This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document

►B

COMMISSION IMPLEMENTING REGULATION (EU) No 389/2011

of 19 April 2011

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase as feed additive for laying hens (holder of authorisation ►M1 Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V. ◄)

(Text with EEA relevance)

(OJ L 104, 20.4.2011, p. 7)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2019/221 of 6 February 2019	L 35	28	7.2.2019

▼B

COMMISSION IMPLEMENTING REGULATION (EU) No 389/2011

of 19 April 2011

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase as feed additive for laying hens (holder of authorisation ►M1 Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V. ◄)

(Text with EEA relevance)

Article 1

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

This Regulation shall enter into force on the 20th day following 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.

ANNEX

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									
4a10	►**M1** Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V. ◄	Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) and subtilisin produced by *Bacillus subtilis* (ATCC 2107), solid form having a minimum activity of: — endo-1,4-beta-xylanase 1 500 U ([1])/g, — subtilisin 20 000 U ([2])/g, — alpha-amylase 2 000 U ([3])/g. *Characterisation of the active substance* Endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) and subtilisin produced by *Bacillus subtilis* (ATCC 2107). *Analytical methods* ([4]) Determination of the active substance in the additive, premixtures and feedingstuffs. 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 cross-linked wheat arabinoxylan substances.	Laying hens	—	endo-1,4-beta-xylanase 300 U subtilisin 4 000 U alpha-amylase 400 U	—	1. In the directions for use of the additive, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize. 3. For safety reasons: breathing protection, glasses and gloves shall be used during handling.	10 May 2021

▼B

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 %			
			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. 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.						

([1]) 1 U is the amount of enzyme which liberates 0,5 μmol of reducing sugar (expressed as xylose equivalents) from a cross-linked oat spelt xylan substrate per minute at pH 5,3 and 50 °C.
([2]) 1 U is the amount of enzyme which liberates 1 μmol of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.
([3]) 1 U is the amount of enzyme which liberates 1 μmol of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6,5 and 37 °C.
([4]) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives