EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

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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

[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

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.

(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.

[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, pp. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN