

EUROPEAN FOOD SAFETY AUTHORITY

Call for scientific data on Aspartame (E 951)

Published: 1 June 2011

Deadline: 30 September 2011

Background

According to Article 32 of Regulation (EC) No 1333/2008¹, all food additives permitted 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 approved food additives was set up by Commission Regulation (EU) No 257/2010², which foresees in its Article 3(c) that the re-evaluation of all approved sweeteners listed in Directive 94/35/EC³, including aspartame, shall be completed by 31 December 2020.

However, on 4 May 2011 the European Commission has asked EFSA to perform the re-evaluation of the safety on Aspartame (E951) as a food additive by 31 July 2012.

In order to ensure an effective re-evaluation of Aspartame (E951), it is important that EFSA acquires from interested parties all necessary data (published, unpublished or newly generated).

Overall objective

The purpose of this call for data is to offer interested parties and/or all stakeholders the opportunity to submit any available documented information, published or unpublished, including also original raw data on Aspartame (E951).

Information sought

The information of interest to EFSA consists in any scientific or technical data that could contribute to the safety assessment of this food additive. The Guidance on submission for food additive evaluations adopted in 2001 by the Scientific Committee on Food⁴ and endorsed by the EFSA Scientific Panel on Food additives and Nutrient Sources added to food in July 2008 provides further information on the type and nature of the information that is of interest to EFSA.

Process of the call for data

The submissions of data will be done in a 2-step process and should be as comprehensive as possible:

Step 1: Registration of the contact details of the interested party and description of the available information

The interested parties should provide EFSA with a **description of available information** (i.e. documents, type of data, reports etc) for the food additive under consideration as well as their **contact details** (name of contact person, name of company, email address and telephone number). This inventory of available data should, as far as possible, be made

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, p. 16-33

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 of the European Parliament and of the Council on food additives. OJ L 90, 26.03.2010, p 19-27

³ European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. OJ L 237, 10.09.1994 p. 0003 - 0012

⁴ SCF 2001 Guidance on submissions for food additive evaluations by the Scientific Committee on Food.: SCF/CS/ADD/GEN/26 Final. 12 July 2001: http://ec.europa.eu/food/fs/sc/scf/out98_en.pdf

according to the structure of the currently applicable guidance document on food additives (SCF 2001 Guidance on submissions for food additive evaluations⁴).

This information needs to be submitted electronically to the following e-mail address foodadditives@efsa.europa.eu, stating clearly in the subject line "aspartame – public call for data" at the latest by **30 September 2011**.

Step 2⁵: Submission to EFSA of the data selected by EFSA

Following the receipt and screening of the submissions, EFSA will request hard and/or electronic copies of selected documents only. Timely receipt of such information is important in ensuring a comprehensive science-based evaluation can be undertaken for the re-evaluation of these additives. Therefore the submission of the selected data should take place **within 20 working days** following EFSA's request. However, please note that this request by EFSA will not necessarily take place immediately after the receipt of the description of the available information (done during step 1) and will usually be made after consultation with the information holder.

N.B.: In case additional documents/data would become available after the deadline defined for the step 1 of this call for data, the interested parties should inform EFSA before 30.09.2011 at the latest. This information needs to be submitted electronically, to the e-mail address: foodadditives@efsa.europa.eu

The interested parties are invited to contact EFSA for further clarification if required.

Confidentiality and unpublished data

Specific issues relating to confidentiality of the data provided will be discussed between the owners of the data and EFSA. In application of Article 8.4 of Regulation 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 and shall notify EFSA and the Member States accordingly.

Correspondence

Please forward all electronic correspondence, including enquiries to the following e-mail address: foodadditives@efsa.europa.eu

Hard copies can also be sent to the address below:

ANS Unit, Food Additives
European Food Safety Authority
Largo N. Palli 5/A
43121 Parma
Italy

⁵ No general deadline is defined for step 2 as step 2 will take place at different points in time following the selection by EFSA of the relevant data.