

Call for scientific and technical data on the permitted food additive glycerol esters of wood rosins (E 445)

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Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 21 January 2019

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 20 May 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 glycerol esters of wood rosins (E 445) 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 glycerol esters of wood rosins (GEWR, E 445) when used as a food additive³.

Regarding GEWR originating from *Pinus palustris* (longleaf pine) and *Pinus elliottii* (slash pine), based on the overall toxicity database, and given the absence of reproductive and developmental toxicity data, the Panel concluded that the current acceptable daily intake (ADI) of 12.5 mg/kg body weight (bw) per day for GEWR (E 445) as established by the Scientific Committee on Food (SCF) in 1994 should be temporary pending the provision of such data. This assessment is restricted to GEWR derived from *P. palustris* (longleaf pine) and *P. elliottii* (slash pine) and with a chemical composition in compliance with GEWR used in the toxicological testing.

The Panel concluded that the mean and the high exposure levels (P95) of the brand-loyal refined exposure scenario did not exceed the temporary ADI in any of the population groups from the use of GEWR (E 445) as a food additive at the reported use levels.

For GEWR originating from *Pinus halepensis* and *Pinus brutia*, the Panel noted that concentrations of the fractions of 'glycerol monoesters', 'free resin acids' and 'neutrals', which are considered to be of particular toxicological relevance, are not known; therefore, the evaluation of chemical equivalence with GEWR originating from *P. palustris* (longleaf pine) and *P. elliottii* (slash pine) is not possible; no data on stability were available; no toxicological data were available. Therefore, the Panel concluded that a safety assessment of GEWR originating from *P. halepensis* and *P. brutia* could not be performed.

The Panel recommended the European Commission to consider an update of the definition of GEWR (E 445) in the EU specifications. It should be indicated that GEWR (E 445) (i) contain, besides the mentioned glycerol di- and triesters, a residual fraction of glycerol monoesters, and (ii) contain residual free resin acids and neutrals (non-acidic other saponifiable and unsaponifiable substances).

Overall purpose of this call for data

To give the opportunity to business operators to submit the scientific technical data needed to address issues identified by EFSA in the re-evaluation of the safety of glycerol esters of wood rosins (E 445) as a food additive.

Scientific and technical data required for E 445

With reference to the conclusions and recommendations of EFSA's Scientific Opinion on the re-evaluation of glycerol esters of wood rosins (GEWR; E 445) as a food additive, information for GEWR (E 445) is sought on:

1. Technical data

- Analytical data on current levels of arsenic, lead, mercury and cadmium in commercial samples of the food additive;
- the lowest technologically achievable level for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications;

³ <https://www.efsa.europa.eu/en/efsajournal/pub/5370>

- analytical data on current levels in commercial samples of the food additive E 445 of impurities of toxicological concern (e.g. butanetriols, acrolein, chlorinated compounds and 3-monochloropropane-1,2-diol), as identified in the EU specifications of the food additive glycerol (E 422)⁴, which can be used in the manufacturing process of E 445;
- the lowest technologically achievable level for impurities of toxicological concern (e.g. butanetriols, acrolein, chlorinated compounds and 3-monochloropropane-1,2-diol) in order to adequately define their maximum limits in the specifications of E 445;
- analytical data on current levels in commercial samples of the food additive E 445 of any impurity present in glycerol (as mentioned in the call for data on the food additive glycerol (E 422)⁴), which can be used in the manufacturing process of E 445;
- the lowest technologically achievable level for any impurity which could be formed during the manufacturing processes of glycerol and be present in E 445, in order to adequately define their maximum limits in the specifications of E 445;
- analytical data on the concentrations of the toxicologically relevant fractions of 'glycerol monoesters', 'free resin acids' and 'neutrals' from a GEWR preparation equivalent to the GEWR which was subject to the toxicological testing;
- detailed information on the chemical composition of GEWR originating from *P. halepensis* and *P. brutia* (and potentially other pine species), in particular on the concentrations of the toxicologically relevant fractions of 'glycerol monoesters', 'free resin acids' and 'neutrals'. Those data are needed to determine whether GEWR originating from *P. halepensis* and *P. brutia* (and potentially other pine species, provided that appropriate data are provided) is chemically (compositionally) equivalent to GEWR originating from *P. palustris* and *P. elliottii*, and, consequently, whether read across of toxicological data obtained with GEWR originating from *P. palustris* and *P. elliottii* would be possible.

The information should be supported by data from at least five independently produced batches, and the analyses should be performed with appropriate analytical methods. 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 limit of quantification (LOQ)).

2. Toxicological data

The limitations in the toxicological database of GEWR (E 445) need to be decreased to allow EFSA to establish an acceptable daily intake (ADI) for this food additive.

- A reproductive and developmental toxicity study, in accordance with the applicable OECD test guidelines, should be conducted using a test material which is representative of the food additive present on the market and taking into account the recommendations made by EFSA for the update of the specifications.

EFSA's "Guidance for submission for food additive evaluations"⁵ provides a description of the data requirements for the evaluation of the safety of a food additive and therefore it will be useful to clarify the nature of the data requested. In addition, EFSA's scientific report on "Indicative

⁴ Call for technical data on the permitted food additive glycerol (E 422) https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

⁵ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2760.pdf

timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products⁶ could be useful.

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 21 January 2019** whether they are interested that glycerol esters of wood rosins (E 445) 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 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 20 May 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". 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 website⁷.

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

⁶ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3553.pdf

⁷ 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, and describing the data submitted. The cover letter should provide the contact details of the data submitter.

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 1331/2008⁸. 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.

⁸ OJ L 354, 31.12.2008, p. 1.