

ANNEX

Identi- fication number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content	Maximum content	Other provisions	End of period of author- isation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a10	Genencor International B.V.	Endo-1,4-beta- xylanase (EC 3.2.1.8), Subtilisin (EC 3.4.21.62) and Alpha-amylase (EC 3.2.1.1)	Additive composition Preparation of endo-1,4-β-xylanase produced with <i>Trichoderma reesei</i> CBS 143953, subtilisin produced with <i>Bacillus subtilis</i> CBS 143946 and α-amylase produced with <i>Bacillus amyoliquefaciens</i> CBS 143954 having a minimum activity of: Endo-1,4-β-xylanase: 1 500 U ⁽¹⁾ /g, Subtilisin: 20 000 U ⁽²⁾ /g, Alpha-amylase: 2 000 U ⁽³⁾ /g. Solid form. Characterisation of the active substance Endo-1,4-beta-xylanase (EC 3.2.1.8) produced with <i>Trichoderma reesei</i> CBS 143953, Subtilisin (EC 3.4.21.62) produced with <i>Bacillus subtilis</i> CBS 143946 and Alpha-amylase (EC 3.2.1.1) produced with <i>Bacillus amyoliquefaciens</i> CBS 143954	Ducks	-	Endo-1,4-β- Xylanase 75 U Subtilisin 1 000 U Alpha-amylase 100 U	-	1. In the directions for use of the additive and premixture, 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	[10 years from the date of entry into force of this Regulat- ion.To be comple- ed by the Service respons- ible for the publicat
				Poultry species for fattening, reared for breeding or reared for laying (except ducks)		Endo-1,4-β- Xylanase 187.5 U Subtilisin 2 500 U Alpha-amylase 250 U			
				Poultry species for		Endo-1,4-β-			

⁽¹⁾ 1 U of endo-1,4-beta-xylanase is the amount of enzyme which releases 0,48 μmol of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4,2 and 50 °C.

⁽²⁾ 1 U subtilisin (protease) is defined as the amount of enzyme, which liberates 2.3 micrograms of phenolic compound (expressed as tyrosine equivalents), per minute from a casein substrate at pH 10.0 and 50°C.

⁽³⁾ 1 U alpha-amylase is defined as the amount of enzyme, which liberates 1 micromole of glucosidic linkages, per minute from a water insoluble cross-linked Starch polymer substrate at pH 6.5 and 37 °C.

			Analytical method ⁽⁴⁾ For the determination of the active substance in the feed additive, premixtures and compound feed: Endo-1,4-beta-xylanase: colorimetric method based on the quantification of water-soluble dyed fragments produced by the action of endo-1,4-beta-xylanase on commercially available azurine crosslinked wheat arabinoxylan substances. Subtilisin: colorimetric method based on the quantification of water-soluble dyed fragments (azurine) produced by the action of subtilisin on commercially available cross-linked casein substances. Alpha-amylase: colorimetric method based on the quantification of water-soluble dyed fragments produced by the action of alpha-amylase on commercially available azurine cross-linked starch polymer substances.	laying (except ducks)		Xylanase 300 U Subtilisin 4 000 U Alpha-amylase 400 U		breathing, eye, and skin protective equipment.	ion/

⁽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.