Commission Implementing Regulation (EU) No 1113/2013 of 7 November 2013 concerning the authorisation of preparations of Lactobacillus plantarum NCIMB 40027, Lactobacillus buchneri DSM 22501, Lactobacillus buchneri NCIMB 40788/CNCM I-4323, Lactobacillus buchneri LN 40177/ATCC PTA-6138, and Lactobacillus buchneri LN 4637/ATCC PTA-2494 as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1113/2013

of 7 November 2013

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(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. Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(1) to (4) thereof sets out specific provisions for the evaluation of products used in the Union as silage additives at the date that Regulation became applicable.

(2) In accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003, the preparations of *Lactobacillus plantarum* NCIMB 40027, *Lactobacillus buchneri* DSM 22501, *Lactobacillus buchneri* NCIMB 40788/CNCM I-4323, *Lactobacillus buchneri* LN 40177/ATCC PTA-6138, and *Lactobacillus buchneri* LN 4637/ATCC PTA-2494 were entered in the Register of Feed Additives as existing products belonging to the functional group of silage additives, for all animal species.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, applications were submitted for the authorisation of those preparations as feed additives for all animal species, requesting those additives to be classified in the category ‘technological additives’ and in the functional group ‘silage additives’. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1113/2013. (See end of Document for details)*

(4) The European Food Safety Authority (the Authority) concluded in its opinions of 12 March 2013[(2)] and 16 April 2013[(3)] that, under the proposed conditions of use, the preparations concerned do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparation of *Lactobacillus plantarum* NCIMB 40027 has the potential to improve the production of silage by increasing lactic acid content and the preservation of dry matter by reducing pH and protein degradation, in easy and moderately difficult to ensile forage at 1×10^8 CFU/kg of fresh material and at 1×10^9 CFU/kg of fresh material in difficult to ensile forage for all species. It also concluded that the preparation of *Lactobacillus buchneri* DSM 22501 has the potential to improve the production of silage by reducing pH and ammonia nitrogen and by the preservation of dry matter, from easy, moderately difficult and difficult to ensile forage; the preparation of *Lactobacillus buchneri* NCIMB 40788/CNCM I-4323 has the potential to improve the aerobic stability of easy, moderately difficult and difficult to ensile forage and the preparations of *Lactobacillus buchneri* LN 40177/ATCC PTA-6138, and of *Lactobacillus buchneri* LN 4637/ATCC PTA-2494 have the potential to improve the aerobic stability of easy to ensile forage for all animal species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparations concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annex to this Regulation.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparations specified in the Annex belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

The preparations specified in the Annex and feed containing them, which are produced and labelled before 28 May 2014 in accordance with the rules applicable before 28 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 7 November 2013.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1113/2013. (See end of Document for details)*

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content CFU/kg of fresh material	Maximum content CFU/kg of fresh material	Other provisions	End of period of authorisation
Category of technological additives. Functional group: silage additives									
1k20743	—	*Lactobacillus plantarum* NCIMB 40027	*Additive composition* Preparation of *Lactobacillus plantarum* NCIMB 40027 containing a minimum of 1×10^{11} CFU/g additive. *Characterisation of the active substance* Viable cells of *Lactobacillus plantarum* NCIMB 40027. *Analytical method*[a] Enumeration in the feed additive: spread	All animal species.	—	—	—	1. 28 November 2023 2.	28 November 2033 1. Directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: — 1×10^8 CFU/kg fresh material in

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

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. Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

c Difficult to ensile forage: < 1,5 % soluble carbohydrates in the fresh material. Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

d Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

				plate method (EN 15787). Identification: Pulsed Field Gel Electrophoresis (PFGE).					easy and moderately difficult to ensile material[b]. — 1×10^9 CFU/kg fresh material in difficult to ensile material[c].
								3.	For safety: it is recommended to use breathing protection and gloves during handling.
1k20738		*Lactobacillus buchneri* DSM 22501		*Additive composition* Preparation of *Lactobacillus buchneri* DSM 22501 containing a minimum of 5×10^{10} CFU/				1.	In the directions for use of the additive and premixture, indicate the storage temperature and

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

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. Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

c Difficult to ensile forage: < 1,5 % soluble carbohydrates in the fresh material. Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

d Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).