Call for technical data on saccharin and its sodium, potassium and calcium salts (E 954)

Related to saccharin (EFSA-Q-2011-00736), sodium saccharin (EFSA-Q-2011-00737), calcium saccharin (EFSA-Q-2011-00738), potassium saccharin (EFSA-Q-2011-00739)

Published: 22/11/2021

Deadline for registering interest: 22/12/2021

Deadline for submission of data: 22/02/2022

Background

Pursuant to Article 32(1) of Regulation (EC) No 1333/2008[1], food additives which were permitted for use in the European Union before 20 January 2009 need to be re-evaluated by the European Food Safety Authority (EFSA). The programme for this re-evaluation is defined by Commission Regulation (EU) No 257/2010[2].

In accordance with the above regulations EFSA started a systematic re-evaluation of authorised food additives and is issuing scientific opinions on these food additives, according to the priorities indicated in the Regulation (EU) No 257/2010, which foresees in article 3(b) that "the re-evaluation of all approved sweeteners listed in Directive 94/35/EC shall be completed by 31 December 2020".

In accordance with Article (5) of the Regulation (EU) No 257/2010, EFSA has already made open call(s) for data for the sweeteners under the re-evaluation programme[3,4]. On the basis of the information received from interested parties and those retrieved from the literature EFSA has started the assessment of these food additives.

As recorded in the minutes of the 33rd meeting[5] of Sweeteners Re-evaluation Working Group of the Food Additives and Flavourings (FAF) Panel and the 24th plenary meeting of FAF Panel[6], during the course of the preliminary assessment of the available data, the need for additional information considered to be relevant for the re-evaluation has been identified for saccharin and its sodium, potassium and calcium salts (E 954).

Therefore, in accordance to article 6(3) of the regulation (EU) No 257/2010, EFSA launches a public call for data in order to acquire documented information (published,

[1] Regulation (EC) No 1333/2008 on food additives, OJ L 354, 31.12.2008

[2] Regulation (EU) No 257/2010, setting up a programme for the re-evaluation of approved food additives in accordance with regulation (EC) No 1333/2008, OJ L 80, 26.03.2010. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0257&from=EN

[3] https://www.efsa.europa.eu/en/data/call/170621

[4] https://www.efsa.europa.eu/en/consultations/call/call-technical-data-sweeteners-authorised-food-additives-eu

[5] https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/sweeteners-m.pdf

[6] https://www.efsa.europa.eu/sites/default/files/2021-10/24th-plenary-meeting-faf-panel-proposed-be-open-observers-minutes.pdf

unpublished or newly generated) on saccharin and its sodium, potassium and calcium salts (E 954).

EFSA will consider the relevance of the information provided for the risk assessment of this food additive. The submission of the requested information is without prejudice to the final opinion of the FAF Panel.

Overall objective

The purpose of this call for data is to offer to interested parties and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of saccharin and its sodium, potassium and calcium salts (E 954).

Deadline for submission of data and disclosure of contact details

Interested parties and stakeholders should provide by **22/02/2022** the information described below.

Within **4 weeks** from the publication of this call, please communicate in writing by e-mail to: fip@efsa.europa.eu, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.

In accordance with Article 6(4) of the Regulation (EU) No 257/2010 any information not submitted within the final deadline shall not be taken into account in the re-evaluation. However, in exceptional cases, EFSA may decide with the agreement of the Commission to take into account information submitted after the deadline, if that information is significant for the re-evaluation of a food additive.

In order to facilitate the collaboration of all interested parties to provide the data needed, we are seeking your consent to disclose your personal data (name, e-mail address and telephone number) to the other parties that have expressed an interest to provide the requested information. If you do not wish to make your contact details available, clearly indicate this in your first communication.

Information sought

EFSA kindly invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit information on the following food additives:

Additive	E number
saccharin	E 954 (i)
sodium saccharin	E 954 (ii)
calcium saccharin	E 954 (iii)
potassium saccharin	E 954 (iv)

1. **Data and information on manufacturing process**

A preliminary assessment of the available data and information on the manufacturing process of saccharin and its sodium, potassium and calcium salts (E 954) was conducted by the WG on Sweeteners Re-evaluation of the FAF Panel. This assessment has highlighted the need for collecting additional data and information on current production method(s) used to manufacture E 954.

Therefore, pursuant to article 6(3) of Commission Regulation (EU) No 257/2010, EFSA seeks additional data and information on manufacturing process(es) which is(are) currently in place to produce saccharin and its salts to be used as the food additive E 954. This information is used in the risk assessment to identify possible remaining impurities in the food additive (e.g. reaction intermediates, precursors, residual solvents, toxic elements).

Saccharin and its sodium, potassium and calcium salts (E 954):

EFSA invites the interested business operators and other interested parties to:

- provide detailed information on any production method used to manufacture E 954 (i), E 954 (ii), E 954(iii), E 954(iv)

- propose a short description of each production method used to manufacture E 954 (i), E 954 (ii), E 954(iii), E 954(iv), including the key steps involved, for possible inclusion in their EU specifications.

- provide analytical data on the identity and content of any impurity derived from each production method used to manufacture E 954 (i), E 954 (ii), E 954(iii), E 954(iv) in preferably at least five independently produced batches of the food additive, using appropriate analytical methods applying state of the art techniques. The results of the analyses should be supported by certificates of analysis. In addition, information on the representativeness of the tested batches should be provided. Specific data on the methods of analysis used should be provided, e.g. the principle and 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 parameters of the method (in particular limit of detection (LOD) and quantification (LOQ)).

- provide the lowest technologically achievable levels for any impurity derived from each production method used to manufacture E 954 (i), E 954 (ii), E 954 (iii), E 954 (iv).

Confidentiality

According to article 8 of Regulation (EU) No 257/2010 setting up a re-evaluation programme of approved food additives, confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties.
Therefore, the business operators and/or the interested parties should indicate which information they wish to be treated as confidential and provide verifiable justification supporting this request. Please also note that the information described in Article 8(2) of Regulation (EU) No 257/2010 cannot be regarded as confidential in any circumstances.

In application of Article 8(4) of Regulation (EU) 257/2010, following a proposal from EFSA, the Commission will decide after consulting the interested business operator and/or the other interested parties, which information may remain confidential.

Submission of information

Interested business operators and/or interested parties should submit the information to EFSA through their chosen internet-based software (submission by email is not allowed) with a:

- cover letter that should contain:
    - Reference to the specific call;
    - Reference to the substance(s) concerned, its E number and its EFSA question number;
    - The contact details[7] (name of contact person, name of company/organisation, e-mail address and telephone number) of the person responsible for the data submission and, if applicable, the list of interested business operators and/or interested parties represented and their contact details;

- statement of the submitter that they hold all the necessary rights to grant EFSA permission to use and, where appropriate, to disclose the submitted information, data, document, paper or study for the purposes better defined in this call. In case the submitter does not enjoy the necessary rights for these data or studies, they should share the contact details of the respective owner(s) of data and/or of the relevant intellectual property right, so that EFSA may seek their approval directly.
- separate folders with the confidential and with the non-confidential parts.

Possibility for EFSA to use the data for the safety assessment of the same or other substance under the same or other legal or regulatory frameworks.

In case future mutual interests arise in exchanging any relevant information (i.e. technical or toxicological data) with the Joint WHO – FAO Expert Committee on Food Additives (JECFA) for the re-evaluation of food additives, we would appreciate your written consent for data sharing between EFSA and JECFA on this additive.

Note that EFSA may, where legally possible, use or re-use relevant information or data (i.e. technical, toxicological data) for the evaluation of the same or another substance under the same or a different legal or regulatory framework from the one mentioned above.

Correspondence

Once internet-based software chosen please kindly send the link and login to fip@efsa.europa.eu . As the password must be provided by phone only, you are kindly asked to call the following phone nr +39 0521 036 246 as soon as email sent.

[7] The interested parties shall notify EFSA of any change in the contact details by sending an e-mail to the FIP mailbox (fip@efsa.europa.eu).