COMMISSION IMPLEMENTING REGULATION (EU) 2022/1249

of 19 July 2022

concerning the authorisation of vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 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 and renewing such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 June 2018 ([3]) and 18 November 2020 ([4]) that, under the proposed conditions of use, vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that due to its high endotoxin content, potential inhalation exposure when handling premixtures and its reported irritancy to skin and eyes, vitamin B12 in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 is considered to pose a risk to user health. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(4) The assessment of vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised.

(5) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance concerned, it is appropriate to allow a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2018;16(7):5336.
([4]) EFSA Journal 2020;18(12):6335.

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

Transitional measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 9 February 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 9 August 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 9 August 2024 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

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, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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 additive/kg of complete feeding stuff with a moisture content of 12 %			
Category of nutritional additives **Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect**								
3a835	'Vitamin B_{12}' or 'cyanocobalamin'	*Additive composition* Preparation of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 containing ≤ 1 % of cyanocobalamin Solid form *Characterisation of active substance* Cyanocobalamin $C_{63}H_{88}CoN_{14}O_{14}P$ CAS number: 68-19-9 Purity: ≥ 96 % *Analytical method* (1) For the quantification of Vitamin B_{12}/cyanocobalamin in the feed additive preparation and feeding stuffs: — 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 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 its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (2).	9 August 2032

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(7):5336).