Commission Implementing Regulation (EU) 2018/1254 of 19 September 2018 concerning the denial of authorisation of riboflavin (80 %) produced by Bacillus subtilis KCCM-10445 as a feed additive belonging to the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1254

of 19 September 2018

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Riboflavin (vitamin B2) was authorised without a time limit by Directive 70/524/EEC as a feed additive belonging to the group of vitamins, pro-vitamins and chemically well-defined substances having similar effect, for all animal species. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of riboflavin, with a purity of minimum 80 %, produced by the genetically modified strain *Bacillus subtilis* KCCM-10445, as a feed additive for all animal species. The applicant requested that the additive be classified in the additive category ‘nutritional additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) In 2010, in accordance with Article 7(3)(f) of Regulation (EC) No 1831/2003 and Article 3 of Commission Regulation (EC) No 378/2005[(3)], the applicant sent samples of the feed additive, in a form in which the feed additive was intended to be placed on the market, to the Reference Laboratory under Regulation (EC) No 1831/2003 (‘the

Reference Laboratory'). In 2013, in accordance with Article 3(3) of Regulation (EC) No 378/2005, the applicant supplied the Reference Laboratory with new samples to replace those expired.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 December 2013[4] that neither the production strain nor its recombinant DNA ('rDNA') was detected in the final product having regard to the information provided by the applicant and that therefore, the final product did not raise any safety concern with regard to the genetic modification of the production strain. It was also concluded that the additive did not have an adverse effect on animal health, human health or the environment.

(6) However, the Commission was informed by the Reference Laboratory that, in the context of an official control performed by a national competent authority, the presence of viable cells and of rDNA from the production strain was detected in some reference samples of the additive by a national laboratory competent for official controls. Those reference samples consisted of a first set submitted to the Reference Laboratory in 2010 together with the application for authorisation and an updated set submitted to the Reference Laboratory in 2013. Such detection resulted from the use of a polymerase chain reaction ('PCR') analysis method developed by a national laboratory competent for official controls in accordance with Article 11(2) of Regulation (EC) No 882/2004 of the European Parliament and of the Council[5].

(7) The Commission and the Reference Laboratory informed the applicant on those findings and gave him the opportunity to provide a suitable method of analysis both for the detection of rDNA and for the presence of viable cells from the production strain in order to proceed to further analysis of various samples of the additive. For that purpose, the applicant requested several laboratories, established both in China and in a Member State, to perform new analyses of the samples. The results of those analyses were negative as regards the detection of both rDNA and viable cells from the specific production strain. However, it appeared that the new analyses carried out by the applicant did not concern the samples submitted in 2010 to the Reference Laboratory.

(8) In parallel, at the request of the Commission and the Reference Laboratory, further analyses of the samples of the additive were carried out by a national laboratory competent for official controls. On its basis, it was concluded that viable cells from the production strain were present in the samples of 2010 and that rDNA from the production strain was present in the samples of 2010 and 2013. That laboratory sent samples to another national laboratory competent for official controls for further analysis, which confirmed the presence of rDNA from the production strain in the samples of 2010 and 2013. Those results were obtained through the use of a PCR analysis method developed by a national laboratory competent for official controls in accordance with Article 11(2) of Regulation (EC) No 882/2004.

(9) In 2015, in order to resolve the divergence of results, it was agreed between the Commission and the Reference Laboratory on one hand and the applicant on the other hand that each of them would request an independent laboratory accredited for a PCR method to perform further analysis of the additive. For that purpose, the samples of

2010 and 2013 would be used and the applicant was invited to provide, among others, samples in the form in which the additive was placed on the market at that time. It was agreed that both the analytical methods used by the applicant and by the national laboratories competent for official controls would be shared and used.

(10) However, the applicant subsequently refused to have the samples submitted in 2010 and 2013 analysed and to provide samples corresponding to the additive placed on the market in 2015. The applicant refused to further cooperate with the Commission and the Reference Laboratory as long as a 'unified analysis standard' method for the detection of rDNA in riboflavin was not established under Union legislation.

(11) Under Regulation (EC) No 1831/2003, the burden is on the applicant to adequately and sufficiently demonstrate that the additive satisfies the conditions for authorisation laid down in that Regulation, its implementing measures[(6)] and applicable Authority's guidance[(7)], in particular through the submission of relevant samples of the additive, all information related to the genetic modification of the production strain, the PCR-based method used, the protocol for extraction of the DNA and other relevant data allowing the Authority to determine the absence of rDNA or viable cells from the production strain.

(12) On the basis of those data indicating the presence of viable cells and rDNA from the production strain in the additive, in August 2016 the Commission requested the Authority to deliver a new opinion on the safety of riboflavin (80 %) produced by the genetically modified strain *Bacillus subtilis* KCCM-10445 as a feed additive for all animal species.

(13) In order to undertake its assessment, the Authority requested the applicant to provide supplementary information and data, related in particular to the method of analysis for the detection of the presence of viable cells of the production strain in the additive. Such supplementary information and data was submitted by the applicant. The Authority also requested the Reference Laboratory to provide further information and data concerning the analyses performed by the national laboratories competent for official controls, which was also furnished.

(14) The Authority concluded in its opinion of 7 March 2018[(8)] that the new data provided by the national laboratory competent for official controls show that reference samples of the additive contain viable cells and/or DNA from the production strain. The production strain *Bacillus subtilis* KCCM-10445 carries four antimicrobial resistance genes, three of them introduced by genetic modifications. Therefore, the Authority concluded that the additive poses a risk for the target species, consumers, users and the environment due to the potential for the spread of viable cells and DNA of a genetically modified strain-harbouring genes coding for resistance to antimicrobials of human and veterinary importance.

(15) Consequently, it has not been established that riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 does not have an adverse effect on animal health, human health or the environment, when used as a feed additive belonging to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'.