

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1569**of 18 October 2018****amending Implementing Regulation (EU) No 1110/2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy)****(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 13(3) 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 authorisation.
- (2) The use of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) was authorised as a feed additive for laying hens, minor poultry species and pigs for fattening by Commission Implementing Regulation (EC) No 1110/2011 ⁽²⁾.
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed to modify the minimum content of the additive for laying hens and pigs for fattening. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').
- (4) The Authority concluded in its opinions of 6 March 2018 ⁽³⁾ that, the reduction of minimum content from 24 000 BXU to 12 000 BXU for laying hens and from 24 000 BXU to 20 000 BXU for pigs for fattening does not have an adverse effect on animal health, human health or the environment and the new proposed doses are efficacious for the target species.
- (5) The assessment of the new proposed doses shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.
- (6) Implementing Regulation (EU) No 1110/2011 should therefore be amended accordingly.
- (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

The Annex to Implementing Regulation (EU) No 1110/2011 is replaced by the text set out in the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) No 1110/2011 of 3 November 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy) (OJ L 287, 4.11.2011, p. 27).⁽³⁾ EFSA Journal 2018; 16(3):5216 and EFSA Journal 2018; 16(3):5217.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

Identification number of the 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 of zootechnical additives. Functional group: digestibility enhancers.

4a8	Roal Oy	Endo-1,4-beta-xylanase EC 3.2.1.8	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (CBS 114044) having a minimum activity of:</p> <p>solid form: 4×10^6 BXU ⁽¹⁾/g</p> <p>liquid form: 4×10^5 BXU/g</p> <p><i>Characterisation of the active substance</i></p> <p>endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (CBS 114044)</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>In the additive and the premixture: reducing sugar assay for endo-1,4-beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield at pH 5,3 and 50 °C</p> <p>In the feedingstuffs: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate</p>	Minor poultry species other than laying birds	—	8 000 BXU	—	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks to their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment.</p>	24 November 2021
				Laying hens	12 000 BXU				
				Laying birds of minor poultry species	24 000 BXU				
				Pigs for fattening	20 000 BXU				

⁽¹⁾ 1 BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>