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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Bifidobacterium longum* CNCM I-5642 as a feed additive for dogs (holder of authorisation: Nestlé Enterprises S.A. Division Nestlé Purina Petcare Europe represented in the EU by Centres de Recherche et Développement Nestlé S.A.S)

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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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Bifidobacterium longum* CNCM I-5642. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of *Bifidobacterium longum* CNCM I-5642, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'physiological condition stabilisers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 June 2022[2] and 28 January 2025[3] that, under the proposed conditions of use, the preparation of *Bifidobacterium longum* CNCM I-5642 is safe for dogs . Furthermore, it stated that there is no need to perform an assessment of the safety for the consumer or the environment because the additive is intended to be used only in feed for dogs. It also concluded that the preparation of *Bifidobacterium longum* CNCM I-5642 is not an irritant to the skin, but it is considered an irritant to the eyes and a skin and a respiratory sensitiser. The Authority further concluded that the preparation of *Bifidobacterium longum* CNCM I-5642, has the potential to be efficacious as a zootechnical additive for dogs as improves stress (physiological and/or behavioural) resilience when exposed to stress factors representing realistic situations of the animals' lives, when added to feed at $3{,}5 \times 10^9$ CFU/kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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.

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

2 EFSA Journal 2022;20(8):7430.https://doi.org/10.2903/j.efsa.2022.7430

3 EFSA Journal. 2025;23:e9254. https://doi.org/10.2903/j.efsa.2025.9254

(5) In view of the above, the Commission considers that the preparation of *Bifidobacterium longum* CNCM I-5642 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for dogs. The Commission considers that a minimum period of use of the additive should be recommended on the label of the additive, premixtures and compound feed to inform the operators and pet owners. 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 'zootechnical additives' and to the functional group 'physiological condition stabilisers', 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