



2025/1776

9.9.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/1776**

**of 8 September 2025**

**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)**

(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 <sup>(1)</sup>, 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 as a feed additive for dogs, 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 <sup>(2)</sup> and 28 January 2025 <sup>(3)</sup> that, under the proposed conditions of use, the preparation of *Bifidobacterium longum* CNCM I-5642 is safe for dogs and for the environment. It also concluded that the preparation of *Bifidobacterium longum* CNCM I-5642 is not an irritant to skin, but it is considered an irritant to 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 when added to feed at  $3,5 \times 10^9$  CFU/kg complete feed as it improves physiological and/or behavioural stress resilience when the dogs are exposed to stress factors representing realistic situations of the animals' lives. The Authority did 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 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 for dogs should be authorised. 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. 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,

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

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

<sup>(3)</sup> EFSA Journal 2025; 23:e9254, <https://doi.org/10.2903/j.efsa.2025.9254>.

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, 8 September 2025.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

Identification number of the feed additive	Name of the holder of authorisation	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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

**Category: zotechnical additives. Functional group: physiological condition stabilisers (improve stress resilience in dogs) <sup>(1)</sup>**

4e001	Nestlé Enterprises S.A. – Division Nestlé Purina Petcare Europe represented in the EU by Centres de Recherche et Développement Nestlé S.A.S	<i>Bifidobacterium longum</i> CNCM I-5642	<p><i>Additive composition</i></p> <p>Preparation of <i>Bifidobacterium longum</i> CNCM I-5642 containing a minimum of <math>5 \times 10^{10}</math> CFU/g Solid form.</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Bifidobacterium longum</i> CNCM I-5642</p> <p><i>Analytical method <sup>(2)</sup></i></p> <p>Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697). Enumeration in the feed additive and compound feed: Pour plate method using a reinforced clostridial agar medium.</p>	Dogs	—	$3,5 \times 10^9$	—	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>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 skin, eye and breathing protective equipment.</li> <li>On the label of the additive, premixtures and compound feed the following shall be indicated: 'It is recommended to use for at least 6 weeks'.</li> </ol>	29 September 2035
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<sup>(1)</sup> The benefit to dogs is an improvement in stress (physiological and/or behavioural) resilience when exposed to stress factors representing realistic situations of the animals' lives.

<sup>(2)</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).