

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1443**of 11 July 2023****concerning the renewal of the authorisation of a preparation of *Lactiplantibacillus plantarum* DSM 19457 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1065/2012****(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 and renewing such authorisation.
- (2) The preparation of *Lactiplantibacillus plantarum* DSM 19457 (previously taxonomically identified as *Lactobacillus plantarum* DSM 19457) was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1065/2012 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Lactiplantibacillus plantarum* DSM 19457 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 22 November 2022 ⁽³⁾ that the applicant has provided evidence that the preparation of *Lactiplantibacillus plantarum* DSM 19457 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. The Authority also concluded that the additive is not irritant to skin or eyes but that, owing to its proteinaceous nature, it should be considered a respiratory sensitiser. The Authority could not conclude, in the absence of data, on the skin sensitisation potential of the additive.
- (5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 1065/2012 of 13 November 2012 concerning the authorisation of preparations of *Lactobacillus plantarum* (DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944) as feed additives for all animal species (OJ L 314, 14.11.2012, p. 15).

⁽³⁾ EFSA Journal 2023;21(1):7697.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (6) The assessment of the preparation of *Lactiplantibacillus plantarum* DSM 19457 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that preparation should be renewed.
- (7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other worker safety requirements under Union law.
- (8) As a consequence of the renewal of the authorisation of the preparation of *Lactiplantibacillus plantarum* DSM 19457 as a feed additive, Implementing Regulation (EU) No 1065/2012 should be amended accordingly.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Lactiplantibacillus plantarum* DSM 19457, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (10) 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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 1065/2012

In the Annex to Implementing Regulation (EU) No 1065/2012, entry 1k20718 on '*Lactobacillus plantarum* (DSM 19457)' is deleted.

Article 3

Transitional measures

The preparation specified in the Annex and feed containing it, which are produced and labelled before 1 August 2024 in accordance with the rules applicable before 1 August 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 11 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: technological additives. Functional group: silage additives								
1k20718	<i>Lactiplantibacillus plantarum</i> DSM 19457	<p><i>Additive composition</i> Preparation of <i>Lactiplantibacillus plantarum</i> DSM 19457 containing a minimum of 1×10^{10} CFU/g additive Solid form</p> <p><i>Characterisation of the active substance</i> Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 19457</p> <p><i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lactiplantibacillus plantarum</i> DSM 19457: — Spread plate method using MRS Agar (EN 15787)</p> <p>Identification of <i>Lactiplantibacillus plantarum</i> DSM 19457: — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods</p>	All animal species	—		—	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions shall be indicated. Minimum dose of the additive when used without combination with other micro-organism as silage additive: 5×10^7 CFU/kg fresh material. 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 and breathing protective equipment. 	1 August 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