

Call for technical 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

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Deadline for registering interest: 18/01/2022

Deadline for submission of data: 08/09/2022

Background

Pursuant to Article 32(1) of 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 established by Commission Regulation (EU) No 257/2010².

In 2004, the former EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) re-examined the safety of sucrose esters of fatty acids as food additives³. In a subsequent opinion⁴, the EFSA Scientific Panel on food additives and nutrient sources added to food (ANS Panel) addressed the safety of sucrose esters of fatty acids produced by a new manufacturing method from sucrose and vinyl esters of fatty acids, and the evaluation of the extension of the use of this additive to flavoured fruit beverages. In 2012⁵ the ANS Panel provided a scientific opinion on the exposure assessment of sucrose esters of fatty acids (E 473) taking into account the

¹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008. Available here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333>

² Commission Regulation (EU) No 257/2010 of 25 March 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. Available here: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0257&from=EN>.

³ Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on Sucrose esters of fatty acids E 473 and sucroglycerides E 474 <https://www.efsa.europa.eu/en/efsajournal/pub/106>

⁴ Scientific Opinion on the 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 <https://www.efsa.europa.eu/en/efsajournal/pub/1512>

⁵ Scientific Opinion on the exposure assessment of sucrose esters of fatty acids (E 473) from its use as food additive <https://www.efsa.europa.eu/en/efsajournal/pub/2658>

additional information on its use as surface treatment agent for food and the additional proposed use in flavourings.

With respect to the re-evaluation to be performed by EFSA under Regulation (EC) No 257/2010, the European Commission suggested that taking into account the conclusions of the 2012 ANS Panel opinion, in the case of this food additive, this could be limited to a refined exposure assessment, which was delivered in 2018⁶ by the ANS Panel. In the 2018 opinion, the ANS Panel reported that the available data did not allow for an adequate assessment of the safety sucrose esters of fatty acids (E 473) for uses in food for infants below 16 weeks of age according to food categories (FC) 13.1.1 (Infant formulae as defined Directive 2006/141/EC) and 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants).

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 this latest advice from the EFSA's Scientific Committee (SC) published guidance document⁷, and considering the conclusions and recommendations in the previous assessments from the AFC and ANS Panel, in 2018, EFSA launched a public call for data⁸ inviting the interested 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) to 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 E 473 as food additive by the EFSA AFC and ANS Panels;
- for the risk assessment of 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 age⁷.

Data to address the safety of impurities of toxicological concerns identified as relevant in recent assessments of food additives similar to E 473 (E 471⁹ and E 472a-f¹⁰) were not requested in the call for data referred to above. For this reason, a follow-up call for data is therein published.

EFSA will consider the relevance of the information provided for the risk assessment of 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

⁶ Refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive <https://www.efsa.europa.eu/en/efsajournal/pub/5087>

⁷ Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. EFSA Scientific Committee, 2017. <https://www.efsa.europa.eu/en/efsajournal/pub/4849>

⁸ 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 <https://www.efsa.europa.eu/en/consultations/call/181129>

⁹ Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives <https://www.efsa.europa.eu/en/efsajournal/pub/5045>

¹⁰ Re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472a-f) as food additives <https://www.efsa.europa.eu/en/efsajournal/pub/6032>

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 and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant for the re-evaluation of sucrose esters of fatty acids (E 473) for its uses in all population groups including infants below 16 weeks of age.

EFSA invites the interested parties to consult the previous call for data on E 473⁸ and to provide any additional information on the previous requests not yet provided, as relevant. In this respect, EFSA notes that according to the information currently available, E 473 is not used in the following food categories despite being authorised¹:

Food category number	Food category name	E-number	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
13.1.1	Infant formulae as defined by Commission Delegated Regulation (EU) 2016/127 ¹¹	E 473	only products containing hydrolysed proteins, peptides or amino acids	120
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	E 473	only products containing hydrolysed proteins, peptides or amino acids	120

The safety of the use in these food categories will not be addressed in any future assessment of the EFSA Scientific Panel on Food Additives and Flavourings (FAF Panel), unless further information is received; this might imply the withdrawal of the authorisation under these food categories.

Deadlines for submission of data and disclosure of contact details

Interested parties and stakeholders should provide earlier or at the latest by **08/09/2022** 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.

⁸ 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 <https://www.efsa.europa.eu/en/consultations/call/181129>

¹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008. Available here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333>

¹¹ Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (Text with EEA relevance). OJ L 25, 2.2.2016, p. 1–29. Available here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0127-20210715>

In order to facilitate the collaboration of all interested business operators and interested parties to provide the data needed, we are seeking your consent to disclose contact details 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.

Information sought

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

Additive	E number
Sucrose esters of fatty acids	E 473

This information will be used:

- for the re-evaluation of sucrose esters of fatty acids (E 473) for its uses in all population groups including infants below 16 weeks of age.

A. Technical data

Fatty acids are used for the manufacturing of E 473. During the re-evaluation of certain food additives e.g. E 471 (EFSA ANS Panel, 2017⁹; EFSA FAF Panel, 2021¹²), E 472a-f (EFSA FAF Panel, 2020¹⁰), some concern regarding the potential presence of carry over and process impurities have been identified. The interested parties are invited to provide information on:

- the source of the fatty acids used for the manufacturing of E 473 along with detailed information of any production method used to manufacture E 473, including indication of the solvents used, time/temperature patterns applied, chemical/physical reactions and/or treatments involved;
- analytical data, supported by certificate of analysis, on current levels of *trans*-fatty acids in commercial samples of E 473;
- analytical data, supported by certificate of analysis, on current levels of erucic acid in commercial samples of E 473;
- analytical data, supported by certificate of analysis, on current levels of any compound of toxicological concern (e.g. 3-MCPD or glycidyl esters) in commercial samples of E 473;
- in addition, depending on the manufacturing process (see first bullet point), information on the presence of any other additional impurity in E 473, along with corresponding analytical data, supported by certificate of analysis;
- the lowest technologically achievable levels for the impurities listed above to adequately propose maximum limits in the current EU specifications for E 473.

The analyses should be performed in possibly at least 5 independently produced batches of the food additive, 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

⁹ Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives <https://www.efsa.europa.eu/en/efsajournal/pub/5045>

¹² Opinion on the re-evaluation of mono- and diglycerides of fatty acids (E471) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additives for uses in foods for all population groups <https://www.efsa.europa.eu/en/efsajournal/pub/6885>

¹⁰ Re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472a-f) as food additives <https://www.efsa.europa.eu/en/efsajournal/pub/6032>

(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).

B. Use levels

- Occurrence data (use levels or analytical data) are requested for authorised food categories e.g. for the food categories contributing most to the exposure to sucrose esters of fatty acids (E 473), like fine bakery wares and certain type of flavoured drinks (see EFSA ANS Panel, 2018⁶). These data should allow for a more precise mapping of use levels to foods as recorded in the EFSA Comprehensive Database, and thus will allow to calculate a more realistic estimates of exposure to E 473 via food. This is also considered relevant for the risk assessment of any impurity of toxicological concern (see also point A).
- As indicated in the 'Overall objective', EFSA notes that according to the information currently available at its level, E 473 is not used in food categories 13.1.1 and 13.1.5.1. Hence, the safety of the use in these food categories will not be addressed in any future assessment, unless further information is received; this might imply the withdrawal of the authorisation under these food categories.

C. Literature

A request for relevant publications from the literature had already been requested in the previous call for data on E 473. An update of the literature search since the cut-off date indicated in the previous call (i.e. 31.12.2019)⁸ should be conducted. Relevant publications retrieved should be provided.

Confidentiality

In accordance with 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, data providers should indicate any information they wish to be treated as confidential and provide verifiable justification supporting this request. Please also note that the information described in Article 8(2) of Regulation (EU) No 257/2010 cannot be regarded as confidential in any circumstances.

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 through their chosen internet-based software (submission by email is not allowed) with

- a cover letter that should contain:
 - Reference to the specific call and the specific EFSA question number indicated (EFSA-Q-2018-00101)

⁶ Refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive <https://www.efsa.europa.eu/en/efsajournal/pub/5087>

⁸ 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 <https://www.efsa.europa.eu/en/consultations/call/181129>

- Reference to the substance concerned and its E number
- The contact details¹³ (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;
- a 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 such rights for the submitted subject matter, they should share the contact details of the respective owner(s) of data and/or the holder(s) of any relevant intellectual property rights, 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.

Please note that EFSA may, where legally possible, 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:

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

¹³ 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).