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COMMISSION IMPLEMENTING REGULATION (EU) 2024/794

of 5 March 2024

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 as a feed additive for all avian species and piglets of all *Suidae* species (holder of authorisation: Victory Enzymes GmbH)

(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 endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371. 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 endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 as a feed additive for all avian species, piglets (weaned and suckling) and minor growing porcine species, 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 4 July 2023 ([2]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 is safe for all avian species, piglets (suckling and weaned) and minor growing porcine species, consumers and the environment. The Authority also concluded that the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 is considered to be non-irritant eyes, but that it should be considered a skin and respiratory sensitiser and that no conclusion could be drawn on the potential for the additive to be irritant to skin. The Authority further concluded that the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 has the potential to be efficacious in all laying birds and all *Suidae* (from suckling to weaning period) at 2 000 U/kg feed and in all other avian species/categories at 1 000 U/kg feed. 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 endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 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 avian species and piglets of all *Suidae* (from suckling to weaning period). 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.

(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, ELI: http://data.europa.eu/eli/reg/2003/1831/oj
([2]) *EFSA Journal* 2023;21(8):8150.

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, 5 March 2024.

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.									
4a44	Victory Enzymes GmbH	Endo-1,4-beta-xylanase (EC 3.2.1.8)	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* CGMCC 7.371 having a minimum activity of 30 000 U ([1])/g. Liquid or solid form. *Characterisation of the active substance* Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Komagataella phaffii* CGMCC 7.371. *Analytical method* ([2]) For the determination of endo-1,4-beta-xylanase in the feed additive, premixtures and compound feed: colorimetric method based the enzymatic reaction of endo-1,4-beta-xylanase on the azurine cross-linked wheat arabinoxylan substrate.	All laying poultry Suckling piglets Weaned piglets Piglets of minor porcine species (suckling and weaned)	—	2 000 U	—	1. In the directions for use of the additive and premixture, 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 breathing and skin protective equipment.	26 March 2034
				All avian species other than laying poultry		1 000 U			

([1]) One xylanase unit (U) is the amount of enzyme required to release one micromole of reducing sugar equivalents from arabinoxylan per minute at 37 °C and pH 6,5.

([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