

## COMMISSION IMPLEMENTING REGULATION (EU) 2022/273

of 23 February 2022

concerning the authorisation of preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028 as silage 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 <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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the authorisation of preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028 as feed additives for all animal species, to be classified in the additive category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 June 2021 <sup>(2)</sup> <sup>(3)</sup> <sup>(4)</sup> <sup>(5)</sup> <sup>(6)</sup> <sup>(7)</sup> that, under the proposed conditions of use, the preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028 do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additives should be considered respiratory sensitisers and indicated that no conclusions could be drawn on the eye and skin irritancy or skin sensitisation potential of the additives. 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 additives. The Authority also concluded that the preparations concerned have the potential to improve the preservation of nutrients in silage prepared with easy and moderately difficult to ensile material. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2021;19(7):6700.

<sup>(3)</sup> EFSA Journal 2021;19(7):6701.

<sup>(4)</sup> EFSA Journal 2021;19(7):6702.

<sup>(5)</sup> EFSA Journal 2021;19(7):6703.

<sup>(6)</sup> EFSA Journal 2021;19(7):6704.

<sup>(7)</sup> EFSA Journal 2021;19(7):6705.

- (5) The assessment of the preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028 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.
- (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*

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 that Annex.

*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, 23 February 2022.

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

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## ANNEX

Identification number of the additive	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 of additive/kg of fresh material			
<b>Category of technological additives. Functional group: silage additives</b>								
1k21701	<i>Lactocaseibacillus rhamnosus</i> IMI 507023	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactocaseibacillus rhamnosus</i> IMI 507023 containing a minimum of <math>1 \times 10^{10}</math> CFU/g additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Lactocaseibacillus rhamnosus</i> IMI 507023.</p> <p>-</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>— Identification: Pulsed-Field Gel Electrophoresis (PFGE)</p> <p>— Enumeration in the feed additives: Spread plate method on MRS agar (EN 15787)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: <math>1 \times 10^9</math> CFU/kg of easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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 skin, eyes and breathing protection.</li> </ol>	16.3.2032

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

<sup>(2)</sup> Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in the fresh material in accordance with Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

Identification number of the additive	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 of additive/kg of fresh material			
<b>Category of technological additives. Functional group: silage additives</b>								
1k21016	<i>Pediococcus pentosaceus</i> IMI 507024	<p><i>Additive composition:</i></p> <p>Preparation of <i>Pediococcus pentosaceus</i> IMI 507024 containing a minimum of <math>1 \times 10^{10}</math> CFU/g additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Pediococcus pentosaceus</i> IMI 507024.</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>— Identification: Pulsed-Field Gel Electrophoresis (PFGE)</p> <p>— Enumeration in the feed additive: Spread plate method on MRS agar (EN 15786)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: <math>1 \times 10^9</math> CFU/kg of easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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 skin, eyes and breathing protection.</li> </ol>	16.3.2032

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					CFU of additive/kg of fresh material			
<b>Category of technological additives. Functional group: silage additives</b>								
1k21017	<i>Pediococcus pentosaceus</i> IMI 507025	<p><i>Additive composition:</i></p> <p>Preparation of <i>Pediococcus pentosaceus</i> IMI 507025 containing a minimum of <math>1 \times 10^{10}</math> CFU/g additive. Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Pediococcus pentosaceus</i> IMI 507025.</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <ul style="list-style-type: none"> <li>— Identification: Pulsed-Field Gel Electrophoresis (PFGE)</li> <li>— Enumeration in the feed additive: Spread plate method on MRS agar (EN 15786)</li> </ul>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: <math>1 \times 10^9</math> CFU/kg of easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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 skin, eyes and breathing protection.</li> </ol>	16.3.2032

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					CFU of additive/kg of fresh material			

**Category of technological additives. Functional group: silage additives**

1k21601	<i>Lactiplantibacillus plantarum</i> IMI 507026	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactiplantibacillus plantarum</i> IMI 507026 containing a minimum of <math>1 \times 10^{10}</math> CFU/g additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Lactiplantibacillus plantarum</i> IMI 507026.</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>— Identification: Pulsed-Field Gel Electrophoresis (PFGE)</p> <p>— Enumeration in the feed additives: Spread plate method on MRS agar (EN 15787)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: <math>1 \times 10^9</math> CFU/kg of easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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 skin, eyes and breathing protection.</li> </ol>	16.3.2032
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					CFU of additive/kg of fresh material			
<b>Category of technological additives. Functional group: silage additives</b>								
1k21602	<i>Lactiplantibacillus plantarum</i> IMI 507027	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactiplantibacillus plantarum</i> IMI 507027 containing a minimum of <math>1 \times 10^{10}</math> CFU/g additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Lactiplantibacillus plantarum</i> IMI 507027.</p> <p>-</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>— Identification: Pulsed-Field Gel Electrophoresis (PFGE)</p> <p>— Enumeration in the feed additives: Spread plate method on MRS agar (EN 15787)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: <math>1 \times 10^9</math> CFU/kg of easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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 skin, eyes and breathing protection.</li> </ol>	16.3.2032

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<b>Category of technological additives. Functional group: silage additives</b>								
1k21603	<i>Lactiplantibacillus plantarum</i> IMI 507028	<p><b>Additive composition:</b></p> <p>Preparation of <i>Lactiplantibacillus plantarum</i> IMI 507028 containing a minimum of <math>1 \times 10^{10}</math> CFU/g additive.</p> <p>Solid form</p> <p><b>Characterisation of the active substance:</b></p> <p>Viable cells of <i>Lactiplantibacillus plantarum</i> IMI 507028.</p> <p><b>Analytical method <sup>(1)</sup></b></p> <p>— Identification: Pulsed-Field Gel Electrophoresis (PFGE)</p> <p>— Enumeration in the feed additives: Spread plate method on MRS agar (EN 15787)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: <math>1 \times 10^9</math> CFU/kg of easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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 skin, eyes and breathing protection.</li> </ol>	16.3.2032

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