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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2177

of 2 September 2024

concerning the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding, sows of all *Suidae* species and all fin fish (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.)

(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 with *Aspergillus oryzae* DSM 33737. 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 a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry, all *Suidae* and all fin fish, requesting that additive 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 1 February 2024 ([2]) that, under the proposed conditions of use, the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 is safe for all poultry, all *Suidae* and all fin fish. It further stated that the preparation is safe for consumers and the environment. The Authority also concluded that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737, in the final formulations of the additive, is not a skin irritant. The two liquid formulations of the additive are not eye irritants, while the two solid ones are to be considered eye irritants. The Authority was not able to conclude on the skin sensitisation of the final formulations of the additive. Due to the proteinaceous nature of the active substance (6-phytase), the additive is considered a respiratory sensitiser. However, exposure by inhalation was considered unlikely. The Authority further concluded that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 has the potential to be efficacious in all poultry for fattening and reared for laying or breeding and in all reproductive *Suidae* at the minimum proposed use level of 200 FYT/kg complete feed and in all fin fish at the minimum proposed use level of 1 000 FYT/kg complete feed. Due to the lack of sufficient data, the Authority was not able to conclude on the efficacy for laying and reproductive poultry, and for *Suidae* for fattening or reared for reproduction. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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) In view of the above, the Commission considers that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening or reared for laying or reared for breeding, sows of all *Suidae* species and all fin fish. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Regarding the target species for which the Authority's opinion was inconclusive, the applicant committed to providing supplementary information.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal*. 2024;22:e8663.

(6) 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

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, 2 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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: zootechnical additives. Functional group: digestibility enhancers									
4a48	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.	6-phytase (EC 3.1.3.26)	*Additive composition* Preparation of 6-phytase (EC 3.1.3.26) produced with *Aspergillus oryzae* DSM 33737 having a minimum activity of: Solid form: 10 000 FYT ([1])/g. Liquid form: 20 000 FYT/g. *Characterisation of the active substance* 6-phytase (EC 3.1.3.26) produced with *Aspergillus oryzae* DSM 33737 *Analytical method* ([2]) For the quantification of phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4. For the quantification of phytase activity in premixtures: — colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.3.	All poultry species for fattening or reared for laying or reared for breeding	-	200 FYT	-	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 the 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 eye (only for the two solid formulations), breathing and skin protective equipment.	23 September 2034
				Sows of all *Suidae* species		200 FYT			
				All fin fish		1 000 FYT			

			For the quantification of phytase activity in compound feed: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024.						

(1) One Phytase Unit (FYT) is defined as the amount of enzyme that releases 1 µmol of inorganic phosphate from phytate per minute (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: https://joint-research-centre.ec.europa.eu/publications/feed-2021-2299_en.

ELI: http://data.europa.eu/eli/reg_impl/2024/2177/oj