

## Call for technical and toxicological data on calcium carbonate (E 170) for uses as food additive in foods for all population groups including infants below 16 weeks of age

**EFSA-Q-number: EFSA-Q-2018-00772**

**Published: 10/10/2018**

**Deadline for registering interest: 21/11/2018**

**Deadline for submission of data: 31/05/2019**

**New Deadline for submission of data: 15/10/2019**

### Background

According to Regulation (EC) No 1333/2008<sup>1</sup>, 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<sup>2</sup>.

EFSA has issued a scientific opinion on the safety of calcium carbonate (E 170) when used as food additive<sup>3</sup> in food categories specified in Annex II to Regulation (EC) No 1333/2008, exempting those for infants below 12 weeks of age. The reason was that 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 this age group<sup>4</sup>. The ANS Panel has, therefore, specified in its opinion that the re-evaluation of uses for this particular age group will be performed separately.

On 31 May 2017, EFSA's Scientific Committee (SC) published a guidance document<sup>5</sup> on the risk assessment of substances present in food intended for infants below 16 weeks of

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<sup>1</sup> 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>

<sup>2</sup> 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>

<sup>3</sup> Re-evaluation of calcium carbonate (E 170) as food additive, EFSA ANS Panel, 2011.

<https://doi.org/10.2903/j.efsa.2011.2318>

<sup>4</sup> Guidance for submission for food additive evaluations. EFSA ANS Panel, 2012.

<https://doi.org/10.2903/j.efsa.2012.2760>

<sup>5</sup> 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>

age, enabling the assessment of the safe use of calcium carbonate (E 170) 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 document<sup>5</sup>, the risk assessment to be performed will address the safety of uses of calcium carbonate (E 170) in foods for infants below 16 weeks of age.

In addition, the ANS Panel identified in the conclusions and recommendations of its published opinion on calcium carbonate (E 170) 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 calcium carbonate (E 170) are included in this call for data.

EFSA will consider the relevance of the information provided for the risk assessment of calcium carbonate (E 170). 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 calcium carbonate (E 170) 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 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 **31/05/2019** 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](mailto: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 calcium carbonate (E 170), as appropriate. This 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 calcium carbonate (E 170) as a food additive by the former EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) published in 2011<sup>3</sup>.
- for the risk assessment of calcium carbonate (E 170) in food for infants below 16 weeks of age in the food categories 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants). Data to be submitted should be in line 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<sup>5</sup>.

### **A. Information regarding the follow up of the conclusions and the recommendations for calcium carbonate (E 170) for uses in all population groups (EFSA ANS Panel, 2011)<sup>3</sup>**

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of calcium carbonate (E 170) as a food additive by the former EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) published in 2011<sup>3</sup> information for calcium carbonate (E 170) is sought on:

#### **1. Technical data**

The characterisation of all the different commercial preparations of the food additive calcium carbonate (E 170) from five non- consecutive batches of each preparation, in relation to:

- analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additive;
- the lowest technologically achievable level for aluminium, lead, mercury, cadmium, and arsenic in order to adequately define their maximum limits in the specifications;
- 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 food additive calcium carbonate (E 170) 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 calcium carbonate (E 170) should be submitted. Information on particle size and particle size distribution for the food additive calcium carbonate (E 170) 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"<sup>6</sup>, is requested. This should allow the establishment of parameters in the EU specifications for calcium carbonate (E 170) that fully characterise the material used as a food additive.

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<sup>6</sup> EFSA Scientific Committee, 2018  
<https://doi.org/10.2903/j.efsa.2018.5327>

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 (LOQ)).

## **2. Literature searches**

Literature searches relevant for the safety evaluation of calcium carbonate (E 170) for all uses in foods for all population groups from 05/07/2011 up to the date of the data submission, should be conducted as described in the Guidance for submission for food additive evaluations (section 5.3)<sup>4</sup>.

## **B. Information required for the risk assessment of calcium carbonate (E 170) for uses in foods for infants below 16 weeks of age**

### **1. Technical data**

For the uses of calcium carbonate (E 170) in the infant formulae for use in special formulae used for infants below 16 weeks of age under special medical conditions (FC 13.1.5.1), EFSA seeks information on:

- the levels of use of calcium carbonate (E 170), as well as analytical data on the concentration of calcium carbonate in these formulae,
- the fate and the reaction products of calcium carbonate (E 170) in the formula ready to use,
- particular specification requirements for identity and the purity of calcium carbonate (E 170) (e.g. with respect to lead, aluminium and other toxic elements). This includes data on physical characterisation regarding the particle size as requested in part A.1 in the food additive and the formulae as consumed.

### **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<sup>5</sup> the following information on the toxicological properties of calcium carbonate (E 170) and its adverse effects relevant for its use in special formulae used for infants below 16 weeks of age under special medical conditions (FC 13.1.5.1):

- 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 level of calcium carbonate (E 170) 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 calcium carbonate in any form to infants and young children.

### 3. Literature searches

Literature searches should be conducted relevant for the safety evaluation of calcium carbonate (E 170) when used in foods for infants below 16 weeks of age, as described in the Guidance for submission for food additive evaluations (section 5.3)<sup>4</sup>.

#### 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-2018-00772);
  - Reference to the substance concerned and its E number;
  - The contact details<sup>7</sup> (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.

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<sup>7</sup> 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).

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:

<b>Section 1. Technical data</b>
<b>Section 2. Biological and Toxicological data</b>
<b>Section 3. Literature searches</b>