EUROPEAN FOOD SAFETY AUTHORITY

Call for scientific data on Patent Blue V (E 131)

Published: 6 June 2011
Deadline: 1 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 of 25 March 2010.

In order to ensure an effective re-evaluation of Patent Blue V (E 131), it is important that EFSA acquires from interested parties all data on genotoxicity that are needed for the ongoing safety assessment (re-evaluation of the food colour Patent Blue V (E 131). These data might be already existing (published or unpublished) or might need to be newly generated.

Overall objective
The purpose of this call for genotoxicity data is to offer all interested parties and stakeholders the opportunity to generate the sought data on Patent Blue V (E 131) through new studies and provide them to EFSA, as outlined below in accordance with the Guidance on submission of food additive evaluations by the Scientific Committee on Food.

Interested parties and stakeholders should submit the requested data on genotoxicity or provide information that they have commissioned the studies before 1 September 2011. If the necessary genotoxicity data have not been made available and genotoxicity studies have been commissioned and new genotoxicity data will be generated, EFSA will set a new deadline for the submission of these data which will be communicated to the parties commissioning the studies and published on EFSA’s website.

In case neither the necessary genotoxicity data nor a commitment to generate and provide the sought genotoxicity data through new studies will have been provided to EFSA by 1 September 2011, EFSA will base its evaluation of the safety of Patent Blue V (E 131), when used as a food colouring substance on the information available.

Information sought
EFSA kindly asks governments, interested organisations, universities, research institutions, companies and other interested parties to submit genotoxicity data as mentioned below on Patent Blue V (E 131). The request for genotoxicity data is made in accordance with the Guidance on submission of food additive evaluations by the Scientific Committee on Food and considering the Draft Scientific Opinion on Genotoxicity Testing Strategies applicable in food and feed safety assessment which was recently endorsed by the Scientific Committee for public consultation.

- Further assessment of genotoxicity in vivo. Any of the following tests may be conducted: (1) an in vivo Comet assay with oral administration and analysis of at least liver, gastrointestinal and blood cells; (2) a transgenic rodent assay (draft OECD TG) with oral administration.

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5 (no OECD TG at present; internationally agreed protocols available, e.g. see: http://cometassay.com)
In case of positive results showing genotoxic effects in vivo, interested parties and stakeholders might consider to test a product with a purity higher to that mentioned in the current EU specification (“Content not less than 85% total colouring matters, calculated as the sodium salt”) on a battery of genotoxicity tests as described in the Draft Scientific Opinion on Genotoxicity Testing Strategies. In case of absence of genotoxicity interested parties and stakeholders are invited to propose new criteria for purity which might be considered when the current specification is revised.

The content of Patent Blue V (E 131) in the test preparation should be clearly specified. It should also be indicated whether the material tested is in accordance with the specifications for Patent Blue V (E 131) as defined in Directive 2008/128/EC. The tests should be carried out 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 data on genotoxicity needs to be submitted electronically by **1 September 2011** at the latest.

In case genotoxicity studies have been commissioned and new genotoxicity data will be generated EFSA needs to be informed by **1 September 2011** at the latest. Based on the timeframe of the commissioned studies on genotoxicity EFSA the new deadline for submission of these data will be communicated to the parties commissioning the studies and generating the data and published on EFSA’s website.

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 should 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**
Please send all electronic correspondence, including enquiries to: **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
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