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►B **COMMISSION IMPLEMENTING REGULATION (EU) No 837/2012**

of 18 September 2012

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) as feed additive for poultry, weaned piglets, pigs for fattening and sows (holder of authorisation DSM Nutritional Products)

(Text with EEA relevance)

(OJ L 252, 19.9.2012, p. 7)

Amended by:

		Official Journal		
		No	page	date
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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 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594). That 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 *Aspergillus oryzae* (DSM 22594) as a feed additive for poultry, weaned piglets, pigs for fattening and sows, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 14 December 2011 ([2]) that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus utilisation in all target species. 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 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) 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.

(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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal 2012*; 10(1):2527.

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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 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.

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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									
4a18	DSM Nutritional Products	6-phytase (EC 3.1.3.26)	*Additive composition* Preparation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) with a minimum activity of: 10 000 FYT ([1])/g in solid form 20 000 FYT/g in liquid form *Characterisation of the active substance* 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) *Analytical method* ([2]) For quantification of 6-phytase in feed: Colorimetric method measuring the inorganic phosphate released by the 6-phytase from phytate (ISO 30024:2009)	Poultry Pigs for fattening Piglets (weaned)	—	500 FYT	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kilogram of complete feed for: — poultry, piglets (weaned) and pigs for fattening: 500-4 000 FYT, — sows: 1 000-4 000 FYT. 3. For use in feed containing more than 0,23 % phytin-bound phosphorus. 4. For safety: breathing protection, glasses and gloves shall be used during handling. 5. For use in weaned piglets up to 35 kg.	9 October 2022
				Sows		1 000 FYT			

([1]) 1 FYT is the amount of enzyme which liberates 1 μmol of inorganic phosphate from phytate per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and 37 °C.
([2]) 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