

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.)****(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) 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. 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 laying poultry, to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded, in its opinion of 29 June 2022 ⁽²⁾, that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 did not have an adverse effect on consumer safety or the environment. As regards the target species, the Authority concluded that the additive is safe and has the potential to be efficacious for laying hens when added to feed at 45 000 U/kg and that the conclusions on laying hens can be extrapolated to all laying poultry species.
- (5) The Authority concluded that that additive was not irritant to eyes and skin but was considered a dermal and respiratory sensitiser.
- (6) The Authority considered that there was no 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.
- (7) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 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.
- (8) 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(7):7439.

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.

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, 22 March 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)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Komagataella phaffii</i> ATCC PTA-127053 with a minimum activity of: 3 000 000 U ⁽¹⁾ /g <i>Solid form</i> <i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Komagataella phaffii</i> ATCC PTA-127053 <i>Analytical method</i> ⁽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. For the determination of endo-1,4-beta-xylanase in 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	—	45 000 U	—	<ol style="list-style-type: none">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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing and skin protection.	13.4.2033

⁽¹⁾ One U unit is the amount of enzyme that releases 0,0067 µmol 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