Commission Implementing Regulation (EU) No 304/2014 of 25 March 2014 concerning the authorisation of the preparations of Enterococcus faecium NCIMB 10415, Enterococcus faecium DSM 22502 and Pediococcus acidilactici CNCM I-3237 as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 304/2014

of 25 March 2014

concerning the authorisation of the preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM 22502 and *Pediococcus acidilactici* CNCM I-3237 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) of Regulation (EC) No 1831/2003, the preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM 22502 and *Pediococcus acidilactici* CNCM I-3237 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, applications were submitted for the authorisation of those preparations 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 European Food Safety Authority ('the Authority') concluded in its opinions of 23 May 2012[(2)], 10 September 2013[(3)] and 10 October 2013[(4)] 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 preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 304/2014. (See end of Document for details)*

22502 and *Pediococcus acidilactici* CNCM I-3237 have the potential to improve the production of silage. 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 preparations 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) 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparations specified in the 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.

Article 2

Transitional measures

The preparations specified in the Annex and feed containing them, which are produced and labelled before 15 October 2014 in accordance with the rules applicable before 15 April 2014 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, 25 March 2014.

For the Commission

The President

José Manuel BARROSO

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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									
1k20601	—	*Enterococcus faecium* NCIMB 10415	*Additive composition* Preparation of *Enterococcus faecium* NCIMB 10415 containing a minimum of 1×10^{10} CFU/g additive. *Characterisation of the active substance* Viable cells of *Enterococcus faecium* NCIMB 10415. *Analytical method*[a] Enumeration in the feed additive: spread plate method using Bile Esculine Azide	All animal species.	—	1×10^8 CFU/Kg fresh material.	—	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/Kg fresh material. 3. For safety: it is recommended to use breathing protection, eye	15 April 2024

a 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