

COMMISSION IMPLEMENTING REGULATION (EU) No 841/2012

of 18 September 2012

concerning the authorisation of *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) 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)(b) and Article 7 of Regulation (EC) No 1831/2003, the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) were entered in the Community 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 the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) 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 applications concern the authorisation of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) as feed additives for all animal species, to be classified in the additive category 'technological additives'.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 December 2011⁽²⁾ that, under the proposed conditions of use, the

micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) do not have an adverse effect on animal health, human health or the environment, and that these micro-organisms have the potential to improve the production of silage from all forages by increasing the preservation of dry matter and reducing the loss of protein. The Authority also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) 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 micro-organisms should be authorised as specified in the Annexes to this Regulation.
- (7) Since modifications to the conditions of authorisation of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) are introduced and as there are no direct immediate effects on safety, a reasonable period should be allowed to elapse before authorisation in order to allow the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, it is appropriate to allow a transitional period for the disposal of existing stocks of those micro-organisms and of feed containing them.
- (8) It is disproportionately complex for operators to adapt repeatedly and from one day to the other labels of feed containing different additives which have been successively authorised according to the procedure laid down in Article 10(2) of Regulation (EC) No 1831/2003 and for which new labelling rules are to be complied with. It is therefore appropriate to reduce the administrative burden on the operators by providing a period of time allowing a smooth conversion of labelling.
- (9) 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 micro-organism specified in Annex I, 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 2012; 10(1):2529.

Article 2

The micro-organism specified in Annex II, 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 3***Labelling requirements**

Feed containing the micro-organisms referred to in Article 1 and in Article 2 shall be labelled in accordance with this Regulation at the latest by 19 May 2013.

However, feed containing the micro-organisms referred to in Article 1 and in Article 2 which has been labelled in accordance

with the previous conditions of authorisation before 19 May 2013 may continue to be placed on the market until stocks are exhausted.

*Article 4***Transitional measures**

Existing stocks of the micro-organisms referred to in Article 1 and in Article 2 and of feed containing them at the date of entry into force of this Regulation may continue to be placed on the market and used under the previous conditions of authorisation until they are exhausted.

Article 5

This Regulation shall enter into force on 19 November 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 September 2012.

For the Commission
The President

José Manuel BARROSO

ANNEX I

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									
1k20713	—	<i>Lactobacillus plantarum</i> (NCIMB 41028)	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus plantarum</i> NCIMB 41028 containing a minimum of 7×10^{10} CFU/g additive</p> <p><i>Characterisation of the active substance</i></p> <p><i>Lactobacillus plantarum</i> NCIMB 41028</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 used not in combination with other micro-organisms as silage additive: 1×10^9 CFU/kg fresh material. 3. For safety: it is recommended to use breathing protection and gloves during handling. 	19 November 2022

⁽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

ANNEX II

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									
1k20714	—	<i>Lactobacillus plantarum</i> (NCIMB 30148)	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus plantarum</i> NCIMB 30148 containing a minimum of 7×10^{10} CFU/g additive</p> <p><i>Characterisation of the active substance</i></p> <p><i>Lactobacillus plantarum</i> NCIMB 30148</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 used not in combination with other micro-organisms as silage additive: 1×10^9 CFU/kg fresh material. 3. For safety: it is recommended to use breathing protection and gloves during handling. 	19 November 2022

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