Call for technical data on the permitted food additive stearyl tartrate (E 483)

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Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 2 March 2021

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 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 stearyl tartrate (E 483) 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 stearyl tartrate (E 483) when used as a food additive[3].

[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/6033)

The previously evaluated toxicological studies were not available, in addition to no genotoxicity data being available. Thus, adequate toxicity data on stearyl tartrate were not available for its re-evaluation. In addition, adequate data demonstrating the complete hydrolysis of stearyl tartrate (E 483) in the gastrointestinal tract and/or presystemically, that could allow read-across from data on its constituents, were lacking. Therefore, the safety of the use of stearyl tartrate as a food additive could not be assessed and the acceptable intake established by the Scientific Committee on Food (SCF) in 1978 could not be confirmed.

Exposure to stearyl tartrate (E 483) was calculated using the maximum level exposure assessment scenario as neither use levels nor analytical data were available. Mean exposure to stearyl tartrate (E 483) as a food additive ranged from 0.1 mg/kg body weight (bw) per day in infants to 82.5 mg/kg bw per day in toddlers. The 95th percentile of exposure ranged from 0 mg/kg bw per day in adults to 192.7 mg/kg bw per day in toddlers. EFSA also noted that information from the Mintel's Global New Products Database (GNPD) indicates that only two products have been labelled with stearyl tartrate (E 483) since 1996. Some recommendations were proposed by EFSA.

Overall purpose of this call for data

To give the opportunity to business operators to submit the scientific and technical data needed to address issues identified by EFSA in the re-evaluation of the safety of stearyl tartrate (E 483) as a food additive.

Scientific and technical data required

The data required to address the various issues identified by EFSA in the re-evaluation of the safety of stearyl tartrate (E 483) as a food additive are the following:

1. Technical data

1.1 Information related to the specifications for stearyl tartrate (E 483)

- Information on all manufacturing processes used for the production of stearyl tartrate (E 483);
- In case a chemical/microbiological manufacturing process is used for the production of stearyl tartrate (E 483), 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);
- Analytical data, if possible supported by certificate of analysis, on current levels of arsenic, lead and mercury in commercial samples of the food additive stearyl tartrate (E 483);
- The lowest technologically achievable level for arsenic, cadmium, lead and mercury and cadmium in order to adequately define maximum limits in the specifications for the food additive stearyl tartrate (E 483);

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).

1.2 Data on uses/use levels of the food additive stearyl tartrate (E 483)

For all the four food categories in which the food additive stearyl tartrate (E 483) is permitted in accordance with Annex II, Part E of Regulation (EC) No 1333/2008, food business operators are

requested to provide data on actual normal/typical use levels, as well as any other information relevant to perform a refined exposure assessment for E 483.

If no use data are provided for a food category in which the intentional addition of E 483 as a food additive is currently authorised, it will be considered that there is no interest that the use of E 483 as a food additive remains authorised in that food category. Consequently, the authorisation for the use of E 483 in that food category will be withdrawn.

Therefore, if an interested party has information that E 483 is used in one or more food categories in which it is 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. Scientific data

The limitations in the toxicological database of stearyl tartrate (E 483) need to be decreased to allow EFSA to assess the safety of this substance when used as food additive. Therefore, a toxicological database should be generated for the food additive stearyl tartrate (E 483) with adequately characterized material, and in line with the tiered approach described in the EFSA Guidance for submission for food additive evaluations (EFSA ANS Panel, 2012)[4].

Procedure of the call for data

Step 1: Registration of the contact details of business operators interested in submitting data

Business operators are requested to communicate to the Commission **by 2 March 2021** whether they are interested that stearyl tartrate (E 483) remains permitted in the EU and therefore whether they are interested in providing the new data required. This communication should include the contact details of the business operator (name of business operator and postal address), as well as a clear indication of which of the requested data the business operator would be interested in providing. This communication should be submitted to the email address Sante-E2-Additives@ec.europa.eu.

Once the deadline for step 1 has elapsed, the Commission will make publicly available (on DG SANTE's website on food additives[5]) the list of business operators having expressed interest in submitting the data required. This aims at facilitating interactions among business operators and a possible coordinated action in the generation and submission of data.

Communication of interest to submit data would be considered as permission for the Commission to include the details of the party concerned in a list to be published online. In case a party objects to the online publication of its contact details, this should be mentioned in the first communication to the Commission.

No reply to the step 1 of the call for data will be considered as an indication that business operators are no longer interested that stearyl tartrate (E 483) remains permitted as a food additive and that it can therefore be removed from the EU list of permitted food additives in Regulation (EC) No 1333/2008 Regulation (EC) No 1333/2008.

Step 2: Confirmation of data submission, deadlines and milestones

Business operators are requested to confirm **by 19 July 2021** their intention to submit the new data required and to provide a list of the data they intend to submit, a timeline for submission of those data as well as a justification for that timeline. When appropriate, the timeline should be in line with EFSA's Scientific Report on "Indicative timelines for submitting

[4] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2760.pdf
[5] http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

additional or supplementary information to EFSA during the risk assessment process of regulated products" [6]. Business operators are also requested to provide a list of intermediate milestones of the data generation and when they will be achieved. This communication should be sent to the email address Sante-E2-Additives@ec.europa.eu.

The Commission will acknowledge receipt of this confirmation of data submission and will confirm the proposed timetable for data submission as well as the defined milestones and their time scheduling. Business operators will be requested to keep the Commission informed of the timely achievement of these milestones.

After completion of this step (step 2), the data to be submitted and both deadlines and milestones will be published on the DG SANTE's website[7].

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"[8] 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 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

[6] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3553.pdf
[7] https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en
[8] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_circabc_data-sub.pdf

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.