Call for technical data on the permitted food additive quillaia extract (E 999)

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Deadline: 14 July 2021

Background

According to Article 32 of Regulation (EC) No 1333/2008[1], food additives permitted in the EU before 20 January 2009 should be subject to a new risk assessment by the European Food Safety Authority (EFSA). The programme for the re-evaluation of these permitted food additives has been set up by Commission Regulation (EU) No 257/2010[2].

So far EFSA has not identified a major safety concern (such as a proven carcinogenic or genotoxic activity) for any of the re-evaluated food additives. In fact, in most cases EFSA confirms the safety of those food additives at their currently reported uses and use levels. However, for some additives EFSA has identified issues that require a follow-up. Additional specific data is needed to address those issues.

The additives whose safety re-evaluation by EFSA was hindered by limited data availability, but which are not expected to pose an immediate food safety concern, are not going to be immediately removed from the Union list of permitted additives, or their uses and/or use levels revised. Instead, business operators are requested to indicate to the Commission their interest in the continuity of approval of the additive(s) under re-evaluation and in providing, by a certain deadline, the data needed by EFSA to complete its risk assessment. In general, new toxicological studies will be needed to generate these missing data.

Once EFSA has assessed the new data, the current authorisation of the additive(s) may be revised, if needed.

If business operators do not provide the requested data (by the predefined deadline) the present authorisation will be revised based on EFSA's current scientific opinion and the additive(s) may be removed from the Union list of permitted additives. The same applies if the new data submitted is not sufficient for EFSA to conclude the risk assessment, since there will be no successive requests for additional data.

Food additives for which EFSA has identified concerns in terms of exposure or specifications will be subject to the same follow-up approach, but EFSA's assessment of the new data may not always be needed.

The Commission will undertake that the time assigned for addressing issues identified by EFSA is as short as possible and dependent on the time needed to generate and assess the required new data.

EFSA's Scientific Opinion on the re-evaluation of quillaia extract (E 999) as a food additive

EFSA's Panel on Food Additives and Flavourings (FAF) delivered a scientific opinion re-evaluating the safety of quillaia extract (E 999) when used as a food additive in March 2019[3]. The Scientific Committee for Food (SCF) in 1978 established an acceptable daily intake (ADI) of 0–5 mg spray-dried extract/kg body weight (bw) per day for E 999. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established in its latest evaluation (2006) a group ADI of 0–1 mg/kg bw per day, expressed as quillaia saponins, for quillaia extract for Type 1 and Type 2.

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] EFSA Journal 2019;17(3):5622 (https://www.efsa.europa.eu/en/efsajournal/pub/5622)

EFSA considered it likely that intact quillaia extract saponins are absorbed to a low extent, are hydrolysed in the gastrointestinal (GI) tract and that the aglycone is absorbed only to a limited extent. The Panel considered that the genotoxicity data available did not indicate a concern for genotoxicity.

Taking into account the available toxicological database, various no observed adverse effect levels (NOAELs) relevant for the derivation of an ADI were identified. The Panel considered that the 2-year study in rats was the most robust and that the NOAEL of 1,500 mg quillaia extract/kg bw per day could be used to derive the ADI for E 999. Considering that the adverse effects reported were due to the presence of saponins in the extract, that saponins were present in quillaia extract Type 1 (around 20%) and using an uncertainty factor of 100, the Panel derived a ADI of 3 mg saponins/kg bw per day for E 999.

None of the exposure estimates for the different population groups of the refined brand-loyal scenario exceeded the ADI of 3 mg saponins/kg bw per day.

EFSA recommended that the European Commission considers:

- Revising the EU specifications for quillaia extract (E 999) in order to differentiate extracts of quillaia according to their saponins content (including a description of the principle of the method of analysis to quantify the content of saponins in line with the JECFA specifications), i.e. Type 1 and Type 2.
- Revising the EU specifications for quillaia extract (E 999) to include the percentage range for polyphenols (including tannins), protein, polysaccharides including fibre, reducing sugars, a maximum limit for calcium oxalate as well as microbiological specifications.
- Lowering the current limits for toxic elements (arsenic, lead and mercury) in the EU specifications for quillaia extract (E 999) in order to ensure that the food additive will not be a significant source of exposure to these toxic elements in food.
- Revising the maximum use levels for quillaia extract (E 999) established in Regulation (EC) No 1333/2008 to be expressed on saponin content.

Overall purpose of this call for data

To give the opportunity to business operators to submit the technical data needed to address issues identified by EFSA in the re-evaluation of the safety of quillaia extract (E 999) as a food additive.

Information required for the food additive quillaia extract (E 999)

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of quillaia extract (E 999) as a food additive by EFSA, information for quillaia extract (E 999) is sought on:

1. Technical data

1.1 Data for the revision of the specifications for quillaia extract (E 999)

The characterisation of commercial preparations of Type 1 and Type 2 extracts (as defined on the basis of the content of saponins in the JECFA specifications for INS No 999(i) and INS No 999(ii)) of the food additive quillaia extract (E 999) from non-consecutive batches of each preparation, in relation to:

- Analytical data, if possible supported by certificate of analysis, on current levels of arsenic, lead and mercury in commercial samples of the food additive (Type 1 and Type 2 extracts);

- The lowest technologically achievable level for arsenic, lead and mercury and cadmium in order to adequately propose maximum limits in the specifications for Type 1 and Type 2 extracts of E 999;
- Analytical data, if possible supported by certificate of analysis, on current levels of polyphenols (including tannins), protein, polysaccharides (including fibre), reducing sugars and calcium oxalate in commercial samples of the food additive (Type 1 and Type 2 extracts);
- The lowest technologically achievable level for polyphenols (including tannins), protein, polysaccharides (including fibre), reducing sugars and calcium oxalate in order to adequately propose maximum limits in the specifications for Type 1 and Type 2 extracts of E 999;

The analyses should be performed 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 (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).

1.2 Use levels for quillaia extract (E 999) expressed on saponin content

In accordance with Annex II, Part E to Regulation (EC) No 1333/2008 quillaia extract (E 999) is authorized for use as a food additive in food category 14.1.4 Flavoured drinks and food category 14.2.3 Cider and perry (excluding *cidre bouché*) at a maximum permitted level of 200 mg quillaia extract/L (calculated as anhydrous extract) in both cases. Given that EFSA recently derived for E 999 an Acceptable Daily Intake (ADI) expressed as quillaia saponins (3 mg saponins/kg bw per day), E 999 maximum use levels Regulation (EC) No 1333/2008 should also be expressed as mg saponins/L.

Consequently, in order to convert the current maximum permitted level of 200 mg quillaia extract/L in food categories 14.1.4 and 14.2.3 into mg saponins/L, information is requested on whether Type 1 or Type 2 extracts of E 999 are used in those two food categories.

Procedure of the call for data

It should be noted that this call concerns only technical data. Therefore, the 2-step procedure used in previous calls for scientific and technical data is not followed, since such procedure is considered to be more appropriate for calls for data requesting scientific data (e.g. toxicological data which require that new toxicological studies are performed). Therefore, the deadline of this call is the final deadline for submission of the requested technical data.

Business operators are requested to submit to the Commission **14 July 2021** the above-requested data.

In order to streamline the data collection exercise, business operators are invited to liaise with the relevant food business operator associations for the data submission. In particular, data providers shall ensure that the same data are not sent several times to the European Commission (for example, they should not be sent by both the business operator and also by the association to which the business operator belongs to).

Any questions about this call for data should be sent to the email address Sante-E2-Additives@ec.europa.eu.

Submission of the required data

Business operators are requested to submit the above-indicated data by the agreed deadline using the online platform CIRCABC. The “Guidance for online data submission on Food Improvement

Agents via CIRCABC Sante-Cad-In Group"[4] provides practical information on how to use the CIRCABC platform for the online submissions.

Common electronic formats (e.g. MS Office®, Adobe Acrobat Reader®) allowing content copying and printing (no content copy protection) should be used for the files to be submitted. The text of the files should be searchable using the search facilities of standard software packages. The submission should include a cover letter stating clearly in the subject line the food additive(s) to which it refers, and describing the data submitted. The cover letter should provide the contact details of the data submitter and should be addressed to:

Bruno Gautrais, Head of Unit E2
European Commission
Directorate-General for Health and Food Safety
Directorate E – Food and feed safety, Innovation
Unit E2 – Food Processing Technologies and Novel Foods
B-1049 Brussels

This cover letter should also be sent separately to the functional mailbox SANTE-E2-Additives@ec.europa.eu.

Once the new data are received, they will be submitted to EFSA for evaluation and preparation of a scientific opinion, if appropriate.

Confidential data

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 in detail which of the information provided they wish to be treated as confidential and they should provide verifiable justification supporting this request. It should be noted that the information described in article 8(2) of the Regulation (EU) No 257/2010 shall not, in any circumstances, be regarded as 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.

Possibility for EFSA to use the data for the safety assessment of the same substance under other legal or regulatory frameworks

In line with Union policy objectives on animal welfare and testing on vertebrates, EFSA aims to avoid the duplication of testing on vertebrates, and to achieve an optimal use of the relevant financial and human resources by the private sector. Therefore, in anticipation of cases where EFSA may be interested in using or reusing relevant information or data (i.e. technical, toxicological data) for the evaluation of the same substance under a different legal or regulatory framework from the one mentioned above, or for the evaluation of another substance under the same or different legal framework as above, please indicate explicitly in writing, whether by participating in the voluntary submission of relevant data or information, you also give EFSA the permission to use and/or reuse these data for other EFSA safety assessments, and/or for a data sharing exercise with third parties or other international bodies.

[4] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_circabc_data-sub.pdf