Commission Regulation (EC) No 1290/2008 of 18 December 2008 concerning the authorisation of a preparation of Lactobacillus rhamnosus (CNCM-I-3698) and Lactobacillus farciminis (CNCM-I-3699) (Sorbiflore) as a feed additive (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1290/2008

of 18 December 2008

concerning the authorisation of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) **[**[F1](Sorbiflore)**]** as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the preparation set out in the Annex. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns a new authorisation of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore), as a feed additive for piglets, to be classified in the additive category ‘zootechnical additives’.

(4) From the Opinion of the European Food Safety Authority (the Authority) of 15 July 2008[(2)] it results that, based on the data provided by the manufacturer, a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore) does not have an adverse effect on animal health, human health or the environment and it is efficacious in improving the weight gain. The Authority further concluded that that preparation may be a potential respiratory sensitiser. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, 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:

Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) No 1334/2013 of 13 December 2013 amending Regulation (EC) No 1290/2008 as regards the name of the holder of the authorisation and as regards the recommended dose of a preparation of Lactobacillus rhamnosus (CNCM-I-3698) and Lactobacillus farciminis (CNCM-I-3699) (Text with EEA relevance).

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, 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 20th day following 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.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species, or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						FU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improving weight gain)									
‘4d2	[F2Danisco (UK) Ltd]	*Lactobacillus rhamnosus* CNCM-I-3698 and *Lactobacillus farciminis* CNCM-I-3699 [F1(Sorbiflore)]	Additive composition: Preparation of *Lactobacillus rhamnosus* CNCM-I-3698 and *Lactobacillus farciminis* CNCM-I-3699 with a minimum concentration of 1 × 10^8 FU[a]/g (ratio 1:1) Characterisation of the active substance: Microbial biomass and milk fermentation medium of *Lactobacillus rhamnosus* CNCM-I-3698	Piglets	—	5×10^8	9×10^8	1. In the directions for use of the additive and premixtures, indicate the storage temperature, storage life, and stability to pelleting. [F2 2. Recommended dose per kilogram of complete feedingstuff: 5×10^8 FU.] 3. For safety: breathing protection, glasses	8.1.2019

a FU: fluorescent units.

b Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives’

			and *Lactobacillus farciminis* CNCM-I-3699 Analytical method[b]: Direct epifluorescent filtration technique (DEFT) using an appropriate dye to stain metabolically active cells as fluorescent units (FU)						and gloves shall be used during handling.

a FU: fluorescent units.

b Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives'

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) No 1334/2013 of 13 December 2013 amending Regulation (EC) No 1290/2008 as regards the name of the holder of the authorisation and as regards the recommended dose of a preparation of Lactobacillus rhamnosus (CNCM-I-3698) and Lactobacillus farciminis (CNCM-I-3699) (Text with EEA relevance).

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (Feedap) on a request from the European Commission on the safety and efficacy of the product Sorbiflore, a preparation of *Lactobacillus rhamnosus* and *Lactobacillus farciminis*, as feed additive for piglets. The EFSA Journal (2008) 771, pp. 1-13.

Status:
Point in time view as at 03/01/2014.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1290/2008.