Call for technical data on the permitted food additive polyglycerol esters of fatty acids (E 475)

Published: 23 November 2018

New deadline: 30 June 2020

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 polyglycerol esters of fatty acids (E 475) 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 polyglycerol esters of fatty acids (PEFA; E 475) when used as a food additive[3]. In 1978, the Scientific Committee on Food (SCF) endorsed an acceptable daily

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] https://www.efsa.europa.eu/en/efsajournal/pub/5089

intake (ADI) of 25 mg/kg body weight (bw) per day previously established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Absorption of intact PEFA in the gastrointestinal tract was extremely low. PEFA was rapidly and almost fully hydrolysed to polyglycerols and fatty acids in the gastrointestinal tract.

The safety of polyglycerols and specific fatty acids has recently been assessed and no adverse effects were identified in the available studies. No adverse effects of PEFA at any dose have been observed in short-term, subchronic or chronic toxicity studies. A no observed adverse effect level (NOAEL) of 9,000 mg/kg bw per day was identified from subchronic studies and of 2,500 mg/kg bw per day from chronic studies, the highest doses tested. No genotoxic potential of PEFA was identified from the limited information available. The reproductive toxicity studies showed no adverse effects of PEFA but had major limitations.

Clinical chemistry and urinalysis, from a clinical study with limited information, did not reveal any adverse effects in volunteers receiving up to 300 mg/kg bw per day for 3 weeks. The highest exposure to PEFA used as a food additive was 2.6 and 6.4 mg/kg bw per day in children at the mean and the 95th percentile, respectively, for the non-brand loyal scenario.

Considering all the above, the Panel concluded that the food additive PEFA (E 475) was not of safety concern at the reported uses and use levels and that there was no need for a numerical ADI.

The Panel recommended some modifications of the EU specifications for E 475.

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 PEFA (E 475) as a food additive.

Technical data required for E 475

With reference to the conclusions and recommendations of EFSA's Scientific Opinion on the re-evaluation of polyglycerol esters of fatty acids (PEFA; E 475) as a food additive, information for PEFSA (E 475) is sought on:

- analytical data on current levels of arsenic, lead, mercury and cadmium in commercial samples of the food additive E 475;
- the lowest technologically achievable level for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 of epichlorohydrin and glycidol, which could be used in the manufacturing processes of polyglycerols (used, in turn, in the manufacturing process of E 475);
- the lowest technologically achievable level for epichlorohydrin and glycidol in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 of trans fatty acids, which can be present in hydrogenated fats and/or oils used in the manufacturing process of E475 by glycerolysis;
- the lowest technologically achievable level for trans fatty acids, in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 of glycidyl esters/glycidol and monochloropropane-1,2-diol esters (3-MCPD esters), since residues that can be present in the raw materials used in the manufacturing of the food additive by transesterification;

- the lowest technologically achievable level for glycidyl esters/glycidol and monochloropropane-1,2-diol esters (3-MCPD esters), in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels of erucic acid in commercial samples of the food additive E 475, given that a residue that can be present among the fatty acids in edible oils, which can be used in the manufacturing process of the food additive;
- the lowest technologically achievable level for erucic acid, in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 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 475;
- 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 475;
- analytical data on current levels in commercial samples of the food additive E 475 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 475;
- the lowest technologically achievable level for any impurity which could be formed during the manufacturing processes of glycerol and be present in E 475, in order to adequately define their maximum limits in the specifications of E 475;

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)).

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 **by 30 June 2019** 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.

[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

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 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 1331/2008[5]. 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.

[5] OJ L 354, 31.12.2008, p. 1.