Official Journal
of the European Union

EN
L series

2023/2802

19.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2802

of 18 December 2023

concerning the authorisation of a preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 as a feed additive for all poultry species for fattening, breeding, and reared for laying or breeding (holder of authorisation: Kemin Europa N.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 endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 as a feed additive. 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* ATCC PTA-127053 as a feed additive for all poultry species, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The use of that preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 has already been authorised for all laying poultry by Commission Implementing Regulation (EU) 2023/668 ([2]) based on the conclusions of the opinion of 29 June 2022 ([3]) of the European Food Safety Authority ('the Authority').

(5) The Authority concluded in its opinions of 29 June 2022 and 11 May 2023 ([4]) that, under the proposed conditions of use, the preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 is safe for all poultry species, consumers and the environment. It also concluded that the preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 is not irritant to the eyes and skin but should be considered a dermal and a respiratory sensitiser. The Authority further concluded that the preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 has the potential to be efficacious for all poultry species under the proposed conditions of use. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) In view of the above, the Commission considers that the preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 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, breeding, and reared for laying or breeding. 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Implementing Regulation (EU) 2023/668 of 22 March 2023 concerning the authorisation of a preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 as a feed additive for all laying poultry (holder of authorisation: Kemin Europa N.V.) (OJ L 84, 23.3.2023, p. 7).
([3]) *EFSA Journal* 2022;20(7):7439.
([4]) *EFSA Journal* 2023;21(6):8047.

(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

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, 18 December 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									
4a36	Kemin Europa N.V.	Endo–1,4-beta-xylanase (EC 3.2.1.8)	***Additive composition*** Preparation of endo–1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 with a minimum activity of 3 000 000 U ([1])/g. Solid form. ***Characterisation of the active substance*** Endo–1,4-beta-xylanase (EC 3.2.1.8) produced by *Komagataella phaffii* ATCC PTA-127053. ***Analytical method*** ([2]) For the determination of endo–1,4-beta-xylanase in the feed additive: colorimetric method based on the enzymatic hydrolysis of endo–1,4-beta-xylanase on the beechwood xylan substrate.	All poultry species for fattening All poultry species reared for laying or breeding	–	30 000 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 potential risks resulting from its 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.	8 January 2034
				All poultry species for breeding		45 000 U			

			For the determination of endo–1,4-beta-xylanase in premixtures and compound feed: colorimetric method based on the enzymatic reaction of endo–1,4-beta-xylanase on the azurine cross-linked wheat arabinoxylan substrate.						

(1) One U is the amount of enzyme that releases 0,0067 micromoles of reducing sugar (xylose equivalent) per minute and per gram of enzyme product at 50°C and pH 5,3.
(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