Commission Implementing Regulation (EU) No 1101/2013 of 6 November 2013 concerning the authorisation of a preparation of Enterococcus faecium DSM 7134 and Lactobacillus rhamnosus DSM 7133 as a feed additive for calves for rearing and amending Regulation (EC) No 1288/2004 (holder of authorisation Lactosan GmbH & CoKG) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1101/2013

of 6 November 2013

concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 as a feed additive for calves for rearing and amending Regulation (EC) No 1288/2004 (holder of authorisation Lactosan GmbH & CoKG)

(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* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 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)]. 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) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of a preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133, as a feed additive for calves for rearing, 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 13 March 2013[(4)] that, under the proposed conditions of use in feed, the preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 does not have an adverse effect on animal and consumer health, and for the environment and it has the potential to improve the zootechnical performance in target animals. It also

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1101/2013. (See end of Document for details)*

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* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 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 consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 contained in Regulation (EC) No 1288/2004 should be deleted. Regulation (EC) No 1288/2004 should be therefore amended accordingly.

(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 interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

In Annex I to Regulation (EC) No 1288/2004 the provisions on E 1706, *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 are deleted.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 27 May 2014 in accordance with the rules applicable before 27 November 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, 6 November 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 1101/2013. (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 % or of milk replacer			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1706	Lactosan GmbH & Co KG	*Enterococcus faecium* DSM 7134 *Lactobacillus rhamnosus* DSM 7133	*Additive composition* Preparation of: *Characterisation of the active substance*	*Calves for rearing*	4 months	1×10^9	—	1. the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For safety: it is recommended to use breathing protection and gloves during handling.	27 November 2023
						Enterococcus faecium DSM 7134 containing a minimum of 7×10^9 CFU/g of additive, and *Lactobacillus rhamnosus* DSM 7133: 3×10^9 CFU/g of additive (ratio 7:3) Solid form			

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