COMMISSION IMPLEMENTING REGULATION (EU) 2017/455

of 15 March 2017

concerning the authorisation of a preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) as a feed additive for dogs

(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 an application was submitted for the authorisation of the preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) as a feed additive for dogs to be classified in the additive category 'technological additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 December 2015 ([2]) that the preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) does not have an adverse effect on animal health, human health or the environment. The Authority has also concluded that the addition of the additive to pasteurised milk or to an oat-based product results in an acidification contributing to the preservation of the resulting food intended for dogs. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) 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) 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

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'preservatives', 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* 2016;14(1):4340.

Article 2

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, 15 March 2017.

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 of additive/kg of feed material			
Category of technological additives. Functional group: preservatives									
1a001	—	*Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640)	*Additive composition* Preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) containing a minimum of total *Lactobacilli* of $1,0 \times 10^8$ CFU/g additive (having a minimum of each *Lactobacillus* of $1,0 \times 10^7$ CFU/g additive) *Characterisation of the active substance* Viable cells of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) *Analytical method* (1) Enumeration in the feed additive: spread plate method on MRS agar (EN 15787) Identification: Pulsed Field Gel Electrophoresis (PFGE).	Dogs	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. This additive shall be used only in oat derived products and pasteurised milk. 3. Recommended use levels of additive: — 6×10^8 CFU/kg of oat derived products (90 % moisture content); — $2,7 \times 10^{10}$ CFU/kg of pasteurised milk. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin protection.	5 April 2027

(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