

COMMISSION IMPLEMENTING REGULATION (EU) No 774/2013

of 12 August 2013

concerning the authorisation of a preparation of *Lactobacillus kefir* DSM 19455 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Lactobacillus kefir* DSM 19455. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of *Lactobacillus kefir* DSM 19455 as a feed additive 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 13 March 2013⁽²⁾ that, under the proposed conditions of use, the preparation does not have an adverse effect on animal health, human health or the environment. The Authority also

concluded that the preparation improves the aerobic stability of silage by increasing the acetic acid production and by reducing silage pH from easy and moderately difficult to ensile materials. 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 preparation 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) 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 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 that Annex.

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, 12 August 2013.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(4):3177.

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									
1k20742	—	<i>Lactobacillus kefir</i> DSM 19455	<p><i>Additive composition</i></p> <p>Preparation of <i>Lactobacillus kefir</i> DSM 19455 containing a minimum of 1×10^{10} CFU/g additive</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Lactobacillus kefir</i> DSM 19455</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 conditions. 2. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additive: 5×10^7 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. 	2 September 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).