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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of cyanocobalamin (vitamin B_{12}) produced with *Ensifer adhaerens* CGMCC 21299 as a feed additive for all animal species

(Text with EEA relevance)

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(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 B_{12}) 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 B_{12}) 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 B_{12}) 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 B_{12}) 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.

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[2] EFSA Journal. 2024;22:e8752.

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

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,

For the Commission
The President
Ursula VON DER LEYEN