Call for technical and toxicological data on guar gum (E 412) for uses as a food additive in foods for all population groups including infants below 16 weeks of age

EFSA-Q-number: 2018-00559

Published: 18/07/2018

Deadline for registering interest: 26/09/2018

Deadline for submission of data: 31/12/2019

Background

According to Regulation (EC) No 1333/2008[1], 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[2].

EFSA has issued a scientific opinion on the safety of guar gum (E 412) when used as food additive[3] in food categories specified in Annexes 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 until now by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) in the re-evaluation of food additives does not apply to this age group[4]. 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[5] on the risk assessment of substances present in food intended for infants below 16 weeks of age, enabling the ANS Panel to assess the safe use of guar gum (E 412) 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[5], the risk assessment to be performed will address the safety of uses of guar gum (E 412) in foods for infants below 16 weeks of age.

[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] Re-evaluation of guar gum (E 412) as a food additive, EFSA ANS Panel, 2017.
https://doi.org/10.2903/j.efsa.2017.4669

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

[5] 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

In addition, the ANS Panel identified in the conclusions and recommendations of its published opinion on guar gum (E 412) 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 guar gum (E 412) are included in this call for data.

EFSA will consider the relevance of the information provided for the risk assessment of guar gum (E 412). 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 guar gum (E 412) 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 **31/12/2019** the information described below.

Within **10 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 your personal data (name, e-mail address and telephone number) to the other parties that has expressed an interest to provide the requested information. If you do not wish to make your 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 guar gum (E 412), as appropriate. This information will be used

- for the follow-up on issues that have been expressed in the conclusions and recommendations of the Scientific Opinion on the re-evaluation of guar gum (E 412) as a food additive by the EFSA ANS Panel published in 2017[3].
- for the risk assessment of guar gum (E 412) in food for infants below 16 weeks of age in the food category 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 age[5].

A. Information regarding the follow up of the conclusions and the recommendations of the EFSA ANS Panel opinion on the safety of guar gum (E 412) as food additive[3]

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of guar gum (E 412) as a food additive by the EFSA ANS Panel published in 2017[3] information for guar gum (E 412) 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
- current levels of residual proteins in clarified and unclarified preparations;
- the possibility to use clarified guar gum to cover all technological needs of the food additive E 412, especially for the use in 13.1.1 (infant formulae) and 13.1.5.2 (dietary foods for babies and young children for special medical purposes) where the additive is authorised only when the formulae contains partially hydrolysed proteins and peptides;
- the lowest technologically achievable level for residual proteins in clarified and unclarified preparations in order to adequately define their maximum limits in the specifications in view of case reports on hypersensitivity reactions associated with guar gum.

In addition, a proposal for separate specifications for clarified and unclarified guar gum (E 412) is requested.

The information should be supported by data from at least five different batches 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 (LOQ).

Such methods should employ state of the art techniques.

- Because of both the botanical origin and the polysaccharidic nature of guar gum, it can be a substrate of microbiological contamination. Data should be provided demonstrating the absence of *Salmonella* spp. and *Escherichia coli* and on the lowest total aerobic microbial count (TAMC) and total combined yeast and mould count (TYMC) that can be reached.

2. **Toxicological data**

According to the conclusions and recommendations in the Scientific opinion on the re-evaluation of guar gum (E 412) as a food additive by the EFSA ANS Panel published in 2017[3], the generation of additional data to assess the potential health effects of guar gum (E 412) in 'dietary foods for infants for special medical purposes and special formulae for infants' (Food category 13.1.5.1) and in 'dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (Food category 13.1.5.2) was recommended. These requirements will be addressed as outlined in section B. 2.

3. Literature searches

Literature searches should be conducted relevant for the safety evaluation of guar gum (E 412) for all uses in foods for all population groups from 12/10/2016[6] 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].

B. Information required for the risk assessment of guar gum (E 412) for uses in foods for infants below 16 weeks of age

For the uses of guar gum (E 412) in foods for infants below 16 weeks EFSA seeks:

1. Technical data

- information on the levels of use of guar gum (E 412), alone or in combination with other thickening agents (indication of food additive name and level of use) in the infant formulae for infants below 16 weeks of age (FC 13.1.1), as well as in special formulae for infants of that age under special medical conditions (FC 13.1.5.1);
- information on the fate and the reaction products of guar gum (E 412) in the infant formulae for infants below 16 weeks of age (FC 13.1.1), as well as in special formulae for infants of that age under special medical conditions (FC 13.1.5.1);
- information on particular specification requirements for identity and the purity of guar gum (E 412) (e.g. with respect to levels of protein residues; use of clarified guar gum or content of toxic elements, furfural, pentachlorophenol, isopropanol, borate) when used in the infant formulae for infants below 16 weeks of age (FC 13.1.1), as well as in special formulae for infants of that age under special medical conditions (FC 13.1.5.1). Analytical data on impurities in the final special formulae 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 age5 the following information on the toxicological properties of guar gum (E 412) and its adverse effects relevant for use in infant formulae in infants below 16 weeks of age, as well as for special formulae used for infants of that age under special medical conditions considering that the studies are of appropriate duration:

- a repeated dose study with direct oral administration of guar gum (E 412) to neonatal animals, which includes analysis of possible local effects on the gastrointestinal tract and its microbiota and on a possible reduction in the bioavailability of nutrients (vitamins and minerals, such as calcium, iron and zinc), that are normally contained in food for infants. The study shall be performed in piglets unless justification for the relevance of a study in another species is given;
- clinical data focusing on gastrointestinal effects when used in dietary foods for special medical purposes in infants below 16 weeks of age (FC 13.1.5.1);

[6] date of last literature search reported in the EFSA ANS opinion

- 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 guar gum (E 412) in the marketed products, where guar gum is already in use;
- published and unpublished case reports (e.g. available nutrivigilance data) on undesired and adverse effects, including e.g. flatulences, gastrointestinal discomfort, changes of stool-frequencies and -consistency, diarrhoea and allergic reactions, associated with the oral administration of guar gum in any form to infants and young children.

3. Literature searches

Literature searches should be conducted relevant for the safety evaluation guar gum (E 412) 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 (see its 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-2018-00559);
  - 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;

[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).

- 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

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 which parts are to be considered confidential:

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