# COMMISSION IMPLEMENTING REGULATION (EU) 2023/1705

## of 7 September 2023

## concerning the authorisation of a preparation of riboflavin (vitamin $B_2$) produced by *Bacillus subtilis* CGMCC 13326 as a feed additive 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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of riboflavin (vitamin $B_2$) produced by *Bacillus subtilis* CGMCC 13326. 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 a preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 as a feed additive 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 1 February 2023 ([2]) that, under the proposed conditions of use, the preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 is safe for all animal species consumers and the environment. The Authority further concluded that riboflavin is a known photosensitiser which may elicit skin and eye photoallergic reactions and that the preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 has a risk for users of exposure by inhalation and that in the absence of data, it cannot conclude on the potential of skin and eye irritation or dermal sensitisation of the additive. The Authority concluded that the additive is efficacious in covering the animal's nutritional requirements. The Authority does 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 preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance 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.
([2]) *EFSA Journal* 2023;21(2):7874.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

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', is authorised as a feed additive 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, 7 September 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** | | | | | | | | |
| 3a825V | 'Riboflavin' or 'Vitamin $B_2$' | *Additive composition*<br>Preparation with ≥ 80 % of Riboflavin.<br>Maximum 3 % water<br>Solid form<br>*Characterisation of active substance*<br>Riboflavin<br>Chemical formula: $C_{17}H_{20}N_4O_6$<br>CAS number: 83-88-5<br>Purity: minimum 98 %<br>Produced by fermentation with *Bacillus subtilis* CGMCC 13326<br>*Analytical method* (1)<br>For the determination of riboflavin in the feed additive preparation and premixtures:<br>— High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1)<br>For the determination of riboflavin (as total vitamin $B_2$) in compound feed:<br>— High Performance Liquid Chromatography with Fluorescence detection, HPLC-FLD (EN 14152) | All animal species | — | — | — | 1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment shall be indicated.<br>2. 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, eye and skin protective equipment. | 28 September 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.