

Call for data on genotoxicity data on maltitol (E 965 i)

Published: 24/01/2023

Deadline for registering interest: 24/02/2023

Deadline for submission of data: 24/07/2023

Background

Pursuant to Article 32(1) of 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 established by Commission 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, 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.

Therefore, in accordance with Article 6(3) of the Regulation (EU) No 257/2010, EFSA is launching a public call for data in order to acquire documented information (published, unpublished or newly generated) on maltitols (E 965).

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, *inter alia*, to the final opinion of the FAF Panel.

Overall objective

The purpose of this call for data is to offer interested parties and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of maltitols.

Deadline for submission of data and disclosure of contact details

Interested parties and stakeholders should provide by **24/07/2023** the information described below.

¹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008. Available here:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333>

² Commission Regulation (EU) No 257/2010 of 25 March 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. Available here: <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-authorized-food-additives-eu>

Within **4 weeks** from the publication of this call, please communicate in writing by e-mail to: ral@efsa.europa.eu, your availability/interest 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 via 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 business operators and interested parties to provide the data needed, we are seeking your consent to disclose contact details 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 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 additive:

Q-Numbers	Additive	E number
EFSA-Q-2017-00490	Maltitol	E 965 i

1. Data on toxicology: genotoxicity

Current EFSA guidance on genotoxicity testing in food and feed safety assessment (EFSA SC, 2011⁵), also applicable to the safety evaluation of food additives (EFSA SC, 2017⁶), recommends a core set of in vitro tests for the detection of three important genetic endpoints: gene mutation, structural chromosomal aberrations (i.e. clastogenicity) and numerical chromosome aberrations (i.e. aneugenicity). A preliminary assessment was conducted by the WG Sweeteners of the FAF Panel to establish whether the available genotoxicity data for each substance would be considered sufficient to progress with the overall safety assessment and to reach a conclusion, or whether the need for additional information was identified. This preliminary assessment did not highlight the need for additional data to be generated for this food additive, therefore maltitols (E 965) was not among the food additives included in the latest call for data on genotoxicity⁷.

However, a substantial proportion of the genotoxicity studies available for the food additives under re-evaluation were completed prior to the provision of the current OECD test guidelines, thus resulting in limitations for several of the current assessments. This also applies to maltitols, and following a full assessment of the reliability and relevance of the available genotoxicity studies, performed according to the criteria stipulated in the protocol on hazard identification and characterisation of the sweeteners⁸, the need for additional genotoxicity data of maltitols (E 965 i,ii) has been identified.

⁵ EFSA Scientific Committee; Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011; 9(9):2379. [69 pp.] <https://doi:10.2903/j.efsa.2011.2379>

⁶ EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, M, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Silano, V, Solecki, R, Turck, D, Younes, M, Aquilina, G, Crebelli, R, Gürtler, R, Hirsch-Ernst, KI, Mosesso, P, Nielsen, E, van Benthem, J, Carfi, M, Georgiadis, N, Maurici, D, Parra Morte, J and Schlatter, J, 2017. Scientific Opinion on the clarification of some aspects related to genotoxicity assessment. EFSA Journal 2017;15(12):5113, 25 pp. <https://doi.org/10.2903/j.efsa.2017.5113>

⁷ <https://www.efsa.europa.eu/en/call/call-data-genotoxicity-data-sweeteners>

⁸ <https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fsp.efsa.2020.EN->

In particular, the lack of a fully reliable in vitro micronucleus test, as requested by EFSA guidance for submission for food additive evaluations (EFSA, 2012), was noted. This data gap was not covered by the available in vivo studies (micronucleus or chromosome aberration assays), which were evaluated by the Sweeteners WG as inconclusive according to the OECD TGs 474 (2014) and 475 (2014) due to the lack of demonstration of exposure of the target cells to the test chemical.

Therefore an in vitro micronucleus test on maltitol (E 965 i), performed following the more recent version of the relevant OECD guideline (TG 487) is requested to complete the assessment. In the event of a negative response in this assay, the assessment will be completed and maltitols considered not genotoxic. Whereas, in the event of positive results, an in vivo follow-up would be needed in accordance with the 2011 EFSA SC Guidance on genotoxicity and the Scientific Committee Guidance on aneugenicity (EFSA, 2021). This would require the preliminary characterization of micronuclei by CREST/FISH techniques.

Confidentiality

In accordance with Article 8 of Regulation (EU) No 257/2010, in the version of the text in force prior to 27 March 2021, 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, data providers should indicate any 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, in the version of the text in force prior to 27 March 2021, cannot be regarded as confidential in any circumstances.

In application of Article 8(4) of Regulation (EU) 257/2010, , in the version of the text in force prior to 27 March 2021, 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 and its E numbers and its EFSA question number;
 - The contact details⁹ (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 such rights for the submitted subject matter, they should share the contact details of the respective owner(s) of data and/or the holder(s) of any relevant intellectual property rights, 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.

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⁹ The interested parties shall notify EFSA of any change in the contact details by sending an e-mail to the FIP mailbox (ral@efsa.europa.eu).



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

Please 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 RAL@efsa.europa.eu. You may provide the password by phone, if so, you are kindly asked to call the following phone nr +39 0521 036 246 as soon as email with the links is sent. Alternatively, it can be sent in a separate email to RAL@efsa.europa.eu.