Call for technical data on the permitted food additives microcrystalline cellulose (E 460(i)), powdered cellulose (E 460(ii)), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), cross-linked carboxy methyl cellulose (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

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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.

[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 celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 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 celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 when used as a food additive in January 2018[3].

The Panel concluded that there was no need for a numerical ADI. Celluloses are not absorbed and are excreted intact in the faeces; in addition, microcrystalline cellulose, powdered and modified celluloses could be fermented by the intestinal flora in animals and humans. Specific toxicity data were not always available for all the celluloses evaluated in the present opinion and for all endpoints. Given their structural, physicochemical and biological similarities, the Panel considered it possible to read-across between all the celluloses. The acute toxicity of celluloses was low and there was no genotoxic concern. Short-term and subchronic dietary toxicity studies performed with E 460(i), E 461, E 462, E 463, E 464, E 466 and E 469 at levels up to 10% did not indicate specific treatment related adverse effects. In chronic toxicity studies performed with E 460(i), E 461, E 463, E 464, E 465 and E 466, the no observed adverse effect level (NOAEL) values reported ranged up to 9,000 mg/kg body weight (bw) per day. No carcinogenic properties were detected for microcrystalline cellulose and modified celluloses. Adverse effects on reproductive performance or developmental effects were not observed with celluloses at doses greater than 1,000 mg/kg bw by gavage (often the highest dose tested). The combined exposure to celluloses (E 460–466, E 468 and E 469) at 95th percentile of the refined (brand-loyal) exposure assessment for the general population was up to 506 mg/kg bw per day. The Panel concluded that that there would be no safety concern at the reported uses and use levels for the unmodified and modified celluloses (E 460(i); E 460(ii); E 461–466; E 468 and E 469). The Panel considered an indicative total exposure of around 660–900 mg/kg bw per day for microcrystalline, powdered and modified celluloses.

The Panel concluded, that the available data did not allow for an adequate assessment of the safety of use of sodium carboxy methyl cellulose (E 466) in infants and young children consuming foods belonging to the categories 13.1.5.1 and 13.1.5.2.

The Panel recommended that the European Commission considers lowering the maximum limits for the toxic elements arsenic, lead, mercury and cadmium present as impurities in the EU specifications for unmodified and modified celluloses re-evaluated (E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469).

EFSA's Panel on Food Additives and Flavourings (FAF) issued on 9 December 2022, a Scientific Opinion on the re-evaluation of sodium carboxy methyl cellulose (E 466) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive for uses in foods for all population groups[4]. For this Opinion, EFSA was requested to address the issues identified during the re-evaluation of sodium carboxy methyl cellulose (E 466) as a food additive and to assess the safety of E 466 for its uses as a food additive in food for infants below 16 weeks of age belonging to food categories (FC) 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants) in line with Regulation (EC) No 1333/2008.

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 microcrystalline cellulose (E 460(i)), powdered cellulose (E 460(ii)), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), cross-linked carboxy methyl cellulose (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469) as food additives.

[3] EFSA Journal 2017;16(1):5047 (https://www.efsa.europa.eu/en/efsajournal/pub/5047)
[4] EFSA Journal 2022;20(12):7665 (https://www.efsa.europa.eu/en/efsajournal/pub/7665)

Information required for the food additives microcrystalline cellulose (E 460(i)), powdered cellulose (E 460(ii)), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), cross-linked carboxy methyl cellulose (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of celluloses, information is sought on:

1. Technical data for the revision of the specifications for microcrystalline cellulose (E 460(i)), powdered cellulose (E 460(ii)), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), cross-linked carboxy methyl cellulose (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469):

    - Analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additives. Business operators are requested to submit the analytical results obtained in the context of Article 17(1)[5] of Regulation (EC) No 178/2002[6] during the last 5 years. The results of the individual samples (including sample ID and sampling date) as well as summary statistics (mean, P50, P95, range) are requested. The results should adequately cover the between-batches variability and should be representative of the food additives currently placed on the EU market. Submission of results from a shorter timespan should be justified. 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, 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).

    - The lowest technologically achievable level for lead, mercury, cadmium and arsenic in order to adequately propose maximum limits in the specifications.

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. The 2-step 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 by **29 November 2023** 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).

[5] Article 17(1) of Regulation (EC) No 178/2002 :Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

[6] OJ L 031 1.2.2002, p. 1

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

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