

สหภาพยุโรปอนุญาต Riboflavin ที่ผลิตโดย *Eremothecium ashbyi* CCTCCM ๒๐๑๙๘๓๓  
เป็นสารเสริมในอาหารสัตว์

Commission Implementing Regulation (EU) ๒๐๒๕/๑๒๕๔ ว่าด้วย การอนุญาตให้ Riboflavin ที่ผลิตโดย *Eremothecium ashbyi* CCTCCM ๒๐๑๙๘๓๓ เป็นสารเสริมในอาหารสัตว์ ใน EU Official Journal L series โดยมีรายละเอียดดังนี้

๑) คณะกรรมาธิการยุโรปเห็นชอบอนุญาตให้ Riboflavin ที่ผลิตโดย *Eremothecium ashbyi* CCTCCM ๒๐๑๙๘๓๓ ในรูป dried inactivated fermentation product เป็นสารเสริมในอาหารสัตว์ (feed additive) ภายใต้กลุ่มสารเสริมทางโภชนาการ (nutritional additives) โดยมีหน้าที่เป็นวิตามิน โปรวิตามิน และสารเคมีที่มีผลคล้ายคลึง (vitamins, pro-vitamins and chemically well-defined substances having similar effect) และอนุญาตให้ใช้กับสัตว์ทุกชนิด เป็นระยะเวลา ๑๐ ปี ตั้งแต่วันที่กฎระเบียบฯ มีผลบังคับใช้ไปจนถึงวันที่ ๑๖ กรกฎาคม ๒๕๗๘ เนื่องจากไม่ส่งผลกระทบต่อสุขภาพสัตว์ ความปลอดภัยของผู้บริโภค และสิ่งแวดล้อม อย่างไรก็ตาม สารดังกล่าวอาจก่อให้เกิดความเสี่ยงจากการใช้งาน ผู้ใช้งานจึงควรสวมใส่อุปกรณ์ป้องกัน

๒) กฎระเบียบดังกล่าวมีผลบังคับใช้ ๒๐ วัน หลังจากตีพิมพ์ใน EU Official Journal (ประกาศ ณ วันที่ ๒๖ มิถุนายน ๒๕๖๘) ทั้งนี้ รายละเอียดของกฎระเบียบดังกล่าว สามารถสืบค้นเพิ่มเติมได้จาก QR code



Commission Implementing  
Regulation (EU) 2025/1254



2025/1254

26.6.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1254

of 25 June 2025

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 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 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 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 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 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 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.

<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. <https://doi.org/10.2903/j.efsa.2021.6462>.

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

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, 25 June 2025.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

| Identification number of the feed 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 the additive/kg of complete feedstuff with a moisture content of 12 % |   |  |                  |                                |
| Category: nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect |   |  |                               |             |   |   |  |                  |                                |
| 3a827  | 'Riboflavin' or 'Vitamin B <sub>2</sub> ' | <p>Additive composition</p> <p>Riboflavin produced from <i>Eremothecium ashbyi</i> CCTCCM 2019833, in the form of a dried inactivated fermentation product, containing a minimum of 5 % riboflavin.</p> <p>Moisture ≤ 7 %</p> <p>Solid form</p> <p>Characterisation of active substance</p> <p>Riboflavin produced from <i>Eremothecium ashbyi</i> CCTCCM 2019833</p> <p>Chemical formula: C<sub>17</sub>H<sub>20</sub>N<sub>4</sub>O<sub>6</sub></p> <p>CAS number: 83-88-5</p> <p>Analytical method (1)</p> <p>For the determination of riboflavin in the feed additive:</p> <p>— High Performance Liquid Chromatography with Fluorescence detection (HPLC-FLD);</p> <p>or</p> <p>— High Performance Liquid Chromatography with UV detection (HPLC-UV) — VDLUFA Bd. III, 13.9.1.</p> | All animal species            | —           | —   | — | <p>1. The directions for use of the additive and the premixture shall indicate the storage conditions, the stability to heat treatment.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection.</p> | 16 July 2035     |                                |

| Identification number of the feed 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 the additive/kg of complete feedstuff with a moisture content of 12 % |                 |                  |                                |
| Category: nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect  |          |   |                               |             |   |                 |                  |                                |
|   |          | For the determination of riboflavin in premixtures:<br>— High Performance Liquid Chromatography with UV detection (HPLC-UV) — VDLUFA Bd. III, 13.9.1.<br><br>For the determination of riboflavin (as total vitamin B2) in compound feed:<br>— High Performance Liquid Chromatography with Fluorescence detection (HPLC-FLD) — EN 14152. |                               |             |   |                 |                  |                                |
| (1) Details of the analytical methods are available at the following address of the Reference Laboratory: <a href="https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en">https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en</a> . |          |   |                               |             |   |                 |                  |                                |