REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1881

of 24 October 2016

amending Implementing Regulation (EU) No 837/2012 as regards the minimum activity of 6-phytase produced by *Aspergillus oryzae* (DSM 22594) as feed additive for sows (holder of authorisation DSM Nutritional Products Ltd)

(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 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 additive concerned by a reduction of minimum activity from 1 000 FYT/kg complete feedingstuff to 500 FYT for sows. 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 26 January 2016 ([3]) that the proposed dose is efficacious in increasing the apparent faecal phosphorus digestibility at the minimum activity of 500 FYT/kg complete feedingstuff. The reduction in the dose proposed for sows would not change the previous conclusions regarding the safety for sows, consumer, user and environment. The Authority concluded that the additive is safe for sows, consumer and the environment; it is not an irritant to skin or eye but it should be treated as a skin sensitiser. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

(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 replaced by the text of the Annex to this Regulation.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 252, 19.9.2012, p. 7.
([3]) *EFSA Journal* 2016; 14(2):4393.

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, 24 October 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

'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 Ltd	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) Sows	—	500 FYT 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: 500-4 000 FYT. 3. For use in feed containing more than 0,23 % phytin-bound phosphorus. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, appropriate personal protective equipment should be used. 5. For use in weaned piglets up to 35 kg.	9 October 2022

(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'