COMMISSION IMPLEMENTING REGULATION (EU) 2023/651

of 20 March 2023

concerning the authorisation of riboflavin (vitamin B_2) produced by *Bacillus subtilis* KCCM 10445 and a preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 as feed additives for all animal species

(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 such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of riboflavin 98 % (vitamin B_2) produced by *Bacillus subtilis* KCCM 10445 and of a preparation of riboflavin 80 % produced by *Bacillus subtilis* KCCM 10445. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of riboflavin produced by *Bacillus subtilis* KCCM 10445 and of a preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 as feed additives for all animal species, to be classified in the category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 5 May 2021 ([2]) and of 27 September 2022 ([3]) that, under the proposed conditions of use, riboflavin (98 %) produced by *Bacillus subtilis* KCCM 10445 and the preparation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM 10445 do not have adverse effects on animal health, consumer safety or the environment. It further concluded that the preparation of riboflavin is not hazardous by inhalation. In the absence of data, no conclusions on the possible risk by inhalation of riboflavin produced by *Bacillus subtilis* KCCM 10445 can be reached. Neither riboflavin nor the preparation of riboflavin are irritant to skin or eyes. In addition, in the absence of data, no conclusions on the skin sensitisation potential of riboflavin produced by *Bacillus subtilis* KCCM 10445 and of the preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 can be reached.

(5) The Authority concluded that riboflavin produced by *Bacillus subtilis* KCCM 10445 and the preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 are an effective source in covering the nutritional needs of animals when administered via feed and/or water for drinking. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) An authorisation of riboflavin with a purity of minimum 80 % produced by *Bacillus subtilis* KCCM 10445 was previously denied and existing stocks of that additive and feed containing it were to be withdrawn from the market as laid down by Commission Implementing Regulation (EU) 2018/1254 ([4]), due to the presence in the additive of viable cells and recombinant DNA from the genetically modified production strain *Bacillus subtilis* KCCM 10445,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(6):6629.
([3]) *EFSA Journal* 2022;20(10):7607.
([4]) 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 (OJ L 237, 20.9.2018, p. 5).

carrying antimicrobial resistance genes and posing a risk for the target species, consumers, users and the environment. The riboflavin for which authorisation was denied as well as the present riboflavin (98 %) produced by *Bacillus subtilis* KCCM 10445 and the preparation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM 10445 are produced by the same production strain (*Bacillus subtilis* KCCM 10445). However, the purity of riboflavin has been improved, by increasing from 80 % in the authorisation that was denied to 98 % in this authorisation. In its above-mentioned opinions, the Authority stated that viable cells and recombinant DNA from *Bacillus subtilis* KCCM 10445 were not detected in the riboflavin and in the preparation of riboflavin subject to this application and that therefore, those additives do not pose any safety concern associated with the genetic modification of the production strain.

(7) The assessment of riboflavin produced by *Bacillus subtilis* KCCM 10445 and of the preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the substance and of the preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of those additives.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance and the preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825 iii	'Riboflavin' or 'Vitamin B_2'	*Additive composition* Riboflavin with a maximum of 1,5 % of water Solid form *Characterisation of active substance* Chemical formula: $C_{17}H_{20}N_4O_6$ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with *Bacillus subtilis* KCCM 10445 *Analytical method* (1) For the determination of riboflavin in the feed additive: — European Pharmacopoeia Ph. Eur 01/2008:0292 For the determination of riboflavin in premixtures: — High Performance Liquid Chromatography with UV detection (HPLC-UV) — VDLUFA Bd. III, 13.9.1 For the determination of riboflavin (as total vitamin B2) in compound feed and water: — High Performance Liquid Chromatography with Fluorescence detection (HPLCFLD) — EN 14152	All animal species	—	—	—	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin and breathing protection.	11.4.2033

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825 IV	'Riboflavin' or 'Vitamin B_2'	*Additive composition* Preparation containing a minimum of 80 % of riboflavin and a maximum of 3 % of water Solid form *Characterisation of active substance* Chemical formula: $C_{17}H_{20}N_4O_6$ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with *Bacillus subtilis* KCCM 10445 *Analytical method* (1) For the determination of riboflavin in the feed additive: European Pharmacopoeia Ph. Eur. monograph:0292 For the determination of riboflavin in premixtures: — High Performance Liquid Chromatography with UV detection (HPLC-UV) — VDLUFA Bd. III, 13.9.1 For the determination of riboflavin (as total vitamin B2) in compound feed and water: — High Performance Liquid Chromatography with Fluorescence detection (HPLCFLD) — EN 14152.	All animal species	—	—	—	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organizational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin protection.	11.4.2033

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports