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

EFSA-Q-number: EFSA-Q-2017-00500

Published: 21/06/2017
Deadline for registering interest: 21/09/2017
Deadline for submitting data: 30/06/2018

Background

According to 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 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.

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 Regulation (EU) No 257/2010, EFSA launches a public call for data in order to acquire documented information (published, unpublished or newly generated) on technical and toxicological data on sweeteners authorised as food additives in the EU.

EFSA will consider the relevance of the information provided for the risk assessment of these food additives. The submission of the requested information is without prejudice to the final opinion of the ANS 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data is to offer to interested parties and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of sweeteners authorised as food additives in the EU.

Deadline for submission of data and disclosure of contact details

Interested parties and stakeholders should provide by 31/03/2018 the information described below.

Within **3 months** 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 throught e-mail and by updating the current call.

[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

In accordance with Article 6(4) of Commission 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 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 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 information on the following food additives:

Food additive	E Number	EFSA-Q-number
Sorbitol	E 420i	EFSA-Q-2011-00644
Sorbitol syrup	E 420ii	EFSA-Q-2011-00645
Mannitol (by hydrogenation)	E 421i	EFSA-Q-2011-00646
Mannitol (manufactured by fermentation)	E 421ii	EFSA-Q-2011-00647
Acesulfame K	E 950	EFSA-Q-2011-00721
Cyclamic acid	E 952i	EFSA-Q-2011-00733
Sodium cyclamate	E 952ii	EFSA-Q-2011-00734
Calcium cyclamate	E 952iii	EFSA-Q-2011-00735
Isomalt	E 953	EFSA-Q-2011-00723
Saccharin	E 954i	EFSA-Q-2011-00736
Sodium saccharin	E 954ii	EFSA-Q-2011-00737
Calcium saccharin	E 954iii	EFSA-Q-2011-00738
Potassium saccharin	E 954iv	EFSA-Q-2011-00739
Sucralose	E 955	EFSA-Q-2011-00724
Thaumatin	E 957	EFSA-Q-2011-00725
Neohesperidine DC	E 959	EFSA-Q-2011-00726
Neotame	E 961	EFSA-Q-2011-00740
Salt of aspartame-acesulfame	E 962	EFSA-Q-2011-00727
Maltitol	E 965i	EFSA-Q-2017-00490
Maltitol syrup	E 965ii	EFSA-Q-2011-00755
Lactitol	E 966	EFSA-Q-2011-00728
Xylitol	E 967	EFSA-Q-2011-00729
Erythritol	E 968	EFSA-Q-2011-00730

Each of these food additives has different specifications and is produced through different manufacturing processes. As a consequence, EFSA seeks data on the specifications, including information on the impurities, for each substance used as a food additive, supported by the analyses of several batches, indicating the analytical method used (preferably as recommended in the Guidance for submission for food additive evaluations[3]). In particular, the following information is requested for the food additives mentioned above:

- Information on the presence of impurities, as appropriate, including toxic elements, such as arsenic, nickel, lead, mercury or aluminium and their

[3] Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760. [60 pp.] doi:10.2903/j.efsa.2012.2760. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2760/epdf

maximum level present in the food additive.

- Information on microbiological specifications, e.g. the present of microorganisms, mycotoxins and other toxins, where relevant, e.g. mannitol manufactured by fermentation (E 421ii), and their maximum levels present in the food additive.
- Information on the nature and the range of percentage of the different components of the food additive, where relevant, e.g. isomalt (E 953).
- If relevant, information on the characterisation of the particle size of these substances when used as food additives: information on the particle size and the particle size distribution (±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 requirements (EFSA guidance on nanomaterials; EFSA, 20114); information on the methodology of sample dispersion.
- Information on the manufacturing process for each food additive.
- Information on the methods of analysis in food for each food additive.
- Information on the stability of each food additive under the normal condition of storage of the food additive and its fate in food, covering also conditions of processing (e.g high temperature).

Furthermore, the following information on the toxicological properties of the sweeteners mentioned above is requested:

- Toxicokinetics (absorption, distribution, metabolism, excretion).
- Genotoxicity.
- Studies on subchronic and chronic toxicity and carcinogenicity.
- Reproductive and developmental toxicity.
- Special studies aimed at investigating e.g. immunotoxicity, neurotoxicity, hypersensitivity, allergy and intolerance, when relevant.
- Other relevant studies (e.g. human studies, including clinical and epidemiological studies and case-reports).
- Any other information relevant to the safety assessment (e.g. acute toxicity, use in pharmaceuticals).

Submission of information

The requested information should follow to the extent possible, the relevant parts of the Guidance for submission for food additive evaluations[5] and shall be submitted 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-2017-00500);
  - Reference to the substance concerned and its E number;

[4] Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011;9(5):2140 [36 pp.] doi:10.2903/j.efsa.2011.2140. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2140/epdf

[5] http://www.efsa.europa.eu/it/search/doc/2760.pdf

- The contact details[6] (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.

It is recommended that one file should be produced for each section (see Annex 1) and should follow the naming convention as described below. Should a section contain different sub-folders/files, the information shall be submitted separately using a,b,c… for each separate sub-folder/file, i.e. E no_Name of data provider_Section no_a/b/c…

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.

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 these additives.

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.

Submissions should be sent to the following address:

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

[6] 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).

Annex

Naming convention to be used for submission of information

Please create one file for each section applicable and name sub-folders/files using the following identification numbers:

Section 1. Technical data
1.1. Identity and Specifications
1.2. Manufacturing process
1.3. Methods of analysis
1.4. Stability, reaction and fate in food
Section 2. Toxicological data
2.1. Toxicokinetics (ADME)
2.2. Studies on genotoxicity
2.3. Studies on subchronic toxicity
2.4. Studies on chronic toxicity/carcinogenicity
2.5. Studies on reproductive and developmental toxicity
2.6. Special studies (e.g. immunotoxicity, neurotoxicity, hypersensitivity, allergy and intolerance)
2.7. Other relevant studies in humans or animals
2.8. Other complimentary information
Section 3. References

Should a section contain different sub-folders/files, the information shall be submitted separately using a,b,c… for each separate sub-folder/file.

Example: E no_Name of data provider_Section no_a/b/c…