Commission Regulation (EU) No 337/2011 of 7 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as feed additive for poultry, weaned piglets and pigs for fattening (holder of the authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 337/2011

of 7 April 2011

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as feed additive for poultry, weaned piglets and pigs for fattening (holder of the authorisation **[**[F1]Danisco (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 the preparation specified in the Annex to this Regulation. The 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 the preparation specified in the Annex as a feed additive for poultry, weaned piglets and pigs for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 10 November 2010[(2)] that the preparation specified in the Annex, under the proposed conditions of use, does not have an adverse effect on animal health, human consumer health or the environment, and that this additive has the potential to improve the zootechnical parameters of the target species. 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.

(5) The assessment of the preparation specified in the Annex 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.

(6) 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 Regulation (EU) No 337/2011. (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									
4a15	[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 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	*Additive* — *composition* Preparation (solid and liquid) of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC 5 PTA 5588) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (ATCC SD 2106) having respectively a minimum	*Turkeys for fattening* (reared) *Laying hens* (reared) Other poultry Piglets (weaned) Pigs for fattening		endo-1,4-beta-xylanase 610 U endo-1,3(4)-beta-glucanase 76 U	endo-1,4-beta-xylanase 1 220 U endo-1,3(4)-beta-glucanase 152 U	1. the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing	28 In April 2021 For

a 1 U 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.

b 1 U is the amount of enzyme which releases 2,4 µmol of reducing sugar (glucose equivalent) per minute from glucan of barley at pH 5,0 and 50 °C.

c Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 337/2011. (See end of Document for details)*

				activity of 12 200 U[a]/g and 1 520 U[b]/g *Characterisation of the active substance* Endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (ATCC SD 2106) *Analytical methods*[c] Characterisation of the active substance in the			more than 30 % wheat, barley, rye and/or triticale. 3. For safety reasons: breathing protection, glasses and gloves shall be used during handling. 4. For piglets (weaned) up to 35 kg.	

a 1 U 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.

b 1 U is the amount of enzyme which releases 2,4 μmol of reducing sugar (glucose equivalent) per minute from glucan of barley at pH 5,0 and 50 °C.

c Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives