Commission Implementing Regulation (EU) No 1021/2012 of 6 November 2012 concerning the authorisation of endo-1,4-beta-xylanase produced by Trichoderma reesei (ATCC PTA 5588) as a feed additive for minor poultry species other than ducks (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 1021/2012

of 6 November 2012

concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for minor poultry species other than ducks (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) and Article 13(3) 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) The use of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) was authorised for 10 years for chickens for fattening, laying hens, ducks and turkeys for fattening by Commission Regulation (EU) No 9/2010(2) and for weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 528/2011(3).

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) for minor poultry species other than ducks requesting that the additive be classified in the additive category ‘zootechnical additives’.

(4) The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003, and by the relevant data to support its requests.

(5) The European Food Safety Authority (‘the Authority’) focused its assessment on safety and efficacy for the new target species. The Authority concluded in its opinion of 22 May 2012(4) that, under the proposed conditions of use, since safety of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) has been established in the major poultry species with a wide margin of safety, this conclusion can be extended to all poultry species requested. They stated that a similar conclusion on efficacy can be

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1021/2012. (See end of Document for details)*

extrapolated from major poultry species to all minor poultry 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (ATCC PTA 5588) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that 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 enzyme as 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 twentieth day following that of 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 1021/2012. (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									
4a11	[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	*Additive composition* Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (ATCC PTA 5588) with a minimum activity of 40 000 U/g[a] *Characterisation of the active substance* endo-1,4-beta-xylanase (EC 3.2.1.8) produced	*Maximum content in poultry feed* —		625U		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For use in feed rich in starch and non-starch polysaccharides (mainly beta-arabinoxylans).	27 November 2022

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 arabinoxylan substrate at pH 5,3 and 50 °C in one minute.

b Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx