II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/196

of 13 February 2020

concerning the renewal of the authorisation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 as a feed additive for chickens for fattening, turkeys for fattening, turkeys reared for breeding, minor avian species (except laying birds) and ornamental birds and repealing Regulations (EC) No 1380/2007, (EC) No 1096/2009 and Implementing Regulation (EU) No 843/2012 (holder of authorisation BASF SE)

(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 and renewing such authorisation.

(2) Endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 was authorised for 10 years as a feed additive for turkeys for fattening by Commission Regulation (EC) No 1380/2007 ([2]), for ducks and chickens for fattening by Commission Regulation (EC) No 1096/2009 ([3]) and for turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds by Commission Implementing Regulation (EU) No 843/2012 ([4]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 as a feed additive for chickens for fattening, turkeys for fattening, turkeys reared for breeding, minor avian species (except laying birds) and ornamental birds, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 February 2019 ([5]) that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority stated that the additive is safe for the target species, for the consumers and the environment. It also concluded that the additive is considered as a potential dermal and respiratory sensitiser. 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 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.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EC) No 1380/2007 of 26 November 2007 concerning the authorisation of endo-1,4-beta-xylanase (Natugrain Wheat TS) as a feed additive (OJ L 309, 27.11.2007, p. 21).

([3]) Commission Regulation (EC) No 1096/2009 of 16 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) as a feed additive for chickens for fattening and the authorisation of a new use of this preparation as a feed additive for ducks (holder of authorisation BASF SE) and amending Regulation (EC) No 1458/2005 (OJ L 301, 17.11.2009, p. 3).

([4]) Commission Implementing Regulation (EU) No 843/2012 of 18 September 2012 concerning the authorisation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) as a feed additive for turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds (holder of authorisation BASF SE) (OJ L 252, 19.9.2012, p. 23).

([5]) *EFSA Journal* 2019;17(3):5652.

(5) The assessment of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1380/2007, (EC) No 1096/2009 and Implementing Regulation (EU) No 843/2012 should be repealed.

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

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulations (EC) No 1380/2007, (EC) No 1096/2009 and Implementing Regulation (EU) No 843/2012 are repealed.

Article 3

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, 13 February 2020.

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
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a62	BASF SE	Endo-1,4-beta-xylanase EC 3.2.1.8	**Additive composition** Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) having a minimum activity of: Solid form: 5 600 TXU [1]/g Liquid form: 5 600 TXU/ml	Turkeys for fattening Turkeys reared for breeding	—	560 TXU	—	1. In the directions for use of the additive and premixtures, 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 its 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 breathing protection.	5.3.2030
			Characterisation of the active substance: Endo-1,4-betaxylanase produced by *Aspergillus niger* (CBS 109.713)	Chickens for fattening Ornamental birds Minor avian species other than laying birds	—	280 TXU	—		
			Analytical method [2] Viscosimetric method based on decrease of viscosity produced by action of endo1,4-beta-xylanase on the xylan-containing substrate (wheat arabinoxylan) at pH 3,5 and 55 °C.						

[1] 1 TXU is the amount of enzyme which liberates 5 micromole of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °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.