EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Animal nutrition, veterinary medicines

Brussels,
SANTE/AR/ng/ddg2.e.5(2016)4561931

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 B_2 (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 B_2 (80'%) as riboflavin produced by *Bacillus subtilis* for all animal species. The opinion was adopted on 4 December 2013[1].

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 B_2 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

[1] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3531.pdf

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

p.o. Stefano Soro
Head of Unit

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 B_2 (80 %) as riboflavin produced by Bacillus subtilis for all animal species, as a nutritional additive. (Table 1)

Table 1 Description of the substance

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

The Community Reference Laboratory on Feed additives informed the Commission 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 corresponded to all the vitamin B_2 dossiers that were under re-evaluation procedure by Article 10(2) to Regulation 1831/2003 on feed additives. The laboratory found recombinant DNA from the production strain in the sample of VITAC EEIG. The other samples were clean.

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 B_2 (80 %) as riboflavin produced by Bacillus subtilis based on the new data indicating the presence of recombinant DNA.