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) (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<sup>(1)</sup>, 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<sup>(2)</sup> 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.

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

- (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:

#### 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.

Done at Brussels, 18 December 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

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#### **ANNEX**

Identifica Nixome		Additive (Tondrosi Sipaçies			MaximuMinimumMaximu@ther			End	
number	of the	name)	chemica	alor	age	content	content	provisio	nsf
of the	holder		formula	a, categor	$\mathbf{y}$	FU/kg (	of		period
additive	of		descrip			comple	te		of
	authori	sation		ca <b>a</b> nimal		feeding	stuff		authorisation
			method			with a			
						moistur	·e		
						content	of		
						12 %			
Categor	ry of zoot	technical	additives	. Functio	nal grou	p: other z	zootechni	cal addit	ives
(improv	ing weig	ht gain)				-			
'4d2	Sorbial	Lactoba	c <i>iAld</i> ditive	Piglets	_	$5 \times 10^8$	$9 \times 10^{8}$		8.1.2019 In
	SAS		u <b>c</b> omposi			3 10	7 10	1.	
			Preparati						the
		I-3698	of						directions
		and	Lactoba	cillus					for
			c <b>illmas</b> mnos						use
			i.CNCM-						of
		CNCM-							the
		I-3699		obacillus					additive
			yweyrcimini						and
		(Solollic	CNCM-	.5					premixtures,
			I-3699						indicate
			with a						the
			minimun	n					storage
			concentr						temperature,
			of 1	ation					storage
									life,
			$\times 10^8$						and
			FU <sup>a</sup> /g						stability
			(ratio						to
			1:1)						pelleting.
			Characte	risation					
			of the					2.	Recommended
			active						dose
			substanc						per
			Microbia	ıl					kilogram
			biomass						of
			and						complete
			milk						feedingstuff:
			fermenta	tion					5
			medium						g.
			of						
			Lactobac	cillus				3.	For
			rhamnos						safety:
			CNCM-						breathing
			I-3698						protection,
									glasses

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'

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	and Lactobacillus farciminis CNCM- I-3699 Analytical methodb: Direct epifluorescent filtration technique (DEFT) using an appropriate dye to stain metabolically active cells as fluorescent	and gloves shall be used during handling.
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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'

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- (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.

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