COMMISSION IMPLEMENTING REGULATION (EU) 2021/2096

of 29 November 2021

concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species (holder of the authorisation: Danisco (UK) Ltd, represented in the Union 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ([2]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that that additive should be considered a respiratory sensitiser and a potential eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive has a potential to be efficacious as a zootechnical additive in sows during the lactation period. 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 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.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2021;19(5):6539.

HAS ADOPTED THIS REGULATION:

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 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.

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

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 feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a11	Danisco (UK) Ltd, represented in the Union 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* CBS 143953 with a minimum activity of 40 000 U/g (1) ***Characterisation of active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* CBS 143953 ***Analytical method*** (2) For quantification of endo-1,4-beta-xylanase activity: colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrates	All poultry species Pigs for fattening Piglets (weaned and suckling) All minor porcine species	-	625 U 2 000 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 potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes and breathing protection.	20.12.2031

(1) 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.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports