



2026/2079

18.9.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/2079

of 17 September 2026

concerning the authorisation of a preparation of alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* CBS 139997 as a feed additive for weaned piglets (holder of authorisation: Industrial Técnica Pecuaria, S.A.)

(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 alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* (previously allocated to the species *Trichoderma longibrachiatum*) CBS 139997. 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 alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* CBS 139997 as a feed additive for weaned piglets requesting the additive 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 27 January 2026 ⁽²⁾ that the preparation of alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* CBS 139997 is safe for weaned piglets at the recommended inclusion level of 20 alpha-galactosidase activity units (GALU) and 25 endo-1,4-beta-xylanase activity units (AXC) units per kg complete feed, as well as for the consumers and the environment. The Authority also concluded that the preparation of alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* CBS 139997 is considered a respiratory sensitiser and exposure by inhalation is considered a risk. No conclusions were reached on the potential of the additive to be irritant to the skin or eyes or a skin sensitiser. The Authority further concluded that the preparation of alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* CBS 139997 has the potential to be efficacious as a zootechnical additive in weaned piglets at the recommended use level of 20 GALU and 25 AXC units per kg complete feed. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2026;24:e9920, <https://doi.org/10.2903/j.efsa.2026.9920>.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 19 March 2020 ⁽³⁾ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the preparation of alpha-galactosidase produced with *Aspergillus tubingensis* ATCC SD 6740 and endo-1,4-beta-xylanase produced with *Trichoderma orientale* CBS 139997 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for weaned piglets. 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.
- (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, 17 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ EFSA Journal 2020;18(4):6086, <https://doi.org/10.2903/j.efsa.2020.6086>.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

ANNEX

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a33	Industrial Técnica Pecuaria, S.A.	Endo-1,4-beta-xylanase (EC 3.2.1.8) and alpha-galactosidase (EC 3.2.1.22)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced with <i>Trichoderma orientale</i> CBS 139997 and alpha-galactosidase (EC 3.2.1.22) produced with <i>Aspergillus tubingensis</i> ATCC SD 6740 having a minimum enzyme activity of: 50 AXC ⁽¹⁾ /g of additive and 40 GALU ⁽²⁾ /g of additive Solid form <i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced with <i>Trichoderma orientale</i> CBS 139997 and alpha-galactosidase (EC 3.2.1.22) produced with <i>Aspergillus tubingensis</i> ATCC SD 6740	Weaned piglets	—	25 AXC 20 GALU	—	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 breathing, eye and skin protective equipment.	8 October 2036

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %			
			<i>Analytical method ⁽³⁾</i> For the quantification of endo-1,4-beta-xylanase in the feed additive, premixtures and compound feed: — colorimetric method based enzymatic reaction of endo-1,4-beta-xylanase i) on a wheat arabinoxylan substrate (for the feed additive and premixtures) and ii) on an azo-xylan substrate (for compound feed). For the quantification of alpha-galactosidase in the feed additive, premixtures and compound feed: — colorimetric method based on the enzymatic reaction of alpha-galactosidase on the para-nitrophenyl-alpha-D-galactopyranoside substrate.						

⁽¹⁾ One unit of endo-1,4-beta-xylanase activity (AXC) is the amount of enzyme, which liberates 0,058 micromoles per minute of reducing sugars, expressed as xylose equivalents, from a wheat arabinoxylan substrate at pH 4,7 and 30 °C.

⁽²⁾ One unit of alpha-galactosidase activity (GALU) is defined as the amount of enzyme which degrades one micromole per minute of para-nitrophenyl-alpha-D-galactopyranoside at pH 5,5 and 37 °C.

⁽³⁾ 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.