

Call for technical data on sweeteners authorised as food additives in the EU

EFSA-Q-number: EFSA-Q-2019-00318

Published: 13/05/2019

Deadline for registering interest: 11/06/2019

Deadline for submission of data: 13/09/2019

Updated deadline: 13/12/2019

Second updated deadline: 28/02/2020

Background

According to Regulation (EC) No 1333/2008¹, 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 Regulation (EU) No 257/2010².

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.

In order to ensure an effective re-evaluation, it is important that EFSA retrieves from interested parties all relevant data for the re-evaluation of the selected food additives. 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regulation (EU) No 257/2010 EFSA launches a public call for data in order to acquire documented information (published, unpublished or newly generated) on sweeteners.

EFSA will consider the relevance of the information provided for the risk assessment of these food additive(s). 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data is to offer to interested parties and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of sweeteners.

Deadline for submission of data and disclosure of contact details

Interested parties and stakeholders should provide by **28/02/2020** the information

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>

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 the information not submitted within the final deadline will only exceptionally be considered and EFSA can finalise its opinions on the basis of the information already provided.

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 has expressed an interest to provide the requested information. If you do not wish to make your contact details available, clearly indicate it in your first communication.

Information sought

EFSA kindly invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit the relevant following information on the characterisation of the particle size of the substance when used as a food additive:

- information on the particle size and the particle size distribution (\pm SD), indicating the percentage of particles (on a particle number basis) in the nano scale (particles with at least one dimension below 100 nm); the indication/description of the methodology used in the particle size analysis should be in line with the "EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health"³ ; information on the methodology used for sample dispersion.

The additional information is sought for the following food additives, currently under re-evaluation:

Additive	E number
Sorbitol	E 420i
Mannitol (by hydrogenation)	E 421i
Mannitol (manufactured by fermentation)	E 421ii
Acesulfame K	E 950
Cyclamic acid	E 952i
Sodium cyclamate	E 952ii
Calcium cyclamate	E 952 iii
Isomalt	E 953
Saccharin	E 954 i
Sodium saccharin	E 954 ii
Calcium saccharin	E 954 iiiii
Potassium saccharin	E 954 iv
Sucralose	E 955
Thaumatococin	E 957

³ EFSA Scientific Committee, 2018. Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. EFSA Journal 2018;16(7):5327, 95 pp. <https://doi.org/10.2903/j.efsa.2018.5327>

Neohesperidine DC	E 959
Neotame	E 961
Salt of aspartame-acesulfame	E 962
Maltitol	E 965i
Lactitol	E 966
Xylitol	E 967
Erythritol	E 968

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 wish to be treated as confidential and provide verifiable justification supporting this request. Note that the information described in article 8(2) of the Regulation (EU) No 257/2010 cannot be confidential.

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 in electronic form (e.g. CD-rom, DVD, etc.) with a

- cover letter that should contain:
 - Reference to the specific call and the specific EFSA question number indicated (EFSA-Q-2019-00318);
 - Reference to the substance concerned and its E number;
 - The contact details⁴ (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

⁴ 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).

for data sharing between EFSA and JECFA on this additive.

Note that EFSA may 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

Please send all electronic correspondence, including enquiries to:
fip@efsa.europa.eu

Submissions should be sent to the following address:

European Food Safety Authority
FIP Unit
Via Carlo Magno 1/a
I-43126 Parma
Italy