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

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(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 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

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 886/2011. (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**
						Units of activity /kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a12	Roal Oy	6-phytase EC 3.1.3.26	*Additive composition:* Preparation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) with a minimum activity of: 40 000 PPU[a] / g in solid form 10 000 PPU / g in liquid form *Characterisation of the*	*Sows*	—	250 PPU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Maximum recommended dose per kilogram of complete feed for sows: 1 000 PPU. 3. For use in feed containing more	26 September 2021

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