

Call for scientific and technical data on the permitted food additives calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b)

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Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 6 December 2018

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 15 April 2019

Background

According to Article 32 of Regulation (EC) No 1333/2008¹, 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 257/2010².

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.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 80, 26.3.2010, p. 19.

EFSA's Scientific Opinion on the re-evaluation of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) as food additives

EFSA's Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered a scientific opinion re-evaluating the safety of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) when used as food additives³. In 1991, the Scientific Committee on Food (SCF) established a group acceptable daily intake (ADI) 'not specified' for silicon dioxide (E 551) and silicates (E 552, E 553a(i) and E 553a(ii)).

The Panel noted that the absorption of silicates and talc was very low; there was no indication for genotoxicity or developmental toxicity for calcium and magnesium silicate and talc; and no confirmed cases of kidney effects have been found in the EudraVigilance database despite the wide and long-term use of high doses of magnesium trisilicate up to 4 g/person per day over decades.

However, the Panel considered that accumulation of silicon from calcium silicate in the kidney and liver was reported in rats, and reliable data on subchronic and chronic toxicity, carcinogenicity and reproductive toxicity of silicates and talc were lacking. Therefore, the Panel concluded that the safety of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) when used as food additives cannot be assessed.

The Panel considered that there is no mechanistic rationale for a group ADI for silicates and silicon dioxide (E 551) and the group ADI established by the SCF is obsolete. Consequently the Panel re-evaluated the safety of silicon dioxide (E 551) in a separate scientific opinion⁴.

Based on the food supplement scenario considered as the most representative for risk characterisation, exposure to silicates and talc (E 552, E 553a(i) and E 553a(ii)) for all population groups was below the maximum daily dose of magnesium trisilicate used as an antacid (4 g/person per day).

The Panel noted that there were a number of approaches, which could decrease the uncertainties in the current toxicological database. These approaches include – but are not limited to – toxicological studies as recommended for a Tier 1 approach as described in the EFSA Guidance for the submission of food additives and conducted with an adequately characterised material. Some recommendations for the revision of the EU specifications were proposed by the Panel.

Overall purpose of this call for data

To give the opportunity to business operators to submit the scientific and technical data needed to address issues identified by EFSA in the re-evaluation of the safety of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) as food additives. The data gaps identified by EFSA for silicon dioxide (E 551) are the subject of a call for data issued by EFSA on 10 October 2018, in the context of its upcoming risk assessment of silicon dioxide (E 551) for uses in food for young infants (see <https://www.efsa.europa.eu/en/consultations/call/181010-2>). Therefore, specific data requirements for all uses of silicon dioxide (E 551) are included in that call for data.

Given that EFSA has concluded that a group ADI cannot be established for silicates and silicon dioxide, the current group of additives (s) "E 551- 553: Silicon dioxide – silicates" needs to be withdrawn. The data on uses and use levels that will be needed to re-assess and re-organise the currently authorised uses of silicates (E 552, E 553a(i), E 553a(ii) and E 553b) and silicon dioxide (E 551) will be the subject of a later specific call for data.

³ <https://www.efsa.europa.eu/en/efsajournal/pub/5375>

⁴ <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

Scientific and technical data required

The data required to address the various issues identified by EFSA in the re-evaluation of the safety of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) as food additives are the following:

1. Technical data for E 552, E 553a(i), E 553a(ii) and E 553b

The characterisation of all commercial preparations marketed as food additive of E 552, E 553a(i), E 553a(ii) and E 553b, from five non-consecutive batches of each preparation, in relation to:

- particle size and particle size distribution for E 552, E 553a(i), E 553a(ii) and E 553b. Because of their potential importance in toxicokinetics and toxicological effects, particle size and particle size distribution, should be included in the EU specifications for calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b). Detailed and comprehensive proposed specifications for the characterisation of the fraction of nanoparticles present in the food additives E 552, E 553a(i), E 553a(ii) and E 553b should be submitted. Information on particle size and particle size distribution for the food additives E 552, E 553a(i), E 553a(ii) and E 553b 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”⁵, is requested. This should allow the establishment of parameters in the EU specifications for calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) that fully characterise the materials used as food additives;
- analytical data on current levels of arsenic, lead and mercury, as well as of aluminium, nickel, fluoride and crystalline silica (alpha-quartz) in E 552, E 553a(i), E 553a(ii) and E 553b;
- the lowest technologically achievable level for lead, mercury, arsenic, aluminium, nickel, fluoride and crystalline silica (alpha-quartz) in E 552, E 553a(i), E 553a(ii) and E 553b, in order to adequately define their maximum limits in their specifications.

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.

2. Toxicological data for E 552, E 553a(i), E 553a(ii) and E 553b

The limitations in the toxicological database of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) need to be decreased so as to allow EFSA to assess the safety of these substances when used as food additives.

In first instance, toxicological studies as recommended for a Tier 1 approach as described in the EFSA Guidance for submission for food additive evaluations (EFSA ANS Panel, 2012)⁶ should be conducted with adequately characterised material(s).

⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/5327>

⁶ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2760.pdf

In the case of proposed read-across from one substance to the others, the relevance of the data obtained with one food additive should be demonstrated for the other food additives under consideration by means of a reasoned justification.

Procedure of the call for data

Step 1: Registration of the contact details of business operators interested in submitting data

Business operators are requested to communicate to the Commission **by 6 December 2018** whether they are interested that calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) remain permitted in the EU and therefore whether they are interested in providing the new data required. This communication should include the contact details of the business operator (name of business operator and postal address), as well as a clear indication of which of the requested data the business operator would be interested in providing. This communication should be submitted to the email address Sante-E2-Additives@ec.europa.eu.

Once the deadline for step 1 has elapsed, the Commission will make publicly available (on DG SANTE's website on food additives⁷) the list of business operators having expressed interest in submitting the data required. This aims at facilitating interactions among business operators and a possible coordinated action in the generation and submission of data.

Communication of interest to submit data would be considered as permission for the Commission to include the details of the party concerned in a list to be published online. In case a party objects to the online publication of its contact details, this should be mentioned on the first communication to the Commission.

Step 2: Confirmation of data submission, deadlines and milestones

Business operators are requested to confirm **by 15 April 2019** their intention to submit the new data required and to provide a list of the data they intend to submit, a timeline for submission of those data as well as a justification for that timeline. When appropriate, the timeline should be in line with EFSA's Scientific Report on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products"⁸. Business operators are also requested to provide a list of intermediate milestones of the data generation and when they will be achieved. This communication should be sent to the email address Sante-E2-Additives@ec.europa.eu.

The Commission will acknowledge receipt of this confirmation of data submission and will confirm the proposed timetable for data submission as well as the defined milestones and their time scheduling. Business operators will be requested to keep the Commission informed of the timely achievement of these milestones.

After completion of this step (step 2), the data to be submitted and both deadlines and milestones will be published on the DG SANTE's website⁹.

Submission of the required data

Business operators are requested to submit the above-indicated data by the agreed deadline in one paper and two electronic copies (standard physical medium such as CD, DVD or USB flash drive). Common electronic formats should be used (e.g. MS Office®, Adobe Acrobat Reader®) allowing

⁷ http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

⁸ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3553.pdf

⁹ https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

content copying and printing (no content copy protection). 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.

All data shall be submitted by registered post to the following contact address:

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

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

Confidential data

Business operators have the right to request a confidential treatment of certain information. They shall indicate which data they wish to be treated as confidential and give verifiable justification for each part for which a confidential treatment is required following the provisions on confidentiality as laid down in Article 12 of Regulation (EC) No 1331/2008¹⁰. Furthermore, the business operator shall provide the Commission with two paper and electronic versions of the dossier, namely the complete dossier and a second version of the complete dossier without confidential information.

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.

¹⁰ OJ L 354, 31.12.2008, p. 1.