

^{F1} ANNEX

Textual Amendments

F1 Substituted by 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).

Identification number of the additive	Name of the holder of authorisation	Additive	Chemical formula, analytical method	Species, category, 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	Additive composition of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (CBS 114044) having a minimum activity of:	Minor poultry species other than laying birds Laying hens Laying birds of minor poultry species Pigs for fattening solid form: 4 × 10 ⁶ BXU ^a /g	—	8 000 BXU 12 000 BXU 24 000 BXU 20 000 BXU	—	1. 2.	24 November 2021 In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. For users of

a 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.

b 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>

Status: Point in time view as at 08/11/2018.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1110/2011, ANNEX. (See end of Document for details)

			liquid form: 4 × 10 ⁵ BXU/ g				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.
			<i>Characterisation of the active substance</i> endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (CBS 114044) <i>Analytical method^b</i> 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				

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		In the feedingstuffs: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate					
a	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.						
b	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						

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