

Call for scientific and technical data on the permitted food additives sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203)

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Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 22 July 2016

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 25 November 2016

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 sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives

The EFSA's Panel on Food Additives and Nutrient Sources added to Food (ANS) recently delivered a scientific opinion³ re-evaluating sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) when used as food additives.

Given the lack of genotoxicity data on calcium sorbate and the available positive genotoxicity data on sodium sorbate, the Panel concluded that calcium sorbate should be excluded from the group ADI. Therefore, the Panel considered that genotoxicity data on calcium sorbate are needed.

The Panel concluded that the present dataset on reproductive and developmental toxicity gives a reason to revise the group ADI of 25 mg/kg bw/day set by the Scientific Committee on Food in 1996. The Panel considered that the no observed adverse effect level of 300 mg sorbic acid/kg bw/day from the two-generation reproductive toxicity study in rats can be used to allocate a temporary group ADI for sorbic acid and its potassium salt. By applying an uncertainty factor of 100, the Panel established a new temporary group ADI expressed as 3 mg sorbic acid/kg bw/day for sorbic acid and its potassium salt. Given the lack of genotoxicity data on calcium sorbate and the available positive genotoxicity data on sodium sorbate, the Panel concluded that calcium sorbate should be excluded from the group ADI.

The Panel noted that the most realistic exposure assessment approach using reported use levels and analytical data in the non-brand-loyal scenario did not exceed the temporary group ADI in any population group at the mean or in adolescents, adults and the elderly at the high level, except in the toddler and children population groups in one country.

The Panel recommended that if divalent transition metals are used as catalysts in the manufacturing process of sorbic acid, maximum residual levels of divalent transition metals should be included in the specifications for sorbic acid (E 200) laid down in Commission Regulation (EU) No 231/2012⁴. In addition, the Panel recommended that the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for sorbic acid and its salts (E 200, 202, 203) should be revised in order to ascertain that sorbic acid/sorbates as food additives will not be a significant source of exposure to those toxic elements in food.

Overall purpose of this call for data

To give the opportunity to business operators to submit the scientific and technical data needed to address issues identified by EFSA in the re-evaluation of the safety of sorbic acid/sorbates as food additives.

Scientific and technical data required

The data required to address the various issues identified by EFSA in the re-evaluation of the safety of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives are the following:

- Data on genotoxicity of calcium sorbate: genotoxicity studies on calcium sorbate need to be performed in order to consider including calcium sorbate in the group ADI;
- Data on reproductive toxicity of sorbic acid/potassium sorbate: an extended one-generation reproductive toxicity study in rats including the second generation by diet needs to be performed in order to reconsider the temporary group ADI;
- Data on the lowest achievable limits for the impurities of toxic elements (lead, mercury and arsenic) for sorbic acid and its salts: the current maximum limits for those impurities in the

³ <https://www.efsa.europa.eu/en/efsajournal/pub/4144>

⁴ OJ L 83, 22.03.2012, p. 1.

EU specifications are too high and therefore should be revised to ensure that food additives will not be a significant source of exposure to those toxic elements in food;

- Data on the use of divalent transition metals as catalysts in the manufacturing process of sorbic acid: If these catalysts are used, information should be provided on the lowest achievable residual levels of divalent transition metals, in order to include them in the EU specifications for sorbic acid.

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 could be useful to clarify the nature of the data requested above. Also EFSA's scientific report on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products"⁶ 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 22 July 2016** whether they are interested that sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) remain permitted in the EU and therefore whether they are interested in providing the new data required. This communication, which should include full contact details of the business operator (name of business operator, name of contact person, postal address, telephone number and email address), 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 25 November 2016** 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.

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

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

⁷ http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

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 website⁸.

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 or DVD). 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.

All data shall be submitted by registered post to the following contact address:

Maria Iglesia, 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 1331/2008⁹. 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 http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

⁹ OJ L 354, 31.12.2008, p. 1.