II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1489

of 3 September 2015

concerning the authorisation of the preparation of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 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. 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.

(2) In accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003, the preparations of *Lactobacillus plantarum* MBS-LP-01 (NCIMB 30238) and of *Pediococcus pentosaceus* MBS-PP-01 (NCIMB 30237) 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 thereof, two applications were submitted for the authorisation of the preparations as feed additives for all animal species, requesting the additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. These 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 opinions of 23 May 2012 ([2]), and 11 September 2014 ([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 mixture of the preparations of *Pediococcus pentosaceus* NCIMB 30237 and *Lactobacillus plantarum* NCIMB 30238, when used in a ratio of 8:2, has the potential to improve the preservation of nutrients in silage prepared from easy, moderately difficult and difficult to ensile material. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2012; 10(6):2732 and 2733.
([3]) EFSA Journal 2014; 12(9):3829.

(5) Two applications were evaluated separately for safety and efficacy, but the Authority concluded that the efficacy was only demonstrated by the mixture in well precise ratio of both. Therefore it is proposed to authorise only one preparation. The assessment of the preparation of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation 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 Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex belonging to the additive category 'technological additives' and to the functional group 'silage additives', is authorised as additive in animal nutrition, subject to the conditions laid down in the Annex.

Article 2

Transitional measures

The preparation specified in the Annex and feed containing it, which are produced and labelled before 24 March 2016 in accordance with the rules applicable before 24 September 2015 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 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

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									
1k21008	—	*Lactobacillus plantarum* NCIMB 30238 *Pediococcus pentosaceus* NCIMB 30237	*Additive composition* Preparation of *Lactobacillus plantarum* NCIMB 30238 containing a minimum of $2,0 \times 10^{10}$ CFU/g additive and *Pediococcus pentosaceus* NCIMB 30237 containing a minimum of $2,6 \times 10^{10}$ CFU/g additive. *Characterisation of the active substance* Viable cells of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237. *Analytical method* (1) Enumeration in the feed additive of *Lactobacillus plantarum* NCIMB 30238: spread plate method using MRS agar (EN 15787). Identification of *Lactobacillus plantarum* NCIMB 30238: Pulsed Field Gel Electrophoresis (PFGE). Enumeration in the feed additive *Pediococcus pentosaceus* NCIMB 30237: spread plate method (EN 15786) Identification of *Pediococcus pentosaceus* NCIMB 30237: pulsed field gel electrophoresis (PFGE).	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237: 1×10^8 CFU (ratio 1:4) per kg fresh material. 3. For safety: it is recommended to use breathing protection, eye protection and gloves during handling.	24 September 2025

(1) 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