EUROPEAN FOOD SAFETY AUTHORITY

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

Published: **15 February 2012**
Deadline: **15 August 2012**

Background

According to Article 32 of Regulation (EC) No 1333/2008 on food additives[1], all food additives permitted in the EU before 20 January 2009 will be subject to a new risk assessment by EFSA. The programme for the re-evaluation of EU permitted food additives has been set up by Commission Regulation (EU) No 257/2010[2]. In order to ensure an effective re-evaluation, it is important that EFSA acquires from interested parties all relevant data (published or unpublished) for the re-evaluation of the selected miscellaneous food additives. These data will be considered for the EFSA Opinions/Statements on the food additives which will be issued in the coming years.

The miscellaneous food additives included in this call for scientific data (see **Annex 1**) have been selected in line with the priorities defined in Commission Regulation (EU) 257/2010. Based on their main technological function, they can be grouped as follows:

a) Acidity regulators
b) Anti-caking agents
c) Firming agents
d) Encapsulating agent
e) Foaming agent

In preparation for the re-evaluation of the food additives listed in Annex 1, and in the absence of new application dossiers, existing information on these food additives needs to be collected.

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all interested parties and stakeholders the opportunity to submit any available documented information (published or unpublished), relevant to the specific areas indicated in the following section.

Information sought

National food authorities, research institutions, academia, food business operators, and other stakeholders are invited to submit information on the selected food additives relevant to the specific areas indicated below.

- Specifications for the finished food additive (e.g. purity and particle size and particle size distribution where appropriate);
- Information on the manufacturing process, including purification and preparation of the product to be commercialised and analytical/production controls, relevant to their use as food additives;
- Analytical methods available for determination of the food additive in food and beverages;

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

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

- Toxicokinetic and toxicity data (acute, subchronic and chronic toxicity; carcinogenicity; genotoxicity; reproduction and developmental toxicity; allergenicity, etc.) and any other information relevant to their safety assessment.

EFSA is interested to receive all the original study reports previously evaluated by the Scientific Committee on Food (SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as well as scientific papers and original study reports not previously considered in SCF and JECFA evaluations.

N.B.: This call does not cover the following areas for which another call for data will be made separately: information on human exposure to the food additives from food, i.e. intake levels, occurrence data (i.e. actual typical and maximum use levels per food category[3]), other factors influencing exposure and, if available, corresponding exposure assessments.

Process of the call for data

Interested parties should submit the information electronically to EFSA on a physical media (e.g. CD, DVD, etc.), with a cover letter stating clearly in the subject the food additive or group of food additives to which it refers. All information should be submitted by **15 August 2012** at the latest.

The cover letter should also contain the **contact details** (name of contact person, name of company, email address and telephone number) of the person responsible for the data submission.

The letter should specify the rights of the provider on the data submitted (especially the right to disclose them to third parties). In case the submitter does not have the rights for these data, the contact details of the respective data owner(s) should also be provided in order to enable EFSA to seek their approval directly.

Interested parties are invited to contact EFSA for further clarification, if required.

Confidentiality and unpublished data

The provider should also specify clearly in the letter any data that should remain confidential (i.e. not to be disclosed to the public) and submit appropriate verifiable justification for this claim. Specific issues relating to confidentiality of the data provided should be discussed between the data providers/owners and EFSA. In application of Article 8.4 of Regulation 257/2010, following a proposal from EFSA, the Commission will decide, after consulting the data providers/owners and/or the other interested parties, which information may remain confidential and will notify EFSA and the Member States accordingly.

Possibility to share data with FDA or JECFA

In anticipation of cases where mutual interests are identified in exchanging any relevant information (i.e. technical, toxicological data) with the U.S. Food and Drug Administration (FDA) or Joint FAO/WHO Expert Committee on Food Additives (JECFA) for the re-evaluation of food additives, **please state whether you give EFSA the permission to share the data provided with the FDA or JECFA.**

[3] As defined in the Annex II, Part D of Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives.

Please note that protection of confidential information exchanged with FDA falls under the applicable legal frameworks in both the US and the EU, as outlined in the statements on confidentiality agreement made between EFSA and FDA[4]. Regarding JECFA, unpublished confidential studies are used for evaluation purposes and only summarised information is included in specifications and/or toxicological monographs, published by the FAO and WHO after the meetings.

Additional data becoming available after 15 August 2012

N.B.: Should additional documents/data become available after **15 August 2012**, the interested parties should inform EFSA before **31.12.2013** at the latest. This information should be submitted electronically to the e-mail address: **foodadditives@efsa.europa.eu**

Contact details

Submissions should be sent to the following address:

Food Ingredients and Packaging Unit, Food Additives

European Food Safety Authority

Via Carlo Magno 1/a
43126 Parma
Italy

All electronic correspondence should be sent to: **foodadditives@efsa.europa.eu**

[4] Cooperation with the United States (http://www.efsa.europa.eu/en/networks/international.htm)

ANNEX 1: Selected EU permitted miscellaneous food additives

Acidity regulators	
E number	**Name**
E 450 (i, ii, iii, v, vi, vii)	Diphosphates
E 451 (i, ii)	Triphosphates
E 452 (i, ii, iii, iv)	Polyphosphates
E 339 (i, ii, iii)	Sodium phosphates
E 340 (i, ii, iii)	Potassium phosphates
E 338	Phosphoric acid
E 341 (i, ii, iii)	Calcium phosphates
E 343 (i, ii)	Magnesium phosphates
E 513	Sulphuric acid
E 514 (i, ii)	Sodium sulphates
E 515 (i, ii)	Potassium sulphates
E 516	Calcium sulphate
E517	Ammonium sulphate
E 640	Glycine and its sodium salt, Aminoacetic acid
E 260	Acetic acid, ethanoic acid
E 261	Potassium acetate
E 262 (i, ii)	Sodium acetates
E 263	Calcium acetate
E 650	Zinc acetate

Anticaking agents	
E number	**Name**
E 552	Calcium silicate
E 553a	Magnesium silicate
E 553b	Talc
E 900	Dimethyl polysiloxane, Siloxanes and silicone, di-methyl

Firming agents	
E number	**Name**
E 507	Hydrochloric acid
E 508	Potassium chloride
E 509	Calcium chloride
E 511	Magnesium chloride

Encapsulating agent	
E number	**Name**
E 459	Beta-cyclodextrin

Foaming agent	
E number	**Name**
E 999	Quillaia extract