Commission Implementing Regulation (EU) No 1061/2013 of 29 October 2013 concerning the authorisation of a preparation of Enterococcus faecium NCIMB 10415 as a feed additive for calves, kids, cats and dogs and amending Regulation (EC) No 1288/2004 (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1061/2013

of 29 October 2013

concerning the authorisation of a preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, kids, cats and dogs and amending Regulation (EC) No 1288/2004 (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o)

(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 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The preparation of *Enterococcus faecium* NCIMB 10415 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on calves by Commission Regulation (EC) No 1288/2004[(3)], for sows by Commission Regulation (EC) No 1200/2005[(4)], for piglets by Commission Regulation (EC) No 252/2006[(5)], for pigs for fattening by Commission Regulation (EC) No 943/2005[(6)], and for cats and dogs by Commission Regulation (EC) No 102/2009[(7)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) The preparation was also authorised for 10 years for chickens for fattening by Commission Implementing Regulation (EU) No 361/2011[(8)].

(4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, cats and dogs and, in accordance with Article 7 of that Regulation, for a new use for kids, requesting that additive to be classified in the additive category ‘zootechnical additives’.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1061/2013. (See end of Document for details)*

That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 January 2013[9] that, under the proposed conditions of use, the preparation of *Enterococcus faecium* NCIMB 10415 does not have an adverse effect on animal health, human health or the environment, and that its use increases final body weight and/or daily weight gain in calves for rearing and fattening and that can be extrapolated to kids for rearing and fattening. It also recognised that the preparation has a beneficial effect in dogs by increasing the intestinal or serum concentration of IgA. 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.

(6) Since small but significant effects on faecal quality were observed in cats, it was considered sufficient to confirm the efficacy in this species.

(7) The assessment of the preparation of *Enterococcus faecium* NCIMB 10415 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.

(8) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 102/2009 should be repealed and Regulation (EC) No 1288/2004 should be amended accordingly.

(9) 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.

(10) 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional groups 'gut flora stabilisers' and 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Repeal of Regulation (EC) No 102/2009

Regulation (EC) No 102/2009 is repealed.

Article 3

Amendment to Regulation (EC) No 1288/2004

In Annex I to Regulation (EC) No 1288/2004 the entry on E 1705, *Enterococcus faecium* NCIMB 10415 is deleted.

Article 4

Transitional measures

The preparation specified in Annex as far as its use for calves is concerned, and feed containing that preparation, which are produced and labelled before 19 May 2014 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

The preparation specified in Annex as far as its use for cats and dogs is concerned, and feed containing that preparation, which are produced and labelled before 19 November 2015 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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, 29 October 2013.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1061/2013. (See end of Document for details)*

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 complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1705	DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o	*Enterococcus faecium* NCIMB 10415	*Additive* — Preparation of *Enterococcus faecium* NCIMB 10415 containing a minimum of: microencapsulated form with shellac and other microencapsulated forms: 1×10^{10} CFU/g additive; non-coated granulated forms: $3,5 \times 10^{10}$ CFU/g additive *Characterisation of the active substance* — *Analytical method*[a] — Preparation of *Enterococcus faecium* NCIMB 10415	Cattle for fattening	—	1×10^{9}	—	In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.	19 November 2023

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx