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COMMISSION IMPLEMENTING REGULATION (EU) 2024/3167

of 18 December 2024

concerning the authorisation of cyanocobalamin (vitamin B_{12}) 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 ([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 cyanocobalamin (vitamin B_{12}) 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 ([2]) and of 4 June 2024 ([3]) 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_{12}) 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.

(5) In view of the above, the Commission considers that cyanocobalamin (vitamin B_{12}) 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.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal* 2023;21(4):7972.
([3]) *EFSA Journal* 2024;22:e8848.

(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, 18 December 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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect								
3a836	'Cyanocobalamin' or 'Vitamin B_{12}'	**Additive composition:** Cyanocobalamin Solid form **Characterisation of the active substance:** Cyanocobalamin $C_{63}H_{88}CoN_{14}O_{14}P$ CAS number: 68-19-9 Purity: ≥ 96 % on dry basis; loss of drying 12 % Produced by fermentation with *Ensifer adhaerens* CGMCC 19596 **Analytical method** (1) For the quantification of cyanocobalamin in the feed additive: European Pharmacopoeia method (Eur. Ph. 0547) based on spectrophotometry (UV/VIS) For the quantification of cyanocobalamin 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. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU/m³ air (2). 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 and skin protective equipment.	8 January 2035

(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
(2) The exposure is calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2023;21(4):7972).