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COMMISSION

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**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)

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**This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.**

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<sup>1</sup>, 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 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 2021<sup>2</sup> and 15 October 2024<sup>3</sup> 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 is not a skin/eye irritant nor a skin sensitiser, but it is considered a respiratory sensitiser. The Authority further concluded that riboflavin

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

<sup>2</sup> EFSA Journal 2021;19(3):6462.

<sup>3</sup> EFSA Journal. 2024;22:e9073.

produced from *Eremothecium ashbyi* CCTCCM 2019833, in the form of a dried inactivated fermentation product, is effective in covering the animals' requirements for vitamin B<sub>2</sub>, 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.

- (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 for authorisation 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 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*