Commission Implementing Regulation (EU) No 886/2011 of 5 September 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by Trichoderma reesei (CBS 122001) as a feed additive for sows (holder of authorisation Roal Oy) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 886/2011

of 5 September 2011

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for sows (holder of authorisation Roal Oy)

(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.
- In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the enzyme preparation 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001). The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for sows, to be classified in the additive category 'zootechnical additives'.
- (4) The use of that preparation was authorised for 10 years for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows by Commission Regulation (EU) No 277/2010⁽²⁾, and for turkeys by Commission Regulation (EU) No 891/2010⁽³⁾.
- (5) New data were submitted in support of the application for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) for sows. The European Food Safety Authority ('the Authority') concluded in its opinion of 15 March 2011⁽⁴⁾ that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the calcium and phosphorus digestibility in sows. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the

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- method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.
- (7) 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 'digestibility enhancers', 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, 5 September 2011.

For the Commission

The President

José Manuel BARROSO

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ANNEX

Identifica Vizom e		Additive Composi		si lipa çies	Maxim				End		
number	of the		chemic	alor	age	content	content	provisio	nsf		
of the	holder		formula	a, categor	y	Units of	f		period		
additive	e of		descrip	ti of i,		activity	/kg		of		
	authori	sation	analytic	ca a nimal		of comp			authorisation		
			method			feeding					
						with a					
						moistur	·e				
						content					
						12 %	01				
Category of zootechnical additives. Functional group: digestibility enhancers											
4a12	Roal	6-	aan vos.	Sololistive	<u> </u>	250 PPU		C 15	26		
4012	Oy					230 110		1.	September		
	Оу	phytase EC		Composi					2021		
		3.1.3.26		Preparat	1011				directions		
		3.1.3.20		of					for		
				6-					use		
				phytase					of		
				(EC					the		
				3.1.3.26)					additive		
				produced	1				and		
				by					premixture,		
				Trichode	erma				indicate		
				reesei					the		
				(CBS					storage		
				122001)					temperature,		
				with					•		
				a					storage		
				minimur	n				life,		
				activity					and		
				of:					stability		
					40				to		
					000 PPU	J ^a			pelleting.		
					/			2.	Maximum		
					g			~ .	recommended		
					in				dose		
					solid						
					form				per kilogram		
					10				of		
					000 PPU	f /			complete		
						,					
					g in				feed		
					liquid				for		
					form				sows:		
				Characte					1		
					ะกเรนเเบท				000 PPU.		
				of the							
				the							

a 1 PPU is the amount of enzyme which liberates 1 μmol of inorganic phosphate from sodium phytate per minute at pH
=5.0 and 37 °C.

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

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	active	3.	F
	substance:	3.	For
	of		use
	6-		in
	phytase		feed
	(EC		containing
	3.1.3.26)		more
	produced		than
	by		0,23 %
	Trichoderma		phytin-
			bound
	reesei		phosphorus.
	(CBS		phosphorus.
	122001)	4.	For
	Analytical		safety:
	method ^b :		breathing
	Colorimetric		protection,
	method		glasses
	quantifying		and
	the		gloves
	activity		shall
	of		be
	6-		
	phytase		used
	by		during
	measuring		handling.
	released		
	inorganic		
	phosphate		
	from		
	sodium		
	phytate		
	by		
	analysing		
	the		
	colour		
	formed		
	by		
	reduction		
	of		
	a		
	phosphomolybdate		
	complex.		
	Joinpion.		1

a 1 PPU is the amount of enzyme which liberates 1 μ mol of inorganic phosphate from sodium phytate per minute at pH =5,0 and 37 °C.

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- (1) OJ L 268, 18.10.2003, p. 29.
- (2) OJ L 86, 1.4.2010, p. 13.
- (**3**) OJ L 266, 9.10.2010, p. 4.
- (4) EFSA Journal 2011; 9(3):2111.