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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1795

of 9 September 2025

concerning the authorisation of riboflavin (vitamin B_2) produced with *Bacillus subtilis* CGMCC 7.449 and a preparation of riboflavin produced with *Bacillus subtilis* CGMCC 7.449, 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 (vitamin B_2) produced with *Bacillus subtilis* CGMCC 7.449 and a preparation of riboflavin produced with *Bacillus subtilis* CGMCC 7.449. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the substance riboflavin (vitamin B_2) produced with *Bacillus subtilis* CGMCC 7.449 and the preparation of riboflavin produced with *Bacillus subtilis* CGMCC 7.449, as feed additives for all animal species, to be classified in the additive 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 opinion of 28 January 2025 ([2]) that, under the proposed conditions of use, riboflavin produced with *Bacillus subtilis* CGMCC 7.449 and the preparation of riboflavin, produced with *Bacillus subtilis* CGMCC 7.449, are safe for all animal species, consumers and the environment. The Authority further concluded that the additives are not dermal nor eye irritants but are dermal and respiratory sensitisers. Inhalation and dermal exposure are considered a risk. The Authority also concluded that the additives are efficacious in covering the animal's nutritional requirements. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that the substance riboflavin produced with *Bacillus subtilis* CGMCC 7.449 and the preparation of riboflavin produced with *Bacillus subtilis* CGMCC 7.449, satisfy the conditions as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of the substance and the preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

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

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal* 2025;23:e9249, https://doi.org/10.2903/j.efsa.2025.9249.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Entry into force

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, 9 September 2025.

For the Commission
The President
Ursula VON DER LEYEN

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								
3a825iii	'Riboflavin' or 'Vitamin B_2'	*Additive composition* Riboflavin with a maximum of 1,5 % of water Solid form *Characterisation of active substance* Riboflavin Chemical formula: $C_{17}H_{20}N_4O_6$ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with *Bacillus subtilis* CGMCC 7.449 *Analytical method* (1) — For the determination of riboflavin in the feed additive: European Pharmacopoeia monograph 0292 or High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1) — For the determination of riboflavin in the premixtures: High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1) — For the determination of riboflavin (as total vitamin B_2) in compound feed and water: High Performance Liquid Chromatography with Fluorescence detection, HPLC-FLD (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 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	29 September 2035

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

ELI: http://data.europa.eu/eli/reg_impl/2025/1795/oj

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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								
3a825vi	'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* Riboflavin Chemical formula: $C_{17}H_{20}N_4O_6$ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with *Bacillus subtilis* CGMCC 7.449 *Analytical method* ([1]) — For the determination of riboflavin in the feed additive and premixtures: High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1) — For the determination of riboflavin (as total vitamin B_2) in compound feed and water: High Performance Liquid Chromatography with Fluorescence detection, HPLC-FLD (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 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	29 September 2035

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ELI: http://data.europa.eu/eli/reg_impl/2025/1795/oj