Call for technical and toxicological data on acacia gum (E 414) as a food additive for uses in foods for all population groups including infants below 16 weeks of age

EFSA-Q-number: EFSA-Q-2018-00775

Published: 10/10/2018
Deadline for registering interest: 21/11/2018
Deadline for submission of data: 28/02/2019

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 acacia gum (E 414) 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 acacia gum in food for infants up to 12 months old and young children, is authorised at the maximum level of 10 mg/kg, only as carry 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. 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 on the risk assessment of substances present in food intended for infants below 16 weeks of age, enabling the assessment the safe use of acacia gum (E 414) and of other food additives for the population group below that age.

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3 Re-evaluation of acacia gum (E 414) as a food additive, EFSA ANS Panel, 2017.

4 Guidance for submission for food additive evaluations. EFSA ANS Panel, 2012.
https://doi.org/10.2903/j.efsa.2012.2760

https://doi.org/10.2903/j.efsa.2017.4849
Following the latest advice from the EFSA’s Scientific Committee (SC) published guidance document\(^3\), the risk assessment to be performed will address the safety of carried over acacia gum (E 414) in foods for infants below 16 weeks of age.

In addition, the ANS Panel identified in the recommendations of its published opinion on acacia gum (E 414) the need for information to allow an update of the specifications according to current standards, relevant for all population groups.

For the sake of efficiency, the European Commission asked EFSA to address the above 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 acacia gum (E 414) are included in this call for data.

EFSA will consider the relevance of the information provided for the risk assessment of acacia gum (E 414). 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 acacia gum (E 414) 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 28/02/2019 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 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 technical and toxicological data on acacia gum (E 414), as appropriate. This information will be used:

- for the follow-up on issues that have been raised in the EFSA opinion’s conclusions and recommendations of the Scientific Opinion on the re-evaluation of acacia gum (E 414) as a food additive by the EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) published in 2017\(^3\).
for the risk assessment of acacia gum (E 414) carried over in foods 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 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.5

A. Information regarding the follow up of the conclusions and the recommendations of the EFSA ANS Panel opinion on the safety of acacia gum (E 414) as food additive3

With reference to the recommendations in the Scientific Opinion on the re-evaluation of acacia gum (E 414) as a food additive by the former EFSA ANS Panel published in 20173 information for acacia gum (E 414) is sought on:

1. Technical data
   - analytical data on current levels of aluminium, 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;
   - current levels of residual proteins and oxidising enzymes (oxidases and peroxidases) in acacia gum (E 414) preparations;
   - the lowest technologically achievable level for residual proteins and oxidising enzymes (oxidases and peroxidases) in acacia gum (E 414) preparations in order to adequately define their maximum limits in the specifications.

The information should be supported by data from at least five different batches independently produced and 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 (LOQ). Such methods should employ state of the art techniques.

   - Because of both the botanical origin and its polysaccharidic nature, acacia gum (E 414) can be a substrate of microbiological contamination. Data are sought with respect to a possible update of the existing microbiological specifications, demonstrating the lowest total aerobic microbial count (TAMC) and total combined yeast and mould count (TYMC) that can be achieved.

2. Literature searches

Literature searches should be conducted relevant for the safety evaluation of acacia gum (E 414) for all uses in foods for all population groups from 08/02/20166 up to the date of the data submission, as described in the Guidance for submission for food additive evaluations (see its section 5.3).4

6 date of last literature search reported in the EFSA ANS opinion
B. Information required for the risk assessment of acacia gum (E 414) as food additive for use in foods for infants below 16 weeks of age

Acacia gum is not authorized for direct use as a food additive in food for infants under the age of 16 weeks. However, in the current EU legislation (Annex III, part 5 section B of Regulation (EC) No 1333/2008), it is authorized as a food additive in nutrients intended for use in food for infants up to 12 months, including those under the age of 16 weeks (FC 13.1.1 and 13.1.5.1), at the maximum level of 10 mg/kg in final products due to carry over.

1. Technical data

For the uses of acacia gum (E 414) in foods for infants below 16 weeks of age (FC 13.1.1 and 13.1.5.1) EFSA seeks:

- information on the resulting concentrations of acacia gum (E 414), alone or in combination with other thickening agents (indication of food additive name and resulting concentration) in these foods;
- information on the fate and the reaction products of acacia gum (E 414) in these food categories;
- information on particular specification requirements for identity and the purity of acacia gum (E 414) to be used in these food categories (e.g. content residual proteins and enzymes, toxic elements). Analytical data on impurities in the final foods for infants below 16 weeks of age need to be provided when no legal limit has been established.

In addition, data should be provided demonstrating the absence of Cronobacter (Enterobacter) sakazakii in the food additive.

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 acacia gum (E 414) and its adverse effects, relevant for its use in nutrients intended for use in FC 13.1.1 and FC 13.1.5.1:

- clinical data focusing on gastrointestinal effects to assess the safety of acacia gum (E 414) when present in foods for infants below 16 weeks of age;
- post-marketing surveillance reports on undesired and adverse reactions (including e.g. flatulences, gastrointestinal discomfort, changes of stool-frequencies and -consistency, diarrhoea and allergic reactions), indicating the ages and other relevant data of the exposed infants and young children and the use level of acacia gum (E 414) in the marketed products;

3. Literature searches

Literature searches should be conducted relevant for the safety evaluation of acacia gum (E 414) when used in foods for infants below 16 weeks of age up to the date of the data submission, 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-2018-00775);
  - Reference to the substance concerned and its E number;
  - The contact details? (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.

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7 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).
Correspondence
Please send all electronic correspondence, including enquiries to:

fip@efsaeuropa.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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