# Call for technical data on the permitted food additive vegetable carbon (E 153)

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**Deadline:** 14 August 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 vegetable carbon (E 153) as a food additive

EFSA's Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered a scientific opinion re-evaluating the safety of vegetable carbon (E 153) when used as a food additive in April 2012[3]. Vegetable carbon has been evaluated previously by the Scientific Committee for Food (SCF) (1977, 1983) and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (1970, 1977, 1987). Neither Committee established an ADI for vegetable carbon, but the SCF concluded that vegetable carbon could be used in food.

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] EFSA Journal 2012;10(4):2592 (https://www.efsa.europa.eu/en/efsajournal/pub/2592)

EFSA considered the available toxicological data too limited to establish an ADI for vegetable carbon. EFSA noted that data on the genotoxicity and carcinogenicity of carbon blacks of hydrocarbon origin has been related to the polycyclic aromatic hydrocarbons (PAHs) content of these substances. However, EFSA noted that the margins of exposure for benzo[a]pyrene exposure from vegetable carbon were considerably higher than those estimated from the dietary benzo[a]pyrene exposure.

EFSA concluded that at the reported use levels vegetable carbon (E 153) containing less than 1.0 µg/kg of residual carcinogenic PAHs expressed as benzo[a]pyrene is not of safety concern. This was also based on the long history of safe use as a medicinal substance and the knowledge that vegetable carbon is an inert substance which is essentially not absorbed from the gastrointestinal tract following oral administration. EFSA considered that it may be appropriate to introduce in the specifications for vegetable carbon a requirement for residual carcinogenic PAHs expressed as benzo[a]pyrene using a validated analytical method of appropriate sensitivity (e.g. LOD of 0.1 µg/kg).

The estimated dietary exposure of European children to vegetable carbon ranged from 3 to 29.7 mg/kg bw/day at the mean, and from 15.3 to 79.1 mg/kg bw/day at the 95th/97.5th percentile. The dietary exposure of UK adults was 3.8 mg/kg bw/day at the mean, and 28.1 mg/kg bw/day for high level (97.5th percentile) consumers.

EFSA's overall conclusion on the safety of E 153 was that considering:

- the lack of absorption of vegetable carbon,
- the consideration that vegetable carbon is not of concern with respect to genotoxicity and carcinogenicity, provided the material of commerce contains less than 1.0 µg/kg of residual carcinogenic PAHs expressed as benzo[a]pyrene, using a validated analytical method of appropriate sensitivity,
- the history of safe use in medicine showing the absence of toxicologically relevant effects upon exposure to vegetable carbon or comparable carbon preparations for pharmaceutical use at levels 18 to 300 times higher than the mean estimated dietary exposure to vegetable carbon resulting from its use as a food colour, and
- the fact that the margins of exposure for PAHs resulting from the use of vegetable carbon as a food colour are much greater than those estimated to PAHs from the diet,

vegetable carbon (E 153) at the reported uses and use levels is not of safety concern.

EFSA considered that the limits for aluminium should be included in the EU specifications for vegetable carbon (E 153). EFSA noted that the JECFA specification for lead is 2 mg/kg, whereas the EU specification is 10 mg/kg. EFSA also noted that the current description of the particle size of vegetable carbon in the specifications does not preclude production of vegetable carbon of a lower particle size.

EFSA concluded that the EU specifications for vegetable carbon may need to be amended to include a restriction of the particle size (< 100 nm) in order to exclude the presence of nanoparticles.

**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 vegetable carbon (E 153) as a food additive.

**Information required for the food additive vegetable carbon (E 153)**

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of vegetable carbon (E 153) as a food additive by EFSA, information for vegetable carbon (E 153) is sought on:

Technical data

The characterisation of all the different commercial preparations of the food additive vegetable carbon (E 153) from non-consecutive batches of each preparation, in relation to:

- Analytical data, if possible supported by certificate of analysis, on current levels of aluminium, arsenic, lead, mercury and cadmium in commercial samples of the food additive;
- The lowest technologically achievable level for aluminium, arsenic, lead, mercury and cadmium in order to adequately propose maximum limits in the specifications;
- Analytical data, if possible supported by certificate of analysis, on current levels of benz[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, benzo[a]pyrene, chrysene, cyclopenta[cd]pyrene, dibenz[a,h]anthracene, dibenzo[a,e]pyrene, dibenzo[a,h]pyrene, dibenzo[a,i]pyrene, dibenzo[a,l]pyrene, indeno[1,2,3-cd]pyrene, 5-methylchrysene, and benzo[c]fluorene in commercial samples of the food additive, using a validated analytical method, preferably based on mass spectrometry, of appropriate sensitivity (LOD of 0.1 µg/kg per individual PAH;
- The lowest technologically achievable level for the above-listed 16 priority PAHs in order to adequately propose maximum limits in the specifications at least for benzo(a)pyrene, as well as for the sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene;
- Because of their potential importance in toxicokinetics and toxicological effects, particle size and particle size distribution should be included in the EU specifications for the food additive vegetable carbon (E 153) in Commission Regulation (EU) No 231/2012. Therefore, detailed and comprehensive proposed specifications for the characterisation of the fraction of nanoparticles present in the food additive vegetable carbon (E 153) should be submitted. Information on particle size and particle size distribution for the food additive vegetable carbon (E 153) 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"[4], is requested. In addition, the latest indications from the EFSA "Draft Guidance on technical requirement for regulated food and feed product applications to establish the presence of small particles including nanoparticles"[5], published recently for public consultation, may be considered. The information provided should allow the establishment of parameters in the EU specifications for vegetable carbon (E 153) that fully characterise the material used as a food additive.

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).

**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 August 2021** the above-requested data.

[4] EFSA Scientific Committee, 2018 (https://doi.org/10.2903/j.efsa.2018.5327)

[5] EFSA Scientific Committee, 2018 (https://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-efsa-guidance-technical-requirements)

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"[6] 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.

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

**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.