Call for technical data on the permitted food additive glycerol (E 422)

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Deadline: 30 June 2019

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 glycerol (E 422) 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 (E 422) when used as a food additive[3]. In 1981, the Scientific Committee on Food (SCF) endorsed the conclusion from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1976 of 'acceptable daily intake (ADI) for man not specified'.

[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/4720

The Panel concluded that glycerol has low acute toxicity and that local irritating effects of glycerol in the gastrointestinal tract reported in some gavage studies were likely due to hygroscopic and osmotic effects of glycerol.

Glycerol did not raise concern with respect to genotoxicity and was of no concern with regard to carcinogenicity. Reproductive and prenatal developmental studies were limited to conclude on reproductive toxicity but no dose-related adverse effects were reported. None of the animal studies available identified an adverse effect for glycerol. The Panel conservatively estimated the lowest oral dose of glycerol required for therapeutic effect to be 125 mg/kg bw per hour and noted that infants and toddlers can be exposed to that dose by drinking less than the volume of one can (330 mL) of a flavoured drink.

The Panel concluded that there is no need for a numerical ADI and no safety concern regarding the use of glycerol (E 422) as a food additive at the refined exposure assessment for the reported uses. The Panel also concluded that the manufacturing process of glycerol should not allow the production of a food additive, which contains genotoxic and carcinogenic residuals at a level which would result in a margin of exposure below 10,000.

The Panel recommended a modification of the EU specifications for E 422. The Panel also recommended that more information on uses and use levels and analytical data should be made available to the Panel.

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 glycerol (E 422) as a food additive.

It should be noted that this call for data does not cover data on uses and use levels and analytical data needed to address EFSA's recommendation on the exposure assessment. Those data will be the subject of a specific call for data, which will be issued by EFSA.

Technical data required for E 422

With reference to the conclusions and recommendations of EFSA's Scientific Opinion on the re-evaluation of glycerol (E 422) as a food additive, information for glycerol (E 422) is sought on:

- 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;
- analytical data on current levels of acrolein in commercial samples of the food additive;
- the lowest technologically achievable level of acrolein, which is an intermediate chemical in the synthesis of glycerol, in order to adequately define its maximum limit in the specifications of E 422;
- the lowest technologically achievable level in food of any compound of toxicological concern (e.g. acrolein, 3-MCPD and glycidyl esters), which can be produced under certain food processing conditions from the food additive glycerol (E 422) (e.g. use of glycerol (E 422) in parallel with lactic acid bacteria; use of glycerol (E 422) in food containing significant amounts of sodium chloride (more than 5%) and treated at temperatures above 160°C, etc.);
- in view that in the Scientific Opinion on the re-evaluation of glycerol (E 422) as a food additive it has been noted that glycerol (E422) can be produced by a variety of methods, and that many of them lead to the presence or formation of contaminants, which are of toxicological concern, the following information is needed:

- Information on the manufacturing process of glycerol to be used as food additive E 422;
- analytical data on current levels of any chemical intermediate that could be formed during the manufacturing process of glycerol in commercial samples of the food additive;
- the lowest technologically achievable level of any chemical intermediate that could be formed during the manufacturing process of glycerol, in order to adequately define maximum limits in the specifications of E 422.

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.

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[4]. 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.

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