Call for technical data on the permitted food additive Patent Blue V (E 131)

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Deadline: 25 November 2025

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 Patent Blue V (E 131) 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 Patent Blue V (E 131) when used as a food additive in July 2012 (published in April 2013)[3].

Patent Blue V (E 131) is a triarylmethane dye permitted for use as a food additive in the EU and was previously assessed by the EU Scientific Committee for Food (SCF) in 1983. The

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] EFSA Journal 2013;11(3):2818. (Re-evaluation of Patent Blue V (E 131) as a food additive | EFSA)

SCF established an acceptable daily intake (ADI) of 0-15 mg/kg bw/day. The ANS Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that became available since then and the data available following a public call for data.

According to new studies provided by industry on request of EFSA, the Panel considered that Patent Blue V (E 131) (at purity level > than 90 %) is not of concern with respect to genotoxicity.

The ANS Panel concluded that the dataset provided a rationale for a re-definition of the ADI. Using the no observed adverse effect level (NOAEL) of 500 mg/kg bw/day from a chronic toxicity study in mice and applying an uncertainty factor of 100 to this NOAEL, the Panel established an ADI of 5 mg/kg bw/day for Patent Blue V. The Panel considered that this ADI will only apply to Patent Blue V with a purity of at least 90 %.

Exposure to Patent Blue V from its use as a food additive has been calculated by using maximum permitted levels of use (MPLs) and by using data on reported use levels provided by food industry or data reported on analytical levels provided by national authorities or found in the literature. These data were combined with national consumption data for the population groups of toddlers, children, adolescents, adults and the elderly from the EFSA Comprehensive Food Consumption Database.

The Panel noted that at the maximum permitted levels of use of Patent Blue V (E 131), exposure estimates for high consumers are above the ADI of 5 mg/kg bw/day in toddlers and children. At the maximum reported use levels of Patent Blue V, exposure estimates are below the ADI of 5 mg/kg bw/day for all groups of the population.

The Panel further noted that the specifications for Patent Blue V (E 131) need to be updated with respect to the percentage of material not accounted for that may represent sodium chloride and/or sodium sulphate as the principal uncoloured components.

In Section 4 of the Opinion, it is also mentioned that the Panel concluded that it would be prudent to modify the specifications to indicate that the level of unsulphonated aromatic amines should be as low as reasonably achievable.

The Panel further noted that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specification for chromium is < 50 mg/kg, whereas no specification for chromium is required in EC specifications.

The Panel also noted that the aluminium lake of the colour could add to the daily intake of aluminium and that therefore specifications for the maximum level of aluminium in the lakes are required[4].

This call for data aims to give the opportunity to business operators to submit the technical data needed to address the issues identified by EFSA in the re-evaluation of the safety of Patent Blue V (E 131) as a food additive, in particular the level of unsulphonated primary aromatic amines. The call for data also aims to collect data to support the revision of the current limits for arsenic, lead, mercury and cadmium in Patent Blue V (E 131), ensuring that the food additive will not be a significant source of exposure to those toxic elements in food.

In addition, please be informed that following the EFSA ANS Opinion, the European Commission, in consultation with the Member States, will proceed with updating the specifications set for Patent Blue V (E 131) in Commission Regulation (EU) No 231/2012 regarding:

- A modification regarding the Assay from '*Content not less than 85% total colouring matters, calculated as the sodium salt*' to '*Content not less than 90 % total colouring matters, calculated as the sodium salt'*;

[4] Already addressed in Commission Regulation (EU) No 380/2012 of 3 May 2012

- The amendment of the specifications with an entry for 'Principal uncoloured components' to be defined as '< 10% sodium chloride and/or sodium sulphate';
- The amendment of the specifications with a limit for Chromium of not more than 50 mg/kg.

The Commission will update the specifications for Patent Blue V (E 131) in one step after the data to this call will have been processed.

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 Patent Blue V (E 131) as a food additive and the technical data to support the revision of the limits for arsenic, lead, mercury and cadmium in Patent Blue V (E 131).

Information required for the food additive Patent Blue V (E 131)

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of Patent Blue V (E 131) as a food additive and to support the revision of the limits for toxic elements, information for Patent Blue V (E 131) is sought on:

Technical data for the revision of the specifications for Patent Blue V (E 131)

- Analytical data on current levels of **unsulphonated primary aromatic amines** in commercial samples of the food additive.
    - Business operators are requested to submit the analytical results on the levels of unsulphonated primary aromatic amines (calculated as aniline) in commercial samples of E 131 obtained in the context of Article 17(1)[5] of Regulation (EC) No 178/2002[6] during the last 5 years. Submission of results from a shorter timespan should be justified. Submission of results covering a longer timespan than the last 5 years, namely data obtained since 2013, can also be provided. 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. 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).
    - Business operators are requested to specify the purity level of the commercial samples for which data are submitted (percentage of total colouring matters, calculated as the sodium salt[7]).

[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

[7] See assay specification set for Patent Blue V (E 131) in Regulation (EU) No 231/2012, referring to the method 'E1% 1cm 2 000 at ca. 638 nm in aqueous solution at pH 5'

- To provide a proposed limit for unsulphonated primary aromatic amines based on the analytical results and its lowest technologically achievable level in the food additive (lower than the current level set in the specifications for Patent Blue V of "*not more than 0,01% (calculated as aniline)*".
- Analytical data on current levels of **lead, mercury, arsenic and cadmium** in commercial samples of the food additive Patent Blue V (E 131).
    - Business operators are requested to submit the analytical results on the levels of lead, mercury, arsenic and cadmium in commercial samples of E 131 obtained in the context of Article 17(1)[5] of Regulation (EC) No 178/2002[6] during the last 5 years. Submission of results from a shorter timespan should be justified. Submission of results covering a longer timespan than the last 5 years, namely data obtained since 2013, can also be provided. 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 additive currently placed on the EU market. 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).
    - Business operators are requested to specify the purity level of the commercial samples for which data are submitted (percentage of total colouring matters, calculated as the sodium salt[7]).
- To provide a proposed limit for lead, mercury, arsenic and cadmium based on the analytical results and its lowest technologically achievable level in the food additive Patent Blue V (E 131).

Procedure of the call for data

It should be noted that this call concerns only technical data. Therefore, the 2-step procedure used in some 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 **by 25 November 2025** 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"[8] 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 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:

Sabine Pelsser, Head of Unit E2
European Commission
Directorate-General for Health and Food Safety
Directorate E – Food Safety, Sustainability and 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.

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.

[8] https://food.ec.europa.eu/document/download/a545dc60-5993-4632-bf19-34bd34d1b355_en?filename=fs_food-improvement-agents_guidance_circabc_data-sub.pdf