Call for technical and toxicological data on silicon dioxide (E 551) for uses as food additive in foods for all population groups including infants below 16 weeks of age

EFSA-Q-number: EFSA-Q-2018-00773

Published: 10/10/2018
Deadline for registering interest: 21/11/2018
Deadline for submission of data: 31/05/2020

Background

According to Regulation (EC) No 1333/2008, 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.

EFSA has issued a scientific opinion on the safety of silicon dioxide (E 551) when used as food additive in food categories specified in Annexes II and III to Regulation (EC) No 1333/2008. In the Annex III, part 5, section B of Regulation (EC) No 1333/2008, the use of silicon dioxide in food for infants up to 12 months old and young children, is authorised at the maximum level of 10 000 mg/kg in nutrient preparations, and can be carried over in final products included in categories 13.1, as in food for infants below 16 weeks of age in the food categories 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). However, the risk assessment approach followed at the time by the former EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) in the re-evaluation of food additives did not apply to infants under the age of 12 weeks.

On 31 May 2017, EFSA’s Scientific Committee (SC) published a guidance document 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 silicon dioxide (E 551) and of other food additives for the population group below that age.

3 Re-evaluation of silicon dioxide (E 551) as a food additive, EFSA ANS Panel, 2017.
4 Guidance for submission for food additive evaluations. EFSA ANS Panel, 2012.
Following the latest advice from the EFSA’s Scientific Committee (SC) published guidance document, the risk assessment to be performed will address the safety of carried over silicon dioxide (E 551) in foods for infants below 16 weeks of age.

In addition, the ANS Panel identified in the recommendations of its published opinion on silicon dioxide (E 551) 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 data needs (data gaps) during its risk assessment of food additives for uses in food for young infants. Therefore, specific data requirements for all uses of silicon dioxide (E 551) are included in this call for data.

EFSA will consider the relevance of the information provided for the risk assessment of silicon dioxide (E 551). 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 silicon dioxide (E 551) carried over 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 opinion 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 31/05/2020 the information described below.

Within 6 weeks from the publication of this call, please communicate in writing by email 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 have 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 technical and toxicological data on silicon dioxide (E 551), as appropriate. The provided information will be used:

- for the follow-up on issues that have been raised in the conclusions and recommendations of the Scientific Opinion on the re-evaluation of silicon
dioxide (E 551) as food additive by the former EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) published in 2015. 

- for the risk assessment of silicon dioxide (E 551) carried over in food for infants below 16 weeks of age in the food categories 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). Data to be submitted 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 age.5

A. Information regarding the follow up of the conclusions and the recommendations for silicon dioxide (E 551) for uses in all population groups (EFSA ANS Panel, 2017)3

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of silicon dioxide (E 551) as food additive by the former EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) published in 2017 information for silicon dioxide (E 551) is sought on:

1. Technical data

- The characterisation of all the different commercial preparations marketed as food additive silicon dioxide (E 551) preferably from at least five independently produced batches of each preparation, in relation to:
  - Particle size and particle size distribution of the food additive silicon dioxide (E 551). Because of their potential importance in toxicokinetics and toxicological effects, particle size and particle size distribution should be included in the EU specifications for the silicon dioxide (E 551) in Commission Regulation (EU) No 231/2012. Detailed and comprehensive proposed specifications for the characterisation of the fraction of nanoparticles present in the food additive silicon dioxide (E 551) should be submitted. Information on particle size and particle size distribution for the food additive silicon dioxide (E 551) supported by analytical data, in line with the "EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health"6, is requested. This should allow the establishment of parameters in the EU specifications for silicon dioxide (E 551) that fully characterise the material used as a food additive;
  - analytical data on current levels of arsenic, lead and mercury;
  - the lowest technologically achievable level for lead, mercury and arsenic in order to adequately define their maximum limits in the specifications.
  - the lowest technologically achievable level for residual solvents which can be used when manufacturing silicon dioxide (E 551).

The analyses should be performed with appropriate analytical methods. EFSA seeks specific data on the methods of analysis used. 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 limit of quantification

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6 EFSA Scientific Committee, 2018
https://doi.org/10.2903/j.efsa.2018.5327
(LOQ). Such methods should employ state of the art techniques.

2. Toxicological data for E 551:

In its 2017 opinion, the former ANS Panel highlighted several limitations to the available toxicological database of silicon dioxide (E 551) that would need to be decreased in order for EFSA to derive an Acceptable Daily Intake (ADI) for silicon dioxide (E 551).

There are a number of approaches which could decrease these limitations, which include, but were not limited to, a chronic toxicity study conducted according to a recognised guideline and with an adequately characterised material representative of silicon dioxide used as a food additive (E 551).

3. Literature searches

Literature searches relevant for the safety evaluation of silicon dioxide (E 551) for all uses in foods for all population groups from 01/11/2015 up to the date of the data submission, should be conducted as described in the Guidance for submission for food additive evaluations\(^4\) (section 5.3).

B. Information required for the risk assessment of silicon dioxide (E 551) for uses in foods for infants below 16 weeks of age

1. Technical data

For the uses of silicon dioxide (E 551) in the infant formulae (FC 13.1.1), as well as in special formulae used for infants under special medical conditions (FC 13.1.5.1) in infants below 16 weeks of age, EFSA seeks:

- information on the concentrations in the infant formula as ready to use;
- information on the fate and the reaction products in the infant formula as ready to use;
- proposals for particular specification requirements for identity and purity in these food categories.

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 age\(^5\) the following information on the toxicological properties of silicon dioxide (E 551) is required. Data requirement can be reduced based on a justified relevant scientific information.

- Performance of an Extended One Generation Reproductive Toxicity Study (EOGRITS) in accordance with OECD TG 443.
- 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;
3. Literature searches

Literature searches relevant for the safety evaluation of silicon dioxide (E 551) 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)\(^4\).

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-2018-00773);
  - Reference to the substance concerned and its E number;
  - The contact details\(^7\) (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

\(^7\) The interested parties shall notify EFSA of any change in the contact details by sending an e-mail to the FIP mailbox (fip@efsaeuropa.eu).
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](mailto: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 numbers_study name abbreviation of your choice, and indicating confidentiality:

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