

Call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age

EFSA-Q-number: EFSA-Q-2018-00954

Published: 29/11/2018

Deadline for registering interest: 10/01/2019

Deadline for submission of data: 31/12/2019

Background

According to Regulation (EC) No 1333/2008¹, 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 257/2010². However, in 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives and EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) had issued a scientific opinion on the safety of sucrose esters of fatty acids (E 473) when used as food additive³. In addition EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) issued scientific opinions on the safety of sucrose esters of fatty acids (E 473) produced by a new manufacturing method and including an extension of the use of this additive in flavoured fruit beverages⁴ and on the exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive⁵, in food categories currently specified in Annex II to Regulation (EC) No 1333/2008, which do not cover those for infants below 12 weeks of age. The reason was that the risk assessment approach followed at the time by the EFSA's Scientific Panels in the re-evaluation of food additives did not apply to this age group⁶.

¹ Regulation (EC) No 1333/2008 on food additives, OJ L 354, 31.12.2008

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1333&from=EN>

² Regulation (EU) No 257/2010, setting up a programme for the re-evaluation of approved food additives in accordance with regulation (EC) No 1333/2008, OJ L 80, 26.03.2010.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0257&from=EN>

³ Request from the Commission related to Sucrose Esters of Fatty Acids (E 473). Adopted, 2004. Modified, 2006. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/106.pdf

⁴ Safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings, 2010. <https://doi.org/10.2903/j.efsa.2010.1512>

⁵ Exposure assessment of sucrose esters of fatty acids (E 473) from its use as food additive, 2012

<https://doi.org/10.2903/j.efsa.2012.2658>

⁶ Opinion of the Scientific Committee on Food on the applicability of the ADI (Acceptable Daily Intake) for food additives to infants. SCF (Scientific Committee on Food), 1998.

https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out13_en.pdf

On 31 May 2017, EFSA's Scientific Committee (SC) published a guidance document⁷ on the risk assessment of substances present in food intended for infants below 16 weeks of age, enabling the assessment of the safe use of sucrose esters of fatty acids (E 473) and of other food additives for the population group below that age.

Following the latest advice from the EFSA's Scientific Committee (SC) published guidance document⁵, the risk assessment to be performed will address the safety of uses of sucrose esters of fatty acids (E 473) in foods for infants below 16 weeks of age.

In addition, the AFC and ANS Panels identified in the conclusions and recommendations of its published opinions on sucrose esters of fatty acids (E 473) data gaps in the risk assessment, relevant for all population groups.

For the sake of efficiency, the European Commission asked EFSA to address the above lack of data (data gaps) during its risk assessment of food additives for uses in food for young infants. Therefore specific data requirements for all uses of sucrose esters of fatty acids (E 473) are included in this call for data.

EFSA will consider the relevance of the information provided for the risk assessment of sucrose esters of fatty acids (E 473). The submission of the requested information is without prejudice to the final opinion of the Panel.

According to Article 6(5) of Regulation (EU) No 257/2010 where the requested information has not been submitted to EFSA within the set deadlines, the food additive may be removed from the Union list in accordance with the procedure laid down in Article 10.3 of Regulation (EC) No 1333/2008.

Overall objective

The purpose of this call for data is to offer interested parties (IPs) the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of sucrose esters of fatty acids (E 473) to be used in foods for infants below 16 weeks of age, as well as to address the data gaps that have been identified for all population groups in the already published EFSA opinions on this food additive.

Deadlines for submission of data and disclosure of contact details

Interested parties and stakeholders should provide earlier or at the latest by **31/12/2019** the information described below.

Within **6 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 the name and address of your organisation/business to the other parties that has expressed an interest to provide the requested information. If you do not wish to make these contact details available, clearly indicate it in your first communication.

⁷ Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. EFSA Scientific Committee, 2017. <https://doi.org/10.2903/j.efsa.2017.4849>

Information sought

EFSA invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit information on the food additive sucrose esters of fatty acids (E 473), as appropriate. This information will be used:

- for the follow-up on issues that have been expressed in the conclusions and recommendations of the EFSA Scientific Opinions on the re-evaluation of sucrose esters of fatty acids (E 473) as food additive by the EFSA AFC and ANS Panels published in 2005 and modified in 2006³ and in 2010⁴. Issues raised in the ANS Panel opinion of 2012⁵ on exposure for all population groups except for infants below 16 weeks of age have been addressed in the ANS Panel refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive in 2017⁸.
- for the risk assessment of sucrose esters of fatty acids (E 473) in food for infants below 16 weeks of age in the food categories 13.1.1 and 13.1.5.1. It should be in accordance with the EFSA Guidance of the Scientific Committee on the risk assessment of substances present in food intended for infants below 16 weeks of age⁵.

A. Information regarding the follow up of the conclusions and the recommendations for the food additive sucrose esters of fatty acids (E 473) for all uses

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of sucrose esters of fatty acids (E 473) as a food additive by the EFSA AFC Panel³ and ANS Panel⁴ and general concerns raised by the ANS Panel regarding heavy metals, information for sucrose esters of fatty acids (E 473) is sought on:

1. Technical data

- analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additive;
- the lowest technologically achievable level for lead, mercury, cadmium, and arsenic in order to adequately define their maximum limits in the specifications;
- the lowest technologically achievable level for impurities currently included in the EU specifications for sucrose esters of fatty acids (E 473).
- the lowest technologically achievable level for vinyl esters of fatty acids when sucrose esters of fatty acids (E 473) are manufactured from sucrose and the vinyl esters of food fatty acids.

2. Toxicological data

- The risk characterisation at the lowest technologically achievable level of any residual of toxicological concern included in the EU specifications of sucrose esters of fatty acids (E 473) as food additive.

3. Literature searches

- Literature searches should be conducted relevant for the safety evaluation of sucrose esters of fatty acids (E 473) for all uses in foods for all population groups from 01/09/2017 up to the date of the data submission, as described in the

⁸ 2017 <https://doi.org/10.2903/j.efsa.2018.5087>

Guidance for submission for food additive evaluations (section 5.3)⁴.

B. Information required for the risk assessment of sucrose esters of fatty acids (E 473) for uses as food additive in foods for infants below 16 weeks of age

1. Technical data

For the uses of sucrose esters of fatty acids (E 473), in foods for infants below 16 weeks (food categories 13.1.1 and 13.1.5.1) EFSA seeks

- information and justification on the concentration of sucrose esters of fatty acids (E 473) alone or in combination with food additives E 322, E 471 and E 472c;
- information on the fate and the reaction products of sucrose esters of fatty acids (E 473) in these foods;
- proposals for particular specification requirements for identity and purity of sucrose esters of fatty acids (E 473) when used in these food categories. In particular, the absence of residuals such as vinyl esters of fatty acids, acetaldehyde and p-methoxyphenol.

2. Toxicological data

Within the frame of the EFSA Guidance of the Scientific Committee on the risk assessment of substances present in food intended for infants below 16 weeks of age⁵ the following information on the toxicological properties of sucrose esters of fatty acids (E 473)⁹ and its adverse effects relevant for its use in food categories for infants below 16 weeks of age 13.1.1 and 13.1.5.1. is required:

- clinical data to assess the safety of sucrose esters of fatty acids (E 473);
- post-marketing surveillance reports on undesired and adverse reactions, indicating the ages and other relevant data of the exposed infants and young children and the use levels in the marketed products;
- published and unpublished case reports (e.g. available nutriviigilance data) on undesired and adverse effects, associated with the oral administration of sucrose esters of fatty acids in any form, to infants and young children.

3. Literature searches

- Literature searches relevant for the safety evaluation of sucrose esters of fatty acids (E 473) when used in foods for infants below 16 weeks of age, should be conducted as described in the Guidance for submission for food additive evaluations (section 5.3)⁴.

⁹ In particular for sucrose esters of lauric acid

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.

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-rom, DVD, etc.) with a

- cover letter that should contain:
 - Reference to the specific call and the specific EFSA question number indicated (EFSA-Q-2018-00954);
 - Reference to the substance concerned and its E number;
 - The contact details¹⁰ (name of contact person, name of company/organisation, e-mail 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 this additive.

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

¹⁰ The interested parties shall notify EFSA of any change in the contact details by sending an e-mail to the FIP mailbox (fip@efsa.europa.eu).

Submissions should be sent to the following address:

European Food Safety Authority
FIP Unit
Via Carlo Magno 1/a
I-43126 Parma
Italy

Annex I

Naming convention to be used for submission of information

Please create a folder with subfolders for each section applicable, as indicated below, and name files using the E number_section, identification number_study, name abbreviation of your choice, and indicating confidentiality:

Section 1. Technical data
Section 2. Biological and Toxicological data
Section 3. Literature searches