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

of **XXX**

**concerning the authorisation of a preparation of riboflavin (vitamin B₂) produced with
Saccharomyces cerevisiae ATCC SD-8628 as a feed additive for all animal species**

(Text with EEA relevance)

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concerning the authorisation of a preparation of riboflavin (vitamin B₂) produced with *Saccharomyces cerevisiae* ATCC SD-8628 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 a preparation of riboflavin (vitamin B₂) produced with *Saccharomyces cerevisiae* ATCC SD-8628. 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 a preparation of riboflavin (vitamin B₂) produced with *Saccharomyces cerevisiae* ATCC SD-8628 as a feed additive for use in feed and in water for drinking for all animal species, requesting that additive 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 5 May 2026² that the use of a preparation of riboflavin (vitamin B₂) produced with *Saccharomyces cerevisiae* ATCC SD-8628 in animal nutrition does not represent a safety concern for the target species, consumers and for the environment. The Authority further concluded that the additive should be considered an irritant to skin, eyes and respiratory tract and that the exposure by any route is considered a risk. The Authority also concluded that the additive is effective in covering the animal's requirements when administered via feed and water for drinking. The Authority recommended reducing the presence of ethylene oxide and propylene oxide, genotoxic and carcinogenic impurities associated with the use of the antifoaming agent in the fermentation process, to levels as low as reasonably achievable. 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 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](http://data.europa.eu/eli/reg/2003/1831/oj).

² *EFSA Journal*, 24(5), e10120. <https://doi.org/10.2903/j.efsa.2026.10120>.

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- (5) In view of the above, the Commission considers that a preparation of riboflavin (vitamin B₂) produced with *Saccharomyces cerevisiae* ATCC SD-8628 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. The Commission considers it appropriate to establish a limit for ethylene oxide and propylene oxide, setting the limit for both substances at 0,1 mg/kg of feed additive. 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 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 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