COMMISSION IMPLEMENTING REGULATION (EU) 2017/896

of 24 May 2017

concerning the authorisation of a preparation of 6-phytase, produced by *Trichoderma reesei* (ATCC SD-6528) as a feed additive in solid form for all poultry species and all porcine species (other than suckling piglets) (holder of the authorisation Danisco (UK) 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 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) The use of preparation of 6-phytase, produced by *Trichoderma reesei* (ATCC SD-6528) in liquid form, was authorised for 10 years for all poultry and all porcine species (other than suckling piglets) by Commission Implementing Regulation (EU) 2016/899 ([2]).

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of 6-phytase, produced by *Trichoderma reesei* (ATCC SD-6528) in solid form. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) That application concerns the authorisation of the preparation of 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) in solid form as a feed additive for poultry and porcine species to be classified in the additive category 'zootechnical additives'.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 October 2016 ([3]) that, under the proposed conditions of use, the preparation of 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) in solid form does not have an adverse effect on animal health, human health or the environment, and that it improves the availability of phytate phosphorus in the 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.

(6) The assessment of the preparation of 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that 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 Plants, Animals, Food and Feed,

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Implementing Regulation (EU) 2016/899 of 8 June 2016 concerning the authorisation of a 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) as a feed additive for all poultry species and all porcine species (other than suckling piglets) (holder of authorisation Danisco (UK) Ltd) (OJ L 152, 9.6.2016, p. 15).
([3]) *EFSA Journal 2016*; 14(11):4625.

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 May 2017.

For the Commission

The President

Jean-Claude JUNCKER

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									
4a24	Danisco (UK) Ltd	6-phytase EC 3.1.3.26	*Additive composition* Preparation of 6-phytase, produced by *Trichoderma reesei* (ATCC SD-6528), having a minimum activity of 20 000 FTU (1)/g. Solid form *Characterisation of the active substance:* 6-phytase (EC 3.1.3.26), produced by *Trichoderma reesei* (ATCC SD-6528) *Analytical method* (2) For the quantification of 6-phytase activity in the feed additive and premixutes: — colorimetric method based on the enzymatic reaction of phytase on the phytate. For the quantification of 6-phytase activity in feedingstuffs: — colorimetric method based on the enzymatic reaction of phytase on the phytate EN ISO 30024.	All poultry species All porcine species (other than suckling piglets)	—	250 FTU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. Maximum recommended dose: 2 000 FTU/kg complete feed. 3. For users of the additive and premixtures in a feed business, operational procedures and appropriate organisational measures shall be established to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalator or eyes exposure cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	14 June 2027

(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports