Commission Implementing Regulation (EU) No 1077/2013 of 31 October 2013 concerning the authorisation of a preparation of Enterococcus faecium NBIMCC 8270, Lactobacillus acidophilus NBIMCC 8242, Lactobacillus helveticus NBIMCC 8269, Lactobacillus delbrueckii ssp. lactis NBIMCC 8250, Lactobacillus delbrueckii ssp. bulgaricus NBIMCC 8244, and Streptococcus thermophilus NBIMCC 8253 as a feed additive for suckling piglets (holder of authorisation Lactina Ltd) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1077/2013

of 31 October 2013

concerning the authorisation of a preparation of *Enterococcus faecium* NBIMCC 8270, Lactobacillus acidophilus NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244, and *Streptococcus thermophilus* NBIMCC 8253 as a feed additive for suckling piglets (holder of authorisation Lactina Ltd)

(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 *Enterococcus faecium* NBIMCC 8270, *Lactobacillus acidophilus* NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244, and *Streptococcus thermophilus* NBIMCC 8253. That 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 *Enterococcus faecium* NBIMCC 8270, *Lactobacillus acidophilus* NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244, and *Streptococcus thermophilus* NBIMCC 8253 as a feed additive for suckling piglets, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 12 March 2013[(2)] that, under the proposed conditions of use, the preparation

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1077/2013. (See end of Document for details)*

of *Enterococcus faecium* NBIMCC 8270, *Lactobacillus acidophilus* NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244, and *Streptococcus thermophilus* NBIMCC 8253 does not have an adverse effect on animal health, human health or the environment. The Authority recognised that it has the potential to increase the body weight in suckling 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 that preparation 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) 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

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, 31 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 1077/2013. (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									
4b1891	Lactina Ltd	*Enterococcus faecium* NBIMCC 8270 *Lactobacillus acidophilus* NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244, and *Streptococcus thermophilus* NBIMCC 8253	Additive composition Preparation of: *Enterococcus faecium* NBIMCC 8270 (minimum of $1{,}4 \times 10^9$ CFU/g of additive), *Lactobacillus acidophilus* NBIMCC 8242 (minimum of 8×10^8 CFU/g of additive), *Lactobacillus helveticus* NBIMCC 8269 (minimum of 5×10^8 CFU/g of additive), *Lactobacillus delbrueckii* ssp.	Suckling piglets	—	5×10^9	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For suckling piglets up to 35 days. 3. For safety: it is recommended to use breathing protection and gloves during handling.	21 November 2023

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

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					lactis NBIMCC 8250 (minimum of 2×10^8 CFU/g of additive), *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244 (minimum of 3×10^8 CFU/g of additive), and *Streptococcus thermophilus* NBIMCC 8253 (minimum of $1{,}8 \times 10^9$ CFU/g of additive) containing a minimum of 5×10^9 CFU/g of additive (total amount)				
				Solid form *Characterisation of the active substance*					

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