



2024/1179

24.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1179

of 23 April 2024

concerning the renewal of the authorisation of preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 as feed additives for all animal species and repealing Implementing Regulation (EU) No 1119/2012

(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) Preparations of *Lactiplantibacillus plantarum* DSM 3676 (previously taxonomically identified as *Lactobacillus plantarum* DSM 3676), *Lactiplantibacillus plantarum* DSM 3677 (previously taxonomically identified as *Lactobacillus plantarum* DSM 3677) and *Lentilactobacillus buchneri* DSM 13573 (previously taxonomically identified as *Lactobacillus buchneri* DSM 13573) were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 1119/2012 ⁽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 preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 as feed additives for all animal species, requesting the additives 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 Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 July 2023 ⁽³⁾ that the preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 remain safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additives are not irritant to skin or eyes and that they should be considered respiratory sensitisers. No conclusions could be drawn on their skin sensitisation potential. The Authority indicated that there is no need for assessing the efficacy of the additives as the application for renewal of the three authorisations does not include a proposal for amending or supplementing the conditions of the original authorisations that would have an impact on the efficacy of the additives.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species (OJ L 330, 30.11.2012, p. 14). ELI: http://data.europa.eu/eli/reg_impl/2012/1119/oj.

⁽³⁾ EFSA Journal 2023;21(7):8162.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 as feed additives in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c) of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 satisfy the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 as feed additives, Implementing Regulation (EU) No 1119/2012 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of preparations of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573, 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.
- (9) 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 preparations 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

Repeal of Implementing Regulation (EU) No 1119/2012

Implementing Regulation (EU) No 1119/2012 is repealed.

Article 3

Transitional measures

The preparations specified in the Annex and feed containing them, which are produced and labelled before 13 May 2025 in accordance with the rules applicable before 13 May 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

⁽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). ELI: <http://data.europa.eu/eli/reg/2005/378/oj>.

*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, 23 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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								
1k20731	<i>Lactiplantibacillus plantarum</i> DSM 3676	<i>Additive composition</i> Preparation of <i>Lactiplantibacillus plantarum</i> DSM 3676 containing a minimum of 6 × 10¹¹ CFU/g additive <i>Solid form</i> _____ <i>Characterisation of the active substance</i> Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 3676 _____ <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lactiplantibacillus plantarum</i> DSM 3676: — Spread plate method on MRS agar (EN 15787) <i>Identification of Lactiplantibacillus plantarum</i> DSM 3676: — Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when it is not used in combination with other micro-organisms as silage additives: 1 × 10⁸ CFU/kg fresh material. 3. The additive shall be used in easy and moderately difficult to ensile fresh material ⁽²⁾. 4. 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.	13 May 2034

1k20732	<i>Lactiplantibacillus plantarum</i> DSM 3677	<i>Additive composition</i> Preparation of <i>Lactiplantibacillus plantarum</i> DSM 3677 containing a minimum of 4×10^{11} CFU/g additive <i>Solid form</i> <i>Characterisation of the active substance</i> Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 3677 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lactiplantibacillus plantarum</i> DSM 3677: — Spread plate method on MRS agar (EN 15787) Identification of <i>Lactiplantibacillus plantarum</i> DSM 3677: — Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when it is not used in combination with other micro-organisms as silage additives: 1×10^8 CFU/kg fresh material. 3. The additive shall be used in easy and moderately difficult to ensile fresh material ⁽²⁾. 4. 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.	13 May 2034
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1k20733	<i>Lentilactobacillus buchneri</i> DSM 13573	<i>Additive composition</i> Preparation of <i>Lentilactobacillus buchneri</i> DSM 13573 containing a minimum of 2×10^{11} CFU/g additive <i>Solid form</i> <i>Characterisation of the active substance</i> Viable cells of <i>Lentilactobacillus buchneri</i> DSM 13573 <i>Analytical method ⁽¹⁾</i> Enumeration in the feed additive of <i>Lentilactobacillus buchneri</i> DSM 13573: — Spread plate method on MRS agar (EN 15787) Identification of <i>Lentilactobacillus buchneri</i> DSM 13573: — Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when it is not used in combination with other micro-organisms as silage additives: 1×10^8 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 and breathing protective equipment.	13 May 2034
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⁽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

⁽²⁾ 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).