Brussels, XXX
SANTE/2171697/2025 CIS
(POOL/G5/2025/2171697/2171697-EN CIS.docx)
[…](2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of riboflavin (vitamin B_2) and a preparation of riboflavin produced with *Bacillus subtilis* CGMCC 7.449 for all animal species

(Text with EEA relevance)

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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 such 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) 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 riboflavin (vitamin B_2) and a 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 and a 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 additives are not dermal nor eye irritants but are dermal and respiratory sensitisers. Inhalation and dermal exposure are considered a risk. The Authority concluded that the additives are 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.

[1] OJ L 268, 18.10.2003, p. 29.

[2] EFSA Journal. 2025;23:e924. https://doi.org/10.2903/j.efsa.2025.9249.

(5) In view of the above, the Commission considers that riboflavin and a preparation of riboflavin produced with *Bacillus subtilis* CGMCC 7.449 satisfy the conditions 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,

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 feed 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,

For the Commission
The President
Ursula VON DER LEYEN