

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/669**  
**of 22 March 2023**

**concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* DSM 33574 as a feed additive for all poultry species for fattening and all poultry species reared for laying and reared for breeding (holder of authorisation: BioResource, international, Inc. represented in the Union by Pen & Tec Consulting, S.L.U.)**

(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 <sup>(1)</sup>, 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* DSM 33574. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* DSM 33574 as a feed additive for all poultry species for fattening and all poultry species reared for laying and reared for breeding, 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 <sup>(2)</sup> that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* DSM 33574 does not have an adverse effect on animal health as regards the target species, on consumer safety or on the environment. In addition, the Authority concluded that the exposure of users to the preparation by inhalation is very likely, that the preparation is a respiratory sensitiser and that it has a potential to be eye irritant. No conclusions could be drawn on the potential of the preparation to cause skin sensitisation.
- (5) The Authority further concluded that the preparation has the potential to be efficacious for all poultry species for fattening and all poultry species reared for laying and reared for breeding. The Authority does 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.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* DSM 33574 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 as specified in the Annex to this Regulation. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of that preparation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2022;20(7):7428.

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

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## 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 %			
<b>Category of zootechnical additives. Functional group: digestibility enhancers</b>									
4a35	BioResource International, Inc. represented in the Union by Pen & Tec Consulting, S.L.U.	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<p><i>Additive composition</i> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Komagataella phaffii</i> DSM 33574 with a minimum activity of: 150 000 XU (°)/g</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Komagataella phaffii</i> (DSM 33574)</p> <p><i>Analytical method</i> (°) For the determination of endo-1,4-beta-xylanase activity in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the beechwood xylan substrate.</p>	All poultry species for fattening All poultry species reared for laying or reared for breeding purposes	—	10 000 XU	—	<ol style="list-style-type: none"> <li>The additive shall not be used in premixtures.</li> <li>In the directions for use of the additive, the storage conditions and stability to heat treatment shall be indicated.</li> <li>For users of the additive, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive shall be used with personal protective equipment, including breathing, skin and eyes protection.</li> </ol>	13.4.2033

			For the determination of endo-1,4-beta-xylanase activity in compound feed: colorimetric method based on the enzymatic reaction of endo-1,4-beta-xylanase on the Xy1X6 substrate.						
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<sup>(1)</sup> One XU unit is the amount of enzyme which releases 1 nano-mol of reducing sugar (xylose equivalent) per second from xylan of beechwood at 50 °C and pH 6,0.

<sup>(2)</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)