consider the relevance of the information provided for the risk assessment of these food additives. The submission of the requested information is without prejudice to the final opinion of the ANS Panel.

Overall objective

The purpose of this call for data is to offer to interested parties and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of L(+)-tartaric acid (E 334) and related food additives.

Deadline for submission of data and disclosure of contact details

Interested parties and stakeholders should provide by 31/12/2016 the information

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described below.

Within **4 weeks** from the publication of this call, please communicate in writing by e-mail to: **fip@efsa.europa.eu**, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.

In accordance with Article 6(4) of the Regulation (EU) No 257/2010 the information not submitted within the final deadline will only exceptionally be considered and EFSA can finalise its opinions on the basis of the information already provided.

In order to facilitate the collaboration of all interested parties to provide the data needed, we are seeking your consent to disclose your personal data (name, e-mail address and telephone number) to the other parties that has expressed an interest to provide the requested information. If you do not wish to make your contact details available, clearly indicate it in your first communication.

**Information sought**

To the extent possible, the following requested information should follow the relevant parts of the applicable Guidance for submissions for food additive evaluations.³

EFSA kindly invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit information on the following food additives:

<table>
<thead>
<tr>
<th>Food additive</th>
<th>E number</th>
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<tbody>
<tr>
<td>L(+)·tartaric acid</td>
<td>E 334</td>
</tr>
<tr>
<td>Monosodium tartrate (sodium salt of L(+)·tartaric acid)</td>
<td>E 335(i)</td>
</tr>
<tr>
<td>Disodium tartrate (dihydrated disodium salt of L(+)·tartaric acid)</td>
<td>E 335(ii)</td>
</tr>
<tr>
<td>Monopotassium tartrate (anhydrous monopotassium salt of L(+)·tartaric acid)</td>
<td>E 336(i)</td>
</tr>
<tr>
<td>Dipotassium tartrate (dipotassium salt with half a molecule of water of L(+)·tartaric acid)</td>
<td>E 336(ii)</td>
</tr>
<tr>
<td>Potassium sodium tartrate (potassium sodium L(+)·tartrate)</td>
<td>E 337</td>
</tr>
<tr>
<td>Metatartaric acid</td>
<td>E 353</td>
</tr>
<tr>
<td>Calcium tartrate (calcium L(+)-2,3-dihydroxybutanedioate dihydrate)</td>
<td>E 354</td>
</tr>
<tr>
<td>Tartaric acid esters of mono- and diglycerides of fatty acids</td>
<td>E472d</td>
</tr>
<tr>
<td>Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids</td>
<td>E472e</td>
</tr>
<tr>
<td>Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids</td>
<td>E472f</td>
</tr>
<tr>
<td>Stearyl tartrate</td>
<td>E 483</td>
</tr>
</tbody>
</table>

Data sought on L(+)-tartaric acid (E334 ) and its salts (E335-337 and 354)

- Tartaric acid can exist in different isomeric forms, however only L(+)-tartaric acid and its salts are authorised as food additives. To ensure that no racemisation takes place during storage or processing of food containing L(+)-tartaric acid and its salts, the following information is needed: stability study under the normal condition of storage of L(+)-tartaric acid and its salts and their fate in food, covering also conditions of processing (e.g high temperature).
- The toxicological data which are available for L(+)-tartaric acid and its salts are limited (very few ADME and toxicity studies; only one chronic toxicity study in rats not performed according to the current standards, limited in vitro genotoxicity studies, limited reproductive and developmental toxicity studies). In addition most of these studies lack adequate stereoisomeric characterisation of the test substance used. Consequently, any information relevant for their safety assessment (including characterisation of the test substance with a well specified stereoisomeric composition) is needed.

Data sought on metatartaric acid (E 353 ), tartaric acid esters of mono- and diglycerides of fatty acids (E 472d), mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E472e), mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E472f) and stearyl tartrate (E 483)

- Information on the composition of the food additive giving the range of percentage of each component and providing full information on the stereochemistry (especially regarding the tartaric acid moiety) of all constituents.
- Information on the manufacturing process indicating the stereochemistry of the starting materials especially regarding tartaric acid.
- Stability study under the normal condition of storage of the food additive and its fate in food, covering also conditions of processing (e.g high temperature)
- Due to the limited biological data of the food additives - especially on metatartaric acid (E 353), stearyl tartrate (E 483), tartaric acid esters of mono- and diglycerides of fatty acids(E 472d) and mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472f)- and the lack of information on their metabolism, additional data supporting the assumption that the ester/lactone group is hydrolysed in the intestinal fluid is needed.
- The toxicological data available for the food additives are limited. Consequently, any relevant information for their safety assessment is needed. Data to be provided should indicate the stereochemistry of the tartaric acid moiety in the test material.

Confidentiality

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.

Information sought is regarded to be complementary to information already received/requested on previous calls.
Therefore the business operators and/or the interested parties should indicate which information wish to be treated as confidential and provide verifiable justification supporting this request. Note that the information described in article 8(2) of the Regulation (EU) No 257/2010 cannot be 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.

Submission of information

Interested business operators and/or interested parties should submit the information to EFSA in electronic form (e.g. CD, DVD, etc.) with a

- cover letter that should contain:
  - Reference to the specific call and the specific EFSA question number indicated (EFSA-Q-2016-00353);
  - Reference to the substance concerned and its E-number;
  - The contact detail (name of contact person, name of company/organisation, email address and telephone number) of the person responsible for the data submission and, if applicable, the list of interested business operators and/or interested parties represented and their contact details;
  - statement of the submitter that they hold all the necessary rights to grant EFSA permission to use and, where appropriate, to disclose the submitted information, data, document, paper or study for the purposes better defined in this call. In case the submitter does not enjoy the necessary rights for these data or studies, they should share the contact details of the respective owner(s) of data and/or of the relevant intellectual property right, so that EFSA may seek their approval directly.
  - separate folders with the confidential and with the non-confidential parts.

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

In case future mutual interests arise in exchanging any relevant information (i.e. technical or toxicological data) with the Joint WHO – FAO Expert Committee on Food Additives (JECFA) for the re-evaluation of food additives, we would appreciate your written consent for data sharing between EFSA and JECFA on the above-mentioned food additives.

Note that EFSA may use or re-use relevant information or data (i.e. technical, toxicological data) for the evaluation of the same or another substance under the same or a different legal or regulatory framework from the one mentioned above.

Correspondence
Please send all electronic correspondence, including enquiries to:

fip@efsa.europa.eu

Submissions should be sent to the following address:
FIP Unit, Food Additives
European Food Safety Authority
Via Carlo Magno 1/a
43126 Parma