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 Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (Text with EEA relevance)

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 **[**F1Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.**]**)

(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 9(2) 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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA 5588, subtilisin produced by *Bacillus subtilis* ATCC 2107 and alpha-amylase produced by *Bacillus amyloliquefaciens* ATCC 3978. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of an enzyme preparation of endo-1,4-beta-xylanase subtilisin and alpha-amylase as a feed additive for laying hens, to be classified in the additive category ‘zootechnical additives’.

(4) The use of the preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase has been authorised for 10 years for chickens for fattening, for ducks, and for turkeys for fattening by Commission Regulation (EC) No 1087/2009(2).

(5) The European Food Safety Authority (the Authority) concluded in its opinion of 7 December 2010(3) that the enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase, under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that that additive has the potential to improve egg parameter production in laying hens. The Authority does not consider

that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(6) The assessment of the enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/221 of 6 February 2019 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives (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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 389/2011. (See end of Document for details)*

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	[F1Danisco (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	*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-	10 May 2021

a	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.
b	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.
c	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.
d	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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 389/2011. (See end of Document for details)*

				form having a minimum activity of: — endo-1,4-beta-xylanase 1 500 U[a]/g, — subtilisin 20 000 U[b]/g, — alpha-amylase 2 000 U[c]/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)				glucans), e.g. containing more than 40 % maize. 3. For safety reasons: breathing protection, glasses and gloves shall be used during handling.

a	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.
b	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.
c	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.
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