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

**of **XXX****

**concerning the authorisation of cyanocobalamin (vitamin B<sub>12</sub>) produced with *Ensifer adhaerens* CGMCC 19596 as a feed additive for all animal species**

(Text with EEA relevance)

**EN**

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

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## concerning the authorisation of cyanocobalamin (vitamin B<sub>12</sub>) produced with *Ensifer adhaerens* CGMCC 19596 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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of cyanocobalamin (vitamin B<sub>12</sub>) produced with *Ensifer adhaerens* CGMCC 19596. 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 cyanocobalamin produced with *Ensifer adhaerens* CGMCC 19596 as a feed additive 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 opinions of 23 March 2023<sup>2</sup> and of 4 June 2024<sup>3</sup> that, under the proposed conditions of use, cyanocobalamin produced with *Ensifer adhaerens* CGMCC 19596 is safe for all animal species, consumers and the environment. The Authority further concluded that cyanocobalamin (vitamin B<sub>12</sub>) produced with *Ensifer adhaerens* CGMCC 19596, is not irritant to skin and eyes. No conclusion on the potential of the additive to be a skin sensitiser could be drawn. The potential endotoxin activity of the additive does not represent a hazard for users handling the additive when exposed by inhalation. The Authority concluded that cyanocobalamin produced with *Ensifer adhaerens* CGMCC 19596 is efficacious in meeting animals’ nutritional requirements when administered via feed. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

<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 2023;21(4):7972.

<sup>3</sup> EFSA Journal. 2024;22:e8848.

- (5) In view of the above, the Commission considers that cyanocobalamin (vitamin B<sub>12</sub>) produced with *Ensifer adhaerens* CGMCC 19596 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. The Commission consider that a maximum endotoxin content of the additive should be set up to minimise the potential hazard for the users. 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*