

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 868/2011

of 31 August 2011

concerning the authorisation of a preparation of *Lactobacillus plantarum* (DSM 21762) and of a preparation of *Lactobacillus buchneri* (DSM 22963) 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of a preparation of *Lactobacillus plantarum* (DSM 21762) and of a preparation of *Lactobacillus buchneri* (DSM 22963). Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the authorisation of a preparation of *Lactobacillus plantarum* (DSM 21762) and of a preparation of *Lactobacillus buchneri* (DSM 22963) as feed additives 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 15 March 2011⁽²⁾ that *Lactobacillus plantarum* (DSM 21762) does not have an adverse effect on animal health, human health or the environment, and that this preparation has the

potential to improve the production of silage from all forages by reducing the pH and increasing the preservation of dry matter. 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 additives in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The Authority concluded in its opinion of 7 April 2011⁽³⁾ that *Lactobacillus buchneri* (DSM 22963) does not have an adverse effect on animal health, human health or the environment, and that this preparation has the potential to improve the production of silage by increasing acetic acid production. 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 additives in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the preparation of *Lactobacillus plantarum* (DSM 21762) and of the preparation of *Lactobacillus buchneri* (DSM 22963) 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.
- (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

The preparations specified in 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2011; 9(3):2113.

⁽³⁾ EFSA Journal 2011; 9(4):2138.

Article 2

This Regulation shall enter into force on the 20th day following 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, 31 August 2011.

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 organic material			
Category of technological additives. Functional group: silage additives.									
1k2071	—	<i>Lactobacillus plantarum</i> (DSM 21762)	<p><i>Additive composition:</i> Preparation of <i>Lactobacillus plantarum</i> (DSM 21762) containing a minimum of 5×10^{11} CFU/g additive</p> <p><i>Characterisation of the active substance:</i> <i>Lactobacillus plantarum</i> (DSM 21762)</p> <p><i>Analytical method</i> ⁽¹⁾: Enumeration: Pour plate method: EN 15787 Identification: Pulsed- Field Gel Electrophoresis (PFGE).</p>	All animal species	—	1×10^8	—	<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. The minimum dose of the additive may be adapted when used in combination with other micro-organisms as silage additives. 3. For safety: it is recommended to use breathing protection and gloves during handling. 	21 September 2021
1k2072	—	<i>Lactobacillus buchneri</i> (DSM 22963)	<p><i>Additive composition:</i> Preparation of <i>Lactobacillus buchneri</i> (DSM 22963) containing a minimum of 5×10^{11} CFU/g additive</p> <p><i>Characterisation of the active substance:</i> <i>Lactobacillus buchneri</i> (DSM 22963)</p> <p><i>Analytical method</i> ⁽¹⁾: Enumeration: Pour plate method: EN 15787 Identification: Pulsed- Field Gel Electrophoresis (PFGE).</p>	All animal species	—	1×10^8	—	<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. The minimum dose of the additive may be adapted when used in combination with other micro-organisms as silage additives. 3. For safety: it is recommended to use breathing protection and gloves during handling. 	21 September 2021

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx