

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1405

of 3 July 2023

concerning the authorisation of a preparation of *Lactiplantibacillus plantarum* ATCC 55058 and a preparation of *Lactiplantibacillus plantarum* ATCC 55942 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. Article 10(7) of Regulation (EC) No 1831/2003 sets out specific provisions for the placing on the market and use of products used in the Union as silage additives at the date that Regulation became applicable.
- (2) In accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003, the preparations of *Lactiplantibacillus plantarum* ATCC 55058 and ATCC 55942 (previously taxonomically identified as *Lactobacillus plantarum* ATCC 55058 and ATCC 55942) were entered in the Register of Feed Additives as existing products belonging to the functional group of silage additives, for all animal species.
- (3) In accordance with Article 10(7) of Regulation (EC) No 1831/2003, in conjunction with Article 7 and Article 10(2) thereof, applications were submitted for the authorisation of the preparations of *Lactiplantibacillus plantarum* ATCC 55058 and ATCC 55942 as feed additives for all animal species, requesting those additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 May 2012 ⁽²⁾ that the use of the preparations of *Lactiplantibacillus plantarum* ATCC 55058 and ATCC 55942 in the production of silage is presumed safe for the target species, consumers of products from animals fed with treated silage and the environment, but found no evidence that those two preparations have a beneficial effect on the preservation of nutrients and therefore could not conclude on their efficacy. In addition, the Authority noted that according to their generic material safety data sheet, the preparations may cause irritation on prolonged contact with skin and eyes and concluded that their potential as skin and respiratory sensitisers should be considered due to the proteinaceous nature of the active agents.
- (5) In its opinion of 10 October 2013 ⁽³⁾, the Authority still could not conclude on the efficacy of those preparations due to the absence of any significant evidence of nutrient preservation. However, based on three new efficacy studies provided by the applicant as supplementary information, the Authority eventually concluded in its opinion of 27 September 2022 ⁽⁴⁾ that the preparations of *Lactiplantibacillus plantarum* ATCC 55058 and ATCC 55942 have the potential to improve the ensiling process by reducing protein degradation in all type of forages as indicated by the reduction of ammonia production.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2012; 10(6):2732.⁽³⁾ EFSA Journal 2013; 11(10):3436.⁽⁴⁾ EFSA Journal 2022; 20(10):7602.

- (6) The assessment of the preparations of *Lactiplantibacillus plantarum* ATCC 55058 and ATCC 55942 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. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparations concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

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 that Annex.

Article 2

Transitional measures

The preparations specified in the Annex and feed containing them, which are produced and labelled before 24 July 2024 in accordance with the rules applicable before 24 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 3 July 2023.

For the Commission

The President

Ursula VON DER LEYEN

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/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k20761	<i>Lactiplantibacillus plantarum</i> ATCC 55058	<i>Additive composition</i> Preparation of <i>Lactiplantibacillus plantarum</i> ATCC 55058 containing a minimum of 1 × 10 ¹⁰ CFU/g additive Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Lactiplantibacillus plantarum</i> ATCC 55058 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive: spread plate method using MRS agar (EN 15787) Identification: Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organism as silage additive: 5 × 10⁶ 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 their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eyes and breathing protective equipment.	24 July 2033

⁽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

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1k20762	<i>Lactiplantibacillus plantarum</i> ATCC 55942	<i>Additive composition</i> Preparation of <i>Lactiplantibacillus plantarum</i> ATCC 55942 containing a minimum of 1 × 10 ¹⁰ CFU/g additive Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Lactiplantibacillus plantarum</i> ATCC 55942 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive: spread plate method using MRS agar (EN 15787) Identification: Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organism as silage additive: 5 × 10⁶ 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 by such procedures and measures, the additive and premixtures shall be used with personal skin, eyes and breathing protective equipment.	24 July 2033

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