Commission Implementing Regulation (EU) 2019/764 of 14 May 2019 concerning the authorisation of a preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/764

of 14 May 2019

concerning the authorisation of a preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 as a feed additive for all animal species to be classified in the additive category ‘technological additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 2 October 2018[(2)] that, under the proposed conditions of use, the preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is considered a potential respiratory sensitiser and that no conclusion could be drawn on skin or eyes sensitisation or irritation by the additive. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation concerned has the potential to improve the production of silage from easy

and moderately difficult to ensile forage materials. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It 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) The assessment of the preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(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.

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, 14 May 2019.

For the Commission

The President

Jean-Claude JUNCKER

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 of additive/ kg of fresh material			
Technological additives: silage additives								
1k20757	*Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/ NCIMB 40788	*Additive composition:* Preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/ NCIMB 40788 containing a minimum of 1.5×10^{11} CFU/g additive (ratio of 1:1). *Characterisation of the active substance:* Viable cells of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri*	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 used without combination with other micro-organisms as silage additives: 3×10^8 CFU/kg (*L. hilgardii* CNCM I-4785 and *L. buchneri*	4 June 2029

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b 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. 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).