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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2646

of 28 November 2023

concerning the authorisation of a preparation of *Lentilactobacillus buchneri* DSM 32650 as a feed additive 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Lentilactobacillus buchneri* DSM 32650. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of *Lentilactobacillus buchneri* DSM 32650 as a feed additive for all animal species, requesting that additive to be classified in the category 'technological additives' and in the functional group 'silage additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 May 2023 ([2]) that, under the proposed conditions of use, the preparation of *Lentilactobacillus buchneri* DSM 32650 is safe for the target species, consumers and the environment. In the absence of data, no conclusion could be drawn on the potential of the additive to be a skin and eye irritant or a skin sensitiser. Given the proteinaceous nature of the active agent, the additive should be considered a respiratory sensitiser. The Authority further concluded that *Lentilactobacillus buchneri* DSM 32650 at the proposed inclusion rate may extend the aerobic stability of silage prepared from easy and moderately difficult to ensile forage material with a dry matter range of 28–45 %. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that the preparation of *Lentilactobacillus buchneri* DSM 32650 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. 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.

(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 preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2023;21(6):8055.

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, 28 November 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								
1k21902	*Lentilactobacillus buchneri* DSM 32650	**Additive composition** Preparation of *Lentilactobacillus buchneri* DSM 32650 containing a minimum of 1×10^{11} CFU/g additive Solid form **Characterisation of the active substance** Viable cells of *Lentilactobacillus buchneri* DSM 32650 **Analytical method** (1) Enumeration in the feed additive of *Lentilactobacillus buchneri* DSM 32650: — Spread plate (or pour plate) method on MRS Agar (EN 15787) Identification of *Lentilactobacillus buchneri* DSM 32650: — Enterobacterial Repetitive Intergenic Consensus – Polymerase Chain Reactions (ERIC-PCR) or DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE) – CEN/TS 17697	All animal species	—		—	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg of easy and moderately difficult to ensile fresh material (2). 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, eye and breathing protective equipment.	19 December 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.

(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).