

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1558**of 17 October 2018****concerning the authorisation of a new use of the preparation of *Lactobacillus acidophilus* (CECT 4529) as a feed additive for cats and dogs (holder of the authorisation Centro Sperimentale del Latte)****(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 new use of the preparation of *Lactobacillus acidophilus* (CECT 4529). 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 the preparation of *Lactobacillus acidophilus* (CECT 4529) as a feed additive for cats and dogs to be classified in the additive category 'zootechnical additives'.
- (4) The preparation of *Lactobacillus acidophilus* (CECT 4529) belonging to the additive category of 'zootechnical additives', was authorised for ten years as a feed additive for laying hens by Commission Implementing Regulation (EU) 2015/38 ⁽²⁾ and for chickens for fattening by Commission Implementing Regulation (EU) 2017/2275 ⁽³⁾.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 April 2018 ⁽⁴⁾ that, under the proposed conditions of use, the preparation of *Lactobacillus acidophilus* (CECT 4529) does not have an adverse effect on animal health, human health and the environment. It also concluded that the additive has the potential to improve the stool consistency of cats and dogs. 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.
- (6) The assessment of the preparation of *Lactobacillus acidophilus* (CECT 4529) 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 preparation should be authorised as specified in the Annex to this Regulation.
- (7) 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

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in the Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2015/38 of 13 January 2015 concerning the authorisation of the preparation of *Lactobacillus acidophilus* CECT 4529 as a feed additive for laying hens and amending Regulation (EC) No 1520/2007 (holder of authorisation Centro Sperimentale del Latte) (OJ L 8, 14.1.2015, p. 4).

⁽³⁾ Commission Implementing Regulation (EU) 2017/2275 of 8 December 2017 concerning the authorisation of a new use of the preparation of *Lactobacillus acidophilus* (CECT 4529) as a feed additive for chickens for fattening (holder of the authorisation Centro Sperimentale del Latte) (OJ L 326, 9.12.2017, p. 47).

⁽⁴⁾ EFSA Journal 2018; 16(5):5278.

Article 2

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, 17 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the 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 of zootechnical additives. Functional group: gut flora stabilisers									
4b1715	Centro Sperimentale del Latte	<i>Lactobacillus acidophilus</i> CECT 4529	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus acidophilus</i> CECT 4529 containing a minimum of: 5×10^{10} CFU/g of additive (solid form).</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Lactobacillus acidophilus</i> CECT 4529.</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: spread plate method using MRS agar (EN 15787).</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>	Cats and dogs	—	5×10^9	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, 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 their 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 eyes, skin and breathing protection. 	7 November 2028

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.