ANNEX

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a33	Industrial Técnica Pecuaria, S.A.	Endo-1,4-beta-xylanase (EC 3.2.1.8) and alpha-galactosidase (EC 3.2.1.22)	***Additive composition*** Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced with *Trichoderma orientale* CBS 139997 and alpha-galactosidase (EC 3.2.1.22) produced with *Aspergillus tubingensis* ATCC SD 6740 having a minimum enzyme activity of: 50 AXC([1])/g of additive and 40 GALU([2])/g of additive Solid form ***Characterisation of the active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced with *Trichoderma orientale* CBS 139997 and alpha-galactosidase (EC 3.2.1.22) produced with *Aspergillus tubingensis* ATCC SD 6740	Weaned piglets	-	25 AXC 20 GALU	-	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, eye and skin protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

([1]) One unit of endo-1,4-beta-xylanase activity (AXC) is the amount of enzyme, which liberates 0.058 micromoles per minute of reducing sugars, expressed as xylose equivalents, from a wheat arabinoxylan substrate at pH 4.7 and 30 °C.

([2]) One unit of alpha-galactosidase activity (GALU) is defined as the amount of enzyme which degrades one micromole per minute of para-nitrophenyl-alpha-D-galactopyranoside at pH 5.5 and 37 °C.

			Analytical method ([3]) For the quantification of endo-1,4-beta-xylanase in the feed additive, premixtures and compound feed: - colorimetric method based enzymatic reaction of endo-1,4-beta-xylanase i) on a wheat arabinoxylan substrate (for the feed additive and premixtures) and ii) on an azo-xylan substrate (for compound feed). For the quantification of alpha-galactosidase in the feed additive, premixtures and compound feed: - colorimetric method based on the enzymatic reaction of alpha-galactosidase on the para-nitrophenyl-alpha-D-galactopyranoside substrate.						

([3]) 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