Subject: Request for a scientific opinion on new data on the safety of Vitamin B2 (80%) as riboflavin produced by Bacillus subtilis for all animal species, based on a dossier submitted by VITAC EEIG

Ref: FAD-2010-0049 / SANTE-2010-0032

Dear Ms Lheureux,

I refer to the scientific opinion on the safety and efficacy of Vitamin B2 (80%) as riboflavin produced by Bacillus subtilis for all animal species, based on a dossier submitted by VITAC EEIG, application of 28 June 2010 for an authorisation under Regulation (EC) No 1831/2003 of Vitamin B2 (80%) as riboflavin produced by Bacillus subtilis for all animal species. The opinion was adopted on 4 December 2013.

We have been informed by the Community Reference Laboratory on Feed additives that, in the context of the official controls, one German official laboratory had analysed the reference samples stored in the Community Reference Laboratory of Feed additives. The samples analysed correspond to all the vitamin B2 dossiers that were under re-evaluation procedure by Article 10(2) to Regulation 1831/2003 on feed additives. The laboratory found recombinant DNA in the sample of VITAC EEIG. The other samples were clean. A report with detailed information is enclosed to this letter.

The applicant indicated in the dossier that the additive did not contain recombinant DNA from the production strain that was genetically modified, while the analysis performed demonstrated the presence of this recombinant DNA, therefore, non-compliance has been identified. The information provided by the applicant is not correct as recombinant DNA is present in the additive.

The EFSA assessment was based on the presumption, according to the information provided by the applicant, that the additive was free of recombinant DNA.

Ms Karine Lheureux  
European Food Safety Authority  
Via Carlo Magno 1°  
43126 Parma  
ITALY


Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIÉ - Tel. +32 22991111
In accordance with Article 29(1) to Regulation (EC) 178/2002 of the European Parliament and of the Council laying down principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures and matters of food safety, I would like to request a new opinion on this additive (FAD-2010-0049) that takes into account this new information indicating the presence of recombinant DNA in the feed additive.

Yours sincerely

[Signature]

[Name]
[Position]

Enclosures: Request for a scientific opinion on new data on the safety of Vitamin B2 (80%') as riboflavin produced by Bacillus subtilis for all animal species, based on a dossier submitted by VITAC EEIG Report with detailed information

Copy: Ms Tiramani
Mr Christoph von Holst
Annex

Request for a scientific opinion on new data on the safety of Vitamin B2 (80 %) as riboflavin produced by Bacillus subtilis for all animal species, based on a dossier submitted by VITAC EEIG

1. Background

Regulation (EC) No 1831/2003 establishes rules governing the Community authorisation of additives for animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, VITAC EEIG, is seeking a Community authorisation of Vitamin B2 (80 %) as riboflavin produced by Bacillus subtilis for all animal species, as a nutritional additive. (Table 1)

Table 1 Description of the substance

<table>
<thead>
<tr>
<th>Category of additive</th>
<th>Nutritional additive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional group of additive</td>
<td>vitamins, pro-vitamins and chemically well-defined substances having similar effect</td>
</tr>
<tr>
<td>Description</td>
<td>Vitamin B2 (80 %) as riboflavin produced by Bacillus subtilis,</td>
</tr>
<tr>
<td>Target animal category</td>
<td>for all animal species</td>
</tr>
<tr>
<td>Applicant</td>
<td>VITAC EEIG</td>
</tr>
<tr>
<td>Type of request</td>
<td>New opinion</td>
</tr>
</tbody>
</table>

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The applicant indicated in the dossier that the additive did not contain recombinant DNA from the production strain that was genetically modified, while the analysis performed demonstrated the presence of this recombinant DNA. Therefore, non-compliance has been identified. The information provided by the applicant is not correct as recombinant DNA is present in the additive.

These new facts that come into knowledge would impact the assessment of this product as EFSA has based its opinion on the information provided by the applicant and on the assumption that the additive is free from recombinant DNA, in accordance with the information provided by the applicant.

2. Terms of reference

In view of the above, the Commission asks the Authority to deliver a new opinion on the safety of Vitamin B2 (80 %) as riboflavin produced by Bacillus subtilis based on the new data indicating the presence of recombinant DNA.