

COMMISSION IMPLEMENTING REGULATION (EU) No 1265/2012

of 17 December 2012

amending Implementing Regulation (EU) No 837/2012 as regards the minimum activity of a preparation of 6-phytase 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)

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 13(3) thereof,

Whereas:

- (1) The use of a preparation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594), belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for use on poultry, weaned piglets, pigs for fattening and sows by Commission Implementing Regulation (EU) No 837/2012⁽²⁾.
- (2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of the preparation concerned by adding a new solid formulation with a minimum activity of 10 000 FYT/g. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').
- (3) The Authority concluded in its opinion of 24 May 2012⁽³⁾ that the new enzyme solid formulation is not

expected to introduce hazards to the target species, consumers, users or the environment not already considered and it is efficacious at the minimum activity of 10 000 FYT/g. 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.

- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Implementing Regulation (EU) No 837/2012 should therefore be amended accordingly.
- (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 Annex to Implementing Regulation (EU) No 837/2012 is amended in accordance with the Annex to this Regulation.

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.

Done at Brussels, 17 December 2012.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 252, 19.9.2012, p. 7.

⁽³⁾ EFSA Journal 2012; 10(6):2730.

ANNEX

The Annex to Implementing Regulation (EU) No 837/2012 is replaced by the following:

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