PAFF 09-10/10/2025

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/6155407/2025 CIS
(POOL/G5/2025/AN/6155407/6155407-EN CIS.docx)
[…](2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 as a feed additive for poultry other than poultry for fattening, poultry reared for laying and reared for breeding and porcine species other than sows of all Suidae species (holder of authorisation: Huvepharma EOOD)

(Text with EEA relevance)

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(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 endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578. 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, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 as a feed additive for laying or breeding hens, piglets (weaned and suckling) and Suidae for fattening, 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 opinions of 23 November 2022[2] and 1 February 2024[3] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 is safe for the target species, consumers and the environment. The Authority also concluded that the preparation in granulated formulation is not an irritant to the skin and eyes but should be considered a skin sensitiser. It further concluded that the liquid formulation of the preparation is considered not to be an irritant to the skin and

[1] OJ L 268, 18.10.2003, p. 29. ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal 2022;20(12):7702. https://doi.org/10.2903/j.efsa.2022.7702.
[3] *EFSA Journal*. 2024;22:e8643. https://doi.org/10.2903/j.efsa.2024.8643.

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eyes, and not a skin sensitiser. However, both formulations of the preparation are considered respiratory sensitisers. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 6 May 2025[4] that the preparation has the potential to be efficacious in all poultry and all porcine species at the proposed use level of 1500 EPU, 100 CU and 100 XGU/kg feed. It 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 23 November 2022 are valid and applicable for the current application In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005[5], an evaluation report of the Reference Laboratory was therefore not required.

(6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 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 poultry other than poultry for fattening, poultry reared for laying and reared for breeding and porcine species other than sows of all Suidae 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.

[4] *EFSA Journal*. 2025;23:e9460. https://doi.org/10.2903/j.efsa.2025.9460.

[5] 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.

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Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN