Call for technical and scientific data on the permitted food additive sodium aluminium silicate (E 554)

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Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 7 December 2022

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 26 April 2023

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].

In most cases EFSA confirms the safety of the 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 sodium aluminium silicate (E 554) as a food additive

The EFSA Panel on Food Additives and Flavourings (FAF) provided on 12 May 2020 a scientific opinion re-evaluating the safety of sodium aluminium silicate (E 554) when used as a food additive[3]. In this opinion, EFSA also evaluated the safety of potassium aluminium silicate (E 555) when used as a food additive. However, the latter food additive is not subject to this call for data.

No information on the physicochemical characterisation of sodium aluminium silicate when used as food additive E 554 was submitted to EFSA. Sodium aluminium silicate was shown to be absorbed to

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] EFSA Journal 2020;18(6):6152 (www.efsa.europa.eu/en/efsajournal/pub/6152)

a limited extent in rats. Only developmental toxicity studies with sodium aluminium silicate in mice, rats, hamsters and rabbits were available. No treatment-related maternal and developmental effects were observed. The reporting of the prenatal developmental studies was limited to allow the use of these data for hazard assessment.

According to Annex II (Part E) of Regulation (EC) No 1333/2008, sodium aluminium silicate (E 554) is authorised with a maximum permitted level of 20 mg/kg carry over in cheese in the food category '12.1.1 Salt', with the restriction of 'Only for salt intended for surface treatment of ripened cheese, food category 01.7.2'. No use levels were reported to EFSA for food category 12.1.1.

According to Annex III, Part 5, section A of Regulation (EC) No 1333/2008, sodium aluminium silicate (E 554) is authorised as a food additive in nutrients except nutrients intended to be used in foods for infants and young children, at a maximum level of 15,000 mg/kg in fat-soluble vitamin preparations. Only use levels for sodium aluminium silicate (E 554) in food supplements (food category 17) were available to EFSA. The exposure to E 554 based on the reported use levels could be up to 2.9 mg/kg bw per day at the mean level and 3.9 mg/kg bw per day at the high intake level (P95), both in children. In this assessment, it was assumed that all food supplements consumed contained sodium aluminium silicate (E 554) at the highest reported use level.

Based on the maximum amount of Al_2O_3 in sodium aluminium silicate (E 554) as stated in the EU specifications, E 554 contains up to 7.8% aluminium. Thus, the maximum exposure to aluminium from the use of E 554 could be up to 1.58 mg/kg bw per week at the mean and up to 2.13 mg/kg bw per week at the P95 for children. This alone would exceed the tolerable weekly intake (TWI) of 1 mg/kg bw per week for dietary aluminium from all sources established by EFSA.

Considering that only very limited toxicological data and insufficient information on the physicochemical characterisation of the food additive were available, the FAF Panel concluded that the safety of sodium aluminium silicate (E 554) could not be assessed.

The Panel recommended that data in line with the current Guidance document on evaluation of food additives[4] is required to perform the risk assessment of this food additive and evaluate the potential exceedance of the TWI for aluminium resulting from its use as food additives.

Overall purpose of this call for data

Considering the potential exceedance of the TWI for aluminium and the identified data gaps, this call gives 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 sodium aluminium silicate (E 554) as a food additive.

Scientific and technical data required

The data required to address the various issues identified by EFSA in the re-evaluation of the safety of sodium aluminium silicate (E 554) as a food additive are the following:

1. Safety evaluation strategy and corresponding testing strategy

Following a mandate (M-2019-0199) from the European Commission, EFSA has published a *Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles* (EFSA SC Guidance on particle-TR).[5] This Guidance establishes information requirements for conventional materials which do not meet the definition of engineered nanomaterial set out in the Novel Food Regulation (EU) 2015/2283. The EFSA SC Guidance on particle-TR is applicable since its publication in August 2021, and outlines appraisal routes (e.g. solubility/dissolution rate; particle size distribution; appropriateness of safety

[4] EFSA Journal 2012;10(7):2760 (https://www.efsa.europa.eu/en/efsajournal/pub/2760)
[5] https://www.efsa.europa.eu/en/efsajournal/pub/6769

studies) to confirm that an assessment of the fraction of small particles including nanoparticles is not needed for the food additive sodium aluminium silicate (E 554), or that is already covered in the safety assessment process following the conventional sectorial guidance (i.e. the EFSA Guidance for submission for food additive evaluations[4]).

As indicated in the EFSA SC Guidance on particle-TR, there are complementary appraisal routes and it is sufficient to demonstrate that the food additive sodium aluminium silicate (E 554) meets at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR to confirm that the conventional risk assessment does not need to be complemented with nano specific considerations. Nevertheless, information on more than one appraisal route may be submitted.

The outcome of this exercise will indicate the guidance document to be used for the risk assessment of sodium aluminium silicate (E 554), i.e. whether data submitted according to the current EFSA Guidance for submission for food additive evaluations[4] will be sufficient or whether these should be complemented with the considerations outlined in the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health.[6]

2. Technical data

2.1 Information related to the identity and specifications for sodium aluminium silicate (E 554)

Food business operators are requested to provide data related to the identity and specifications for sodium aluminium silicate (E 554) in line with the applicable EFSA Guidance(s) (See section 1 under 'Scientific and technical data required' in this call).

2.2 Data on uses/use levels of the food additive sodium aluminium silicate (E 554)

Uses in accordance with Annex II, Part E of Regulation (EC) No 1333/2008

According to Annex II (Part E) of Regulation (EC) No 1333/2008, sodium aluminium silicate (E 554) is authorised with a maximum permitted level of 20 mg/kg carry over in cheese in the food category '12.1.1 Salt', with the restriction of 'Only for salt intended for surface treatment of ripened cheese, food category 01.7.2'.

Food business operators are requested to provide data on actual normal/typical use levels and maximum use levels for this food category, as well as any other information relevant to perform a refined exposure assessment for E 554 and for aluminium from the use of E 554.

If no use data are provided for the food category 12.1.1. in which the intentional addition of E 554 as a food additive is currently authorised, it will be considered that there is no interest that the use of E 554 as a food additive remains authorised in that food category. Consequently, the authorisation for the use of E 554 in that food category will be withdrawn.

Therefore, if an interested party has information that E 554 is not used in food category 12.1.1., this information should also be provided. Such information will be cross-checked with information sent by all interested parties replying to the call.

Uses in accordance with Annex III, Section A of Part 5 of Regulation (EC) No 1333/2008

Sodium aluminium silicate (E 554) is authorised according to Annex III of Regulation (EC) No 1333/2008 as a food additive in nutrients except nutrients intended to be used in foods for infants and young children, at a maximum level of 15,000 mg/kg in fat-soluble vitamin preparations (Annex III, Part 5, Section A). Food business operators are requested to provide the following data for this authorised use:

[6] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5327

- data on actual normal/typical use levels and maximum use levels of E 554 in the preparation as well as in the final food.
- information on whether the reported use concerns all preparations or only certain preparations (when appropriate).

If no data are provided for the authorised use of E 554 as food additives in accordance with Annex III, Part 5, Section A, it will be considered that there is no interest that this use remains authorised. Consequently, the authorisation for the use of E 554 as food additive in accordance with Annex III, Part 5, Section A will be withdrawn.

Therefore, if an interested party has information that E 554 is not used in accordance with Annex III, Part 5, Section A, this information should also be provided. Such information will be cross-checked with information sent by all interested parties replying to the call.

In addition, any other information relevant to perform a refined exposure assessment for E 554 and for aluminium from the use of E 554 should be submitted. In this context, reference is made to Section 3.3.3. of the EFSA opinion[3] explaining the assumptions in the exposure assessment.

3. Scientific data

The limitations in the toxicological database of sodium aluminium silicate (E 554) need to be decreased to allow EFSA to assess the safety of this substance when used as food additive. Therefore, a toxicological database should be generated for the food additive sodium aluminium silicate (E 554) with adequately characterized material, and in line with the applicable EFSA Guidance(s) (See section 1 under 'Scientific and technical data required' in this call). The safety evaluation strategy and the corresponding testing strategy should be described and justified with rationales for inclusion and exclusion of specific studies and for not performing higher Tier testing.

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 7 December 2022** whether they are interested that sodium aluminium silicate (E 554) remains 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 additives[7]) 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 in the first communication to the Commission.

No reply to the step 1 of the call for data will be considered as an indication that business operators are no longer interested that sodium aluminium silicate (E 554) remains permitted

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

as a food additive and that it can therefore be removed from the EU list of permitted food additives in Regulation (EC) No 1333/2008.

Step 2: Confirmation of data submission, deadlines and milestones

Business operators are requested to confirm **by 26 April 2023** 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.

According to Article 7c of Regulation (EU) No 257/2010 setting up a re-evaluation programme of approved food additives, interested business operators and other interested parties shall, without delay, notify EFSA of any study commissioned or carried out by them to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation. Laboratories and other testing facilities located in the Union shall also, without delay, notify EFSA of any study commissioned by business operators and other interested parties, carried out by such laboratories or other testing facilities to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation.

After completion of step 2, the data to be submitted, the deadlines and milestones will be published on the DG SANTE's website[9].

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"[10] 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

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

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, interested business operator or other interested party may submit a request to treat certain parts of the information or data submitted in accordance with this Regulation as confidential. Such requests shall be accompanied by verifiable justifications. You must submit confidentiality requests complying with EFSA's Practical Arrangements concerning transparency and confidentiality[11], and in particular with Articles 9 and 10 thereof. Confidentiality requests may be submitted exclusively via the Portalino[12] to EFSA. The following information is available on the EFSA website:

- Information on how to submit confidentiality requests[13]
- Information on how to use this tool[14]
- A user guide providing concrete tips on the submission of confidentiality requests[15].

Please note that whenever a confidentiality request is submitted, a non-confidential version and a confidential version of information claimed confidential must be submitted together with each confidentiality request. You are also required to box or earmark information claimed confidential in the confidential version of the information you submit. Please note that confidentiality requests must be submitted prior to the submission of the data via CIRCABC, and that if you do not submit the elements listed above within the given timeline, EFSA is required to proactively publish all information, documents and data already submitted without delay, pursuant to Article 38(1)(c) and (d) of the general food law and Article 6(1) of EFSA's Practical Arrangements of transparency and confidentiality.

The confidentiality requests shall be assessed in accordance with Article 12 of Regulation (EC) No 1331/2008, which shall apply *mutatis mutandis*.

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

[11] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf
[12] https://confportal.efsa.europa.eu/
[13] https://www.efsa.europa.eu/en/about/transparency
[14] https://www.efsa.europa.eu/sites/default/files/2021-05/portalino-quick-guide-business-users.pdf
[15] https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf

these data for other EFSA safety assessments, and/or for a data sharing exercise with third parties or other international bodies.