



2024/1325

13.5.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1325

of 8 May 2024

concerning the authorisation of a preparation of cyanocobalamin (vitamin B₁₂) produced with
Ensifer adhaerens CGMCC 21299 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 ⁽¹⁾, 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 a preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299. 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 a preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299 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 opinion of 22 March 2024 ⁽²⁾ that, under the proposed conditions of use, the preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299 is safe for all animal species, consumers and the environment. The Authority further concluded that the preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299, due to the presence of nickel, is considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. Due to the lack of data, the Authority could not conclude on the potential of the preparation to be an eye irritant. The Authority concluded that the preparation 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.
- (5) In view of the above, the Commission considers that the preparation cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299 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,

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

⁽²⁾ EFSA Journal. 2024;22(4),e8752.

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, 8 May 2024.

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 active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a837	‘Cyanocobalamin’ or ‘Vitamin B ₁₂ ’	<i>Additive composition</i> Preparation with ≤ 1 % of cyanocobalamin Nickel: maximum 0,5 mg/kg Solid form <i>Characterisation of active substance</i> Cyanocobalamin Chemical formula: C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P CAS number: 68-19-9 Purity: minimum 96 % Produced by fermentation with <i>Ensifer adhaerens</i> CGMCC 21299 <i>Analytical method</i> ⁽¹⁾ For the quantification of cyanocobalamin (vitamin B ₁₂) in the feed additive preparation and in compound feed: reversed phase high performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV).	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	2 June 2034

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.