



2024/1196

26.4.2024

**COMMISSION IMPLEMENTING REGULATION (EU) 2024/1196**

**of 25 April 2024**

**concerning the renewal of the authorisation of a preparation of *Lentilactobacillus buchneri* DSM 19455 as a feed additive for all animal species and repealing Implementing Regulation (EU) No 774/2013**

**(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 and renewing such authorisation.
- (2) The preparation of *Lentilactobacillus buchneri* (previously identified as *Lactobacillus kefir*) DSM 19455 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 774/2013 <sup>(2)</sup>.
- (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 *Lentilactobacillus buchneri* DSM 19455 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 Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2023 <sup>(3)</sup> that the preparation of *Lentilactobacillus buchneri* DSM 19455 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Lentilactobacillus buchneri* DSM 19455 tested with inulin as a carrier is not irritant to skin and eyes but that it should be considered a respiratory sensitiser. The Authority could not conclude on the skin sensitisation potential of the additive. It also indicated that there is no need for assessing the efficacy of the additive as the application for renewal of its authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation which would have an impact on the efficacy of the additive.
- (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 preparation of *Lentilactobacillus buchneri* DSM 19455 as a feed additive 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 <sup>(4)</sup>, an evaluation report of the Reference Laboratory is therefore not required.

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

<sup>(2)</sup> Commission Implementing Regulation (EU) No 774/2013 of 12 August 2013 concerning the authorisation of a preparation of *Lactobacillus kefir* DSM 19455 as a feed additive for all animal species (OJ L 217, 13.8.2013, p. 30, ELI: [http://data.europa.eu/eli/reg\\_impl/2013/774/oj](http://data.europa.eu/eli/reg_impl/2013/774/oj)).

<sup>(3)</sup> EFSA Journal 2023;21(10):8352.

<sup>(4)</sup> 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>).

- (6) In view of the above, the Commission considers that the preparation of *Lentilactobacillus buchneri* DSM 19455 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive 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 additive. 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 preparation of *Lentilactobacillus buchneri* DSM 19455 as a feed additive, Implementing Regulation (EU) No 774/2013 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Lentilactobacillus buchneri* DSM 19455, 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 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

##### **Repeal of Implementing Regulation (EU) No 774/2013**

Implementing Regulation (EU) No 774/2013 is repealed.

#### Article 3

##### **Transitional measures**

The preparation specified in the Annex and feed containing it, which are produced and labelled before 16 May 2025 in accordance with the rules applicable before 16 May 2024 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, 25 April 2024.

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

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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			
<b>Category: technological additives. Functional group: silage additives</b>								
1k20742	<i>Lentilactobacillus buchneri</i> DSM 19455	<p><i>Additive composition</i> Preparation of <i>Lentilactobacillus buchneri</i> DSM 19455 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> Viable cells of <i>Lentilactobacillus buchneri</i> DSM 19455</p> <p><i>Analytical method</i> <sup>(1)</sup> Enumeration in the feed additive of <i>Lentilactobacillus buchneri</i> DSM 19455:</p> <p>— Spread plate method using MRS Agar (EN 15787)</p> <p>Identification of <i>Lentilactobacillus buchneri</i> DSM 19455:</p> <p>— Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods</p>	All animal species	—		—	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>Minimum content of the additive when it is not used in combination with other micro-organisms as silage additives: <math>5 \times 10^7</math> CFU/kg fresh material.</li> <li>The additive shall be used in easy and moderately difficult to ensile fresh material <sup>(2)</sup>.</li> <li>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.</li> </ol>	16 May 2034

<sup>(1)</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

<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).