COMMISSION IMPLEMENTING REGULATION (EU) 2023/1167

of 15 June 2023

concerning the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* CBS 146250 as a feed additive for all poultry species and all pigs (holder of authorisation: Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)

(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 an authorisation.

(2) 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* CBS 146250. 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 the preparation of 6-phytase produced by *Trichoderma reesei* CBS 146250 as a feed additive for all poultry species and all pigs, to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2022 ([2]) that the genetic modification of the production strain *Trichoderma reesei* CBS 146250 does not give rise to safety concerns, that the preparation of 6-phytase is safe for all poultry species and all pigs at the proposed conditions of use, and that its use as a feed additive does not give rise to concerns for consumer health and the environment. It also concluded that the preparation is considered a respiratory sensitiser, due to the proteinaceous nature of the active substance, and stated that in the absence of data it could not conclude on the potential of the additive to be irritant to eyes or skin. The Authority further concluded that the preparation is efficacious in increasing the phosphorus utilisation at the proposed conditions of use. It did 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 the preparation of 6-phytase produced by *Trichoderma reesei* CBS 146250 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. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2022;20(11):7610.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Entry into force

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, 15 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

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									
4a37	Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.	6-phytase (EC 3.1.3.26)	*Additive composition* Preparation of 6-phytase produced by *Trichoderma reesei* CBS 146250 with a minimum enzyme activity of: 30,000 FTU (1)/g Liquid or solid form *Characterisation of the active substance* 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* CBS 146250 *Analytical method* (2) For the quantification of phytase activity in the feed additive: colorimetric method based on the enzymatic reaction of phytase on phytate – VDLUFA 27.1.4. For the quantification of phytase activity in premixtures: colorimetric method based on the enzymatic reaction of phytase on phytate – VDLUFA 27.1.3. For the quantification of phytase activity in compound feeds: colorimetric method based on the enzymatic reaction of phytase on phytate – EN ISO 30024	All poultry except poultry for laying All pigs All poultry for laying	— —	500 FTU 300 FTU	— —	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	6 July 2033

(1) One phytase unit (FTU) is the amount of enzyme which releases 1 micromol of inorganic orthophosphate from a sodium phytate substrate per minute at pH 5,5 and 37 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en