COMMISSION IMPLEMENTING REGULATION (EU) 2021/981

of 17 June 2021

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 as a feed additive for poultry species, ornamental birds and weaned piglets (holder of the authorisation: BASF SE), and repealing Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011

(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) An enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 ('the preparation concerned') was authorised for 10 years as a feed additive for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening by Commission Regulation (EC) No 271/2009 ([2]) and for chickens reared for laying, turkeys for breeding purposes, turkeys reared for breeding, other minor avian species (other than ducks for fattening) and ornamental birds by Commission Implementing Regulation (EU) No 1068/2011 ([3]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation concerned as feed additive for poultry species, ornamental birds and weaned piglets in the additive category 'zootechnical additives'. The 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 18 November 2020 ([4]) that the applicant had provided data demonstrating that the preparation concerned complies with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that the preparation concerned does not have an adverse effect on animal health, consumer health or the environment. It also stated that the additive is to be considered as a potential skin 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 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 concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed as specified in the Annex to this Regulation.

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

([2]) Commission Regulation (EC) No 271/2009 of 2 April 2009 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening (holder of the authorisation BASF SE) (OJ L 91, 3.4.2009, p. 5.).

([3]) Commission Implementing Regulation (EU) No 1068/2011 of 21 October 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404) as a feed additive for chickens reared for laying, turkeys for breeding purposes, turkeys reared for breeding, other minor avian species (other than ducks for fattening) and ornamental birds (holder of authorisation BASF SE) (OJ L 277, 22.10.2011, p. 11).

([4]) *EFSA Journal* 2020;18(12):6331.

(6) As a consequence of the renewal of the authorisation of the preparation concerned as a feed additive, Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011 should be repealed.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation concerned, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(8) 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 preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 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

1. The preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 and premixtures containing it, which are produced and labelled before 8 January 2022 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the preparation referred to in paragraph 1, which are produced and labelled before 8 July 2022 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for food-producing animals.

3. Feed materials and compound feed containing the preparation referred to in paragraph 1, which are produced and labelled before 8 July 2023 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for non-food-producing animals.

Article 3

Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011 are repealed.

Article 4

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, 17 June 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: zootechnical additives. Functional group: digestibility enhancers.									
4a7	BASF SE	Endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,4-beta-glucanase (EC 3.2.1.4)	***Additive composition*** Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18404 having a minimum activity of 5 600 TXU ([1]) and 2 500 TGU ([2])/g in solid or liquid form ***Characterisation of active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18404 ***Analytical method*** ([3]) For quantification of endo-1,4-beta-xylanase in the feed additive, premixtures, feed materials and compound feed: Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta- xylanase on the xylan containing substrate (wheat arabinoxylan) at pH = 3,5 and 55 °C.	Chickens for fattening and reared for laying Laying hens All minor poultry species for fattening and laying Ornamental birds	-	280 TXU 125 TGU	-	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 skin and breathing protection.	8 July 2031
				Turkeys Weaned piglets		560 TXU 250 TGU			

			For quantification of endo-1,4-beta-glucanase in the feed additive, premixtures, feed materials and compound feed: Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta- glucanase on the glucan containing substrate (barley betaglucan) at pH = 3,5 and 40 °C.						

(1) One TXU is defined as the amount of enzyme that liberates 5 µmol of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH = 3,5 and 55 °C
(2) One TGU is defined as the amount of enzyme that liberates 1 µmol of reducing sugars (glucose equivalents) from barley betaglucan per minute at pH = 3,5 and 40 °C
(3) 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