EUROPEAN FOOD SAFETY AUTHORITY

Call for scientific data on Indigo Carmine (E 132)

Published: 26 January 2011
Deadline: 30 September 2011

Background
According to Article 32 of Regulation (EC) No 1333/2008, 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 has been set up by Commission Regulation (EU) No 257/2010.

Indigo Carmine (E132) is included into the programme for re-evaluation of food additives. In order to ensure an effective re-evaluation of Indigo Carmine (E 132), it is important that EFSA acquires from interested parties all necessary data (published, unpublished or newly generated).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 specific set of data is to offer all interested parties and stakeholders the opportunity to submit the data on Indigo Carmine (E 132) as identified by the ANS Panel and outlined below in accordance with the Guidance on submission of food additive evaluations by the Scientific Committee on Food (published).

Information sought
EFSA kindly asks governments, interested organisations, universities, research institutions, companies and other interested parties to submit the following information and data on Indigo Carmine (E 132):

1. An in vivo bone marrow micronucleus test with Indigo Carmine (E 132) in rodents performed according to the OECD Guideline for the Testing of Chemicals No. 474 and according to the principles of Good Laboratory Practice (GLP) described in Directives 2004/9/EC and 2004/10/EC and accompanied by a statement of GLP compliance.

Process of the call for data
The above information needs to be submitted electronically to EFSA by 30 September 2011. 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Confidentiality and unpublished data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 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

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Please forward all electronic correspondence, including enquiries to the following e-mail address:
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**Hard copies can also be sent to the address below:**
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