

EUROPEAN FOOD SAFETY AUTHORITY

Call for scientific data on miscellaneous food additives permitted in the EU and belonging to several functional classes

Published: 9 June 2010 – modified on 16 June 2010¹

Deadline²: 9 December 2010

Background

According to Article 32 of Regulation (EC) No 1333/2008³, all food additives permitted before 20 January 2009 should be subject to a new risk assessment by EFSA. The programme for the re-evaluation of approved food additives has been set up by Commission Regulation (EU) No 257/2010⁴. In order to ensure an effective re-evaluation, it is important that EFSA acquires from the interested parties all data (published or unpublished) relevant to the re-evaluation of the selected miscellaneous food additives. These data will be considered for the EFSA opinions/statements on the food additives to be re-evaluated in the coming years in accordance with the priorities and deadlines set in the Regulation³.

The miscellaneous food additives to be re-evaluated (see tables in [Annex](#)) have been selected in line with the priorities defined by the Commission Regulation (EU) 257/2010, and based on their technological function, can be grouped as follows:

- a) [Preservatives and antioxidants](#)
- b) [Flavour enhancers](#)
- c) [Acidity regulators](#)
- d) [Emulsifiers, stabilisers, gelling agents and anti-caking agents.](#)

In preparation for their re-evaluation and in the absence of new application dossiers, existing information on the selected miscellaneous food additives needs to be collected, collated and summarised.

Overall objective

The purpose of this call for data is to offer all interested parties and stakeholders the opportunity to submit any available documented information, published or unpublished, relevant to the specific areas indicated below.

Information sought

EFSA kindly ask governments, interested organisations, universities, research institutions, companies and other interested parties to submit information on food additives relevant to the specific areas indicated below.

- Present use patterns (intake, actual use levels (typical and maximum) and exceptions to these levels), and, if available, corresponding exposure assessments;
- Purity of miscellaneous additives presently in use, including particle size and particle size distribution when relevant;
- Production methods;
- Analytical methods available for determination in food;
- Toxicokinetics and toxicity (subchronic toxicity, genotoxicity, chronic toxicity and carcinogenicity, reproduction and developmental toxicity, allergenicity etc.) and any information relevant to their safety assessment.

¹ The food additives already addressed in the public call for data published in November 2009 (emulsifiers, stabilisers and gelling agents) have been removed. Cf. <http://www.efsa.europa.eu/en/dataclosed/call/ans091123.htm>

² The deadline is defined for step 1 (registration of the contact details and description of the information available). 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.

³ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

⁴ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives.

N.B.: EFSA is interested to receive all the original study reports previously evaluated by the SCF and JECFA as well as scientific papers and original study reports not previously considered in SCF and JECFA evaluations.

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 each particular food additive or given group of food additives (as predefined by EFSA, shown in the [Annex](#)) 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 according to the structure of the currently applicable guidance document on food additives (SCF 2001 Guidance on submissions for food additive evaluations⁵).

This information needs to be submitted electronically to the following e-mail address foodadditives@efsa.europa.eu, stating clearly in the subject line the food additive or group of food additives it refers to.

Step 2⁶: Submission to EFSA of the data selected by EFSA

Following the receipt and screening of all 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 will 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 will be able to inform EFSA before 31.12.2012 at the latest. This information needs to be submitted electronically, to the e-mail address: foodadditives@efsa.europa.eu

Confidentiality and unpublished data

Specific issues relating to confidentiality of the data provided should be discussed between the owners and EFSA. In application of the 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.

Contact details

All electronic correspondence, including enquiries, should be sent to: foodadditives@efsa.europa.eu

⁵ 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

⁶ 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.

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

ANNEX

A selection of miscellaneous food additives permitted in the EU

a) Preservatives & Antioxidants	
E number	Name
E512	Stannous chloride
E586	4-Hexylresorcinol

b) Flavour Enhancers	
E number	Name
E620	Glutamic acid
E621	Monosodium glutamate
E622	Monopotassium glutamate
E623	Calcium diglutamate
E624	Monoammonium glutamate
E625	Magnesium diglutamate
E626	Guanylic acid
E627	Disodium guanylate
E628	Dipotassium guanylate
E629	Calcium guanylate
E630	Inosinic acid
E631	Disodium inosinate
E632	Dipotassium inosinate
E633	Calcium inosinate
E634	Calcium 54-ribonucleotides
E635	Disodium 54-ribonucleotides

c) Acids and Acidity regulators	
E number	Name
E290	Carbon dioxide
E297	Fumaric acid
E270	Lactic acid
E325	Sodium lactate
E326	Potassium lactate
E327	Calcium lactate
E330	Citric acid
E331(i)	Monosodium citrate
E331(ii)	Disodium citrate
E331(iii)	Trisodium citrate
E332(i)	Monopotassium citrate
E332(ii)	Tripotassium citrate
E333(i)	Monocalcium citrate
E333(ii)	Dicalcium citrate
E333(iii)	Tricalcium citrate
E380	Triammonium citrate

c) Acids and Acidity regulators	
E number	Name
E334	Tartaric acid (L(+)-)
E335(i)	Monosodium tartrate
E335(ii)	Disodium tartrate
E336(i)	Monopotassium tartrate
E336(ii)	Dipotassium tartrate
E337	Sodium potassium tartrate
E353	Metatartaric acid
E354	Calcium tartrate
E296	Malic acid
E350(i)	Sodium malate
E350(ii)	Sodium hydrogen malate
E351	Potassium malate
E352(i)	Calcium malate
E352(ii)	Calcium hydrogen malate
E355	Adipic acid
E356	Sodium adipate
E357	Potassium adipate

d) Emulsifiers, stabilisers, gelling agents and anti-caking agents	
E number	Name
E422	Glycerol
E431	Polyoxyethylene (40) stearate
E551	Silicon dioxide
E1404	Oxidised starch
E1410	Monostarch phosphate
E1412	Distarch phosphate
E1413	Phosphated distarch phosphate
E1414	Acetylated distarch phosphate
E1420	Acetylated starch
E1422	Acetylated distarch adipate
E1440	Hydroxy propyl starch
E1442	Hydroxy propyl distarch phosphate
E1450	Starch sodium octenyl succinate
E1451	Acetylated oxidised starch
E1452	Starch aluminium Octenyl succinate

