

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 308/2013

of 3 April 2013

concerning the authorisation of a preparation of *Lactobacillus plantarum* NCIMB 30083 and of a preparation of *Lactobacillus plantarum* NCIMB 30084 as feed additives 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. 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) of Regulation (EC) No 1831/2003, a preparation of *Lactobacillus plantarum* NCIMB 30083 and of a preparation of *Lactobacillus plantarum* NCIMB 30084 were entered in the European Union 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 thereof, 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.

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 December 2012⁽²⁾ that, under the proposed conditions of use, the preparations concerned are considered safe for target species, consumers of products from animals fed treated silage and for the environment. The Authority also concluded that both preparations have the potential to improve the production of silage by increasing the preservation of dry matter and by reducing protein degradation with easy and moderately difficult to ensile forage 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,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(1):3041.

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 24 October 2013 in accordance with the rules applicable before 24 April 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, 3 April 2013.

For the Commission
The President
José Manuel BARROSO

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	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives									
1k20736	—	<i>Lactobacillus plantarum</i> (NCIMB 30083)	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus plantarum</i> (NCIMB 30083) containing a minimum of 5×10^{10} CFU/g additive</p> <p><i>Characterisation of the active substance</i></p> <p><i>Lactobacillus plantarum</i> (NCIMB 30083)</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration in the feed additive: spread plate method (EN 15787)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>	All animal species	—	—	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additive: 1×10^8 CFU/kg of fresh material. 3. The additive shall be used in easy and moderately difficult to ensile material ⁽²⁾. 4. For safety: it is recommended to use breathing protection and gloves during handling. 	24 April 2023
1k20737	—	<i>Lactobacillus plantarum</i> (NCIMB 30084)	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus plantarum</i> (NCIMB 30084) containing a minimum of 5×10^{10} CFU/g additive</p> <p><i>Characterisation of the active substance</i></p> <p><i>Lactobacillus plantarum</i> (NCIMB 30084)</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration in the feed additive: spread plate method (EN 15787)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>	All animal species	—	—	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additive: 1×10^8 CFU/kg of fresh material. 3. The additive shall be used in easy and moderately difficult to ensile material ⁽²⁾. 4. For safety: it is recommended to use breathing protection and gloves during handling. 	24 April 2023

⁽¹⁾ 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

⁽²⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. As defined by Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).