



2024/2180

3.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2180

of 2 September 2024

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 sows of all *Suidae* species (holder of authorisation: Huvepharma EOOD)

(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 all reproductive *Suidae* and all *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 opinion of 1 February 2024 ⁽²⁾ 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 does not have adverse effects on animal health, consumer safety or 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 eyes, and not a skin sensitiser. However, both formulations of the preparation are considered respiratory sensitisers. The Authority further concluded that the preparation has the potential to be efficacious in all reproductive *Suidae* at the use level of 1 500 EPU, 100 CU and 100 XGU/kg complete feed. Due to the lack of sufficient data, the Authority was not able to conclude on the efficacy for *Suidae* for fattening. 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 378/2005 ⁽³⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the 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, 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 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. Regarding the target species for which the Authority's opinion was inconclusive, the applicant committed to providing supplementary information.

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

⁽²⁾ EFSA Journal. 2024;22:e8643.

⁽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>.

- (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, 2 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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 %			
Category: zootechnical additives. Functional group: digestibility enhancers									
4a39	Huve-pharma EOOD	Endo-1,4-beta-xylanase (EC 3.2.1.8) Endo-1,4-beta-glucanase (EC 3.2.1.4) Xyloglucan-specific-endo-beta-1,4-glucanase (EC 3.2.1.151)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with <i>Trichoderma citrinoviride</i> DSM 33578 having a minimum activity of: Endo-1,4-beta-xylanase: 15 000 EPU ⁽¹⁾ /g, Endo-1, 4-beta-glucanase: 1 000 CU ⁽²⁾ /g, Xyloglucan-specific endo- beta-1,4-glucanase: 1 000 XGU ⁽³⁾ /g. Granulated or liquid form. <i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8), endo-1,4-beta-glucanase (EC 3.2.1.4) and xyloglucan-specific-endo-beta-1,4-glucanase (EC 3.2.1.151) produced with <i>Trichoderma citrinoviride</i> DSM 33578 <i>Analytical method ⁽⁴⁾</i> For the determination of endo-1,4-beta-xylanase activity in the feed additive, premixtures and compound feed: — colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrate.	Sows of all <i>Suidae</i> species	-	Endo-1,4-b-eta-xylanase 1 500 EPU Endo-1, 4-beta- glu- canase 100 CU Xyloglucan- specific endo- beta-1,4-glu- canase 100 XGU	-	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 and skin protective equipment.	23 September 2034

			For the determination of endo-1,4-beta-glucanase activity in the feed additive, premixtures and compound feed: — colorimetric method based on the quantification of water soluble dyed fragments (azurine) produced by the action of endo-1,4-beta-glucanase on azurine-crosslinked cellulose. For the determination of xyloglucan-specific-endo-beta-1,4-glucanase activity in the feed additive, premixtures and compound feed: — colorimetric method based on the quantification of soluble dyed labelled fragments produced by the action of xyloglucan-specific-endo-beta-1,4-glucanase on xyloglucan substrate.						
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⁽¹⁾ One EPU unit is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 50 °C.

⁽²⁾ One CU unit is the amount of enzyme that liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

⁽³⁾ One XGU unit is the amount of enzyme that releases low-molecular fragments from dyed xyloglucan in amount equal to the amount of such fragments liberated from 1 unit enzyme standard under the conditions of the assay (50 °C and pH 4,5).

⁽⁴⁾ 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.