



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/8473214/2024 CIS
(POOL/G5/2024/8473214/8473214-EN
CIS.docx)
[...](2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of riboflavin produced from *Eremothecium ashbyi*
CCTCCM 2019833, in the form of a dried inactivated fermentation product, as a feed
additive for all animal species**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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concerning the authorisation of riboflavin produced from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product, 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 nutrition¹, 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 produced from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product. 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 from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product, as a feed additive for all animal species, requesting that additive 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 10 February 2021² and 15 October 2024³ that, under the proposed conditions of use, riboflavin produced from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product, is safe for all animal species, consumers and the environment. It also concluded that it is not a skin/eye irritant nor a skin sensitiser, but it is considered a respiratory sensitiser. The Authority further concluded that riboflavin produced from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product, is effective in covering the animals’ requirements for vitamin B₂, when administered via feed. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² EFSA Journal 2021;19(3):6462. <https://doi.org/10.2903/j.efsa.2021.6462>.

³ EFSA Journal. 2024;22:e9073. <https://doi.org/10.2903/j.efsa.2024.9073>.

- (5) In view of the above, the Commission considers that riboflavin produced from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product, 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,

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The substance 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 an 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,

For the Commission
The President
Ursula VON DER LEYEN