

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1417

of 22 August 2022

concerning the authorisation of a preparation of *Lactobacillus acidophilus* CECT 4529 as a feed additive for all poultry species and categories, other than laying hens and chickens for fattening, and for ornamental birds and amending Implementing Regulation (EU) 2017/2275 (holder of authorisation: Centro Sperimentale del Latte S.r.l.)

(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 an authorisation.
- (2) A preparation of *Lactobacillus acidophilus* CECT 4529 was authorised for a period of 10 years as a feed additive for laying hens by Commission Implementing Regulation (EU) 2015/38 ⁽²⁾, for chickens for fattening by Commission Implementing Regulation (EU) 2017/2275 ⁽³⁾ and for cats and dogs by Commission Implementing Regulation (EU) 2018/1558 ⁽⁴⁾.
- (3) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of new uses 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.
- (4) The application concerns the authorisation of the preparation of *Lactobacillus acidophilus* CECT 4529 as a feed additive in feedingstuffs and in water for drinking for all poultry species and categories and for ornamental birds, to be classified in the category 'zootechnical additives'.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 January 2022 ⁽⁵⁾ that, under the proposed conditions of use, the preparation of *Lactobacillus acidophilus* CECT 4529 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that this preparation is an eye/skin irritant and a skin/respiratory sensitiser. 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 also concluded that the preparation has the potential to be efficacious as a zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods 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.

⁽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⁾ 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) (OJ L 261, 18.10.2018, p. 13).

⁽⁵⁾ EFSA Journal 2022;20(3):7150.

- (6) For clarity reasons, in particular in relation to the labelling provisions, Implementing Regulation (EU) 2017/2275 should therefore be amended accordingly.
- (7) 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.
- (8) 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 I, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

The Annex to Implementing Regulation (EU) 2017/2275 is replaced by Annex II to this Regulation.

Article 3

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, 22 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives
Functional group: gut flora stabilisers

4b1715	Centro Sperimentale del Latte S.r.l.	<i>Lactobacillus acidophilus</i> CECT 4529	<i>Additive composition</i> Preparation of <i>Lactobacillus acidophilus</i> CECT 4529 containing a minimum of 5×10^{10} CFU/g Solid form	All poultry species and categories except laying hens and chickens for fattening	-	1×10^9	-	5×10^8	-	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 eyes, skin and breathing protection.	12.9.2032
			<i>Characterisation of the active substance</i> Viable cells of <i>Lactobacillus acidophilus</i> CECT 4529								
			<i>Analytical method ⁽¹⁾</i> Enumeration: — spread plate method using MRS agar (EN 15787) Identification: — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods								

⁽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

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			
Category of zootechnical additives Functional group: gut flora stabilisers											
4b1715	Centro Sperimentale del Latte	Lactobacillus acidophilus CECT 4529	Additive composition Preparation of Lactobacillus acidophilus CECT 4529 containing a minimum of 5 × 10 ¹⁰ CFU/g Solid form	Chickens for fattening	-	1 × 10 ⁹	-	-	-	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 eyes, skin and breathing protection.	29.12.2027
			Characterisation of the active substance Viable cells of Lactobacillus acidophilus CECT 4529	Chickens for fattening	-	-	-	5 × 10 ⁸	-		12.9.2032
			Analytical method ⁽¹⁾ Enumeration: — spread plate method using MRS agar (EN 15787) Identification: — Pulsed Field Gel Electrophoresis (PFGE). or DNA sequencing methods								

⁽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