



Brussels, **XXX**
SANTE/8529953/2024 CIS
(POOL/G5/2024/8529953/8529953-EN
CIS.docx)
[...](2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 114044 as a feed additive for pigs for fattening, laying hens and minor poultry species (AB Enzymes Finland Oy)

(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 nutrition¹, 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 with *Trichoderma reesei* CBS 114044. 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 the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 114044 as a feed additive for pigs for fattening, laying hens and minor poultry species, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 18 September 2024² that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 114044 is safe for the target species, consumers and the environment. The Authority also concluded that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 114044, in all the forms is non-irritant to the skin but is considered to be respiratory sensitiser. All liquid forms of that preparation are non-irritant to the eyes and are not dermal sensitisers. The Authority could not conclude on the potential of the solid forms to be eye irritants and dermal sensitisers. The Authority further concluded that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 114044 has the potential to be efficacious in pigs for fattening at 20,000 BXU/kg of complete feed, in laying hens and laying minor poultry species at 12,000 BXU/kg of complete feed and in minor poultry species other than laying birds at 8000 BXU/kg of

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

² EFSA Journal. 2024;22:e9025. <https://doi.org/10.2903/j.efsa.2024.9025>

complete feed. It did not consider that there is a need for specific requirements of post-market monitoring.

- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005³, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning the same additive are valid and applicable for the current application.
- (6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 114044 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 pigs for fattening, laying hens and minor poultry species. 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,

For the Commission
The President
Ursula VON DER LEYEN

³ 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>).