

COMMISSION IMPLEMENTING REGULATION (EU) 2016/2150**of 7 December 2016****concerning the authorisation of the preparations of *Lactobacillus plantarum* DSM 29025 and *Lactobacillus plantarum* NCIMB 42150 as feed additives for all animal species****(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 applications were submitted for the authorisation of the preparations of *Lactobacillus plantarum* DSM 29025 and *Lactobacillus plantarum* NCIMB 42150. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) Those applications concern the authorisation of the preparations of *Lactobacillus plantarum* DSM 29025 and *Lactobacillus plantarum* NCIMB 42150 as feed additives for all animal species to be classified in the category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 April 2016 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Lactobacillus plantarum* DSM 29025 does not have an adverse effect on animal health, human health or the environment. However, the additive should be considered to have the potential to be a respiratory sensitiser. The Authority also concluded that the concerned preparation has the potential to improve the production silage prepared from easy, moderately difficult and difficult to ensile material. 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.
- (5) The Authority concluded in its opinion of 24 May 2016 ⁽³⁾ that, under the proposed conditions of use, the preparation of *Lactobacillus plantarum* NCIMB 42150 does not have an adverse effect on animal health, human health or the environment. However, the additive should be considered to have the potential to be a respiratory sensitiser. The Authority also concluded that the preparation concerned has the potential to reduce the protein degradation in silage prepared from easy, moderately difficult and difficult to ensile material. 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.
- (6) The assessment of the preparations of *Lactobacillus plantarum* DSM 29025 and *Lactobacillus plantarum* NCIMB 42150 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations 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,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2016; 14(6):4479.⁽³⁾ EFSA Journal 2016; 14(6):4506.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparations specified in the Annex belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in the 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, 7 December 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU of additive/kg of fresh material			
Technological additives: silage additives								
1k20750	Lactobacillus plantarum DSM 29025	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus plantarum</i></p> <p>DSM 29025 containing a minimum of 8×10^{10} CFU/g additive.</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Lactobacillus plantarum</i></p> <p>DSM 29025.</p> <p><i>Analytical method (*)</i></p> <p>Enumeration in the feed additive: spread plate method on MRS agar (EN 15787).</p> <p>Identification of the feed additive: Pulsed Field Gel Electrophoresis (PFGE).</p>	All animal species	—	—	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 5×10^7 CFU/kg fresh material. 3. 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 breathing protection. 	28 December 2026
1k20751	Lactobacillus plantarum NCIMB 42150	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus plantarum</i></p> <p>NCIMB 42150 containing a minimum of 1×10^{11} CFU/g additive.</p>	All animal species	—	—	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage conditions. 	28 December 2026

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU of additive/kg of fresh material			
		<p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Lactobacillus plantarum</i></p> <p>NCIMB 42150.</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration in the feed additive: spread plate method on MRS agar (EN 15787).</p> <p>Identification of the feed additive: Pulsed Field Gel Electrophoresis (PFGE).</p>					<p>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg fresh material.</p> <p>3. 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 breathing protection.</p>	

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx