Commission Implementing Regulation (EU) No 797/2013 of 21 August 2013 concerning the authorisation of a preparation of Enterococcus faecium NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation Chr. Hansen A/S) and repealing Regulation (EC) No 1333/2004 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 797/2013

of 21 August 2013

concerning the authorisation of a preparation of *Enterococcus faecium* NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation Chr. Hansen A/S) and repealing Regulation (EC) No 1333/2004

(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) A preparation of *Enterococcus faecium* NCIMB 11181 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on calves for rearing and for fattening and weaned piglets by Commission Regulation (EC) No 1333/2004[(3)]. That preparation was subsequently entered in the European Union Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) 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 that preparation as a feed additive for calves for rearing and for fattening and weaned piglets, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was 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 opinion of 1 February 2012[(4)] that, under the proposed conditions of use, the preparation of *Enterococcus faecium* NCIMB 11181 does not have an adverse effect on animal health, human health or on the environment, and that it is efficacious in improving

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 797/2013. (See end of Document for details)*

zootechnical performance of calves for rearing and for fattening and weaned piglets. 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 *Enterococcus faecium* NCIMB 11181 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 preparation should be authorised as specified in the Annex to this Regulation.

(6) As a new authorisation is granted in accordance with Regulation (EC) No 1831/2003, Regulation (EC) No 1333/2004 should be repealed.

(7) 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 the disposal of existing stocks of the additive, pre-mixtures and compound feed containing it, as authorised by Regulation (EC) No 1333/2004.

(8) 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 ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 1333/2004 is repealed.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 11 March 2014 in accordance with the rules applicable before 11 September 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 21 August 2013.

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 complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1708	Chr. Hansen A/S	*Enterococcus faecium* (NCIMB 11181)	Additive composition Preparation of *Enterococcus faecium* (NCIMB 11181) containing a minimum of: Solid form: 5×10^{10} CFU/g of additive; Solid water soluble form: 2×10^{11} CFU/g additive. *Characterisation of the active substance* Viable cells	Calves for rearing and for fattening	6 months	5×10^{8}	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting and in water. 2. May be used in milk replacers for calves for rearing and for fattening. 3. For weaned piglets up	11 September 2023
				Piglets (weaned)	—	5×10^{8}	—		

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives.