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) (Text with EEA relevance)

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)

(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 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 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 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, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that preparation was authorised for 10 years for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening and weaned piglets by Commission Regulation (EC) No 271/2009[(2)].

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1068/2011. (See end of Document for details)*

(5) New data were submitted in support of the application for the authorisation of the 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) 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. The European Food Safety Authority ('the Authority') concluded in its opinion of 11 May 2011[(3)] that, under the proposed conditions of use, the 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) 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 does not have an adverse effect on animal health, human health or the environment, and that the use of that preparation can improve the zootechnical performances 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the 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) 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.

(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:

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 Implementing Regulation (EU) No 1068/2011. (See end of Document for details)*

[F1ANNEX

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2017/950 of 2 June 2017 amending Implementing Regulation (EU) No 1068/2011 as regards the minimum content 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) as a feed additive for chickens reared for laying and all avian species for laying (holder of authorisation BASF SE) (Text with EEA relevance).

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									
4a7	BASF SE	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.4	*Additive composition* 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) having	Minor poultry species for fattening (other than ducks for fattening) and ornamental birds	—	280 TXU 125 TGU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.	11.11.2021
				Chickens reared for laying, and all minor avian species for laying		280 TXU 125 TGU		2. Recommended doses per	

a 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.

b 1 TGU is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley ß-glucan per minute at pH 3,5 and 40 °C.

c 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]

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1068/2011. (See end of Document for details)*

			a minimum activity of: *Characterisation of the active substance* endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger*	Turkeys for breeding purposes Solid form: 5 600 TXU[a] and 2 500 TGU[b]/g Liquid form: 5 600 TXU and 2 500 TGU/g		560 TXU 250 TGU			kilogram of complete feedingstuffs: — minor poultry species for fattening (other than ducks) and ornamental birds: 280-840 TXU/125-375 TGU, — chickens reared for laying, and all minor avian species for laying: 280-840 TXU/125-375 TGU, — turkeys for breeding purposes, turkeys reared for breeding: 560-840 TXU/250-375 TGU.

a	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.
b	1 TGU is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley ß-glucan per minute at pH 3,5 and 40 °C.
c	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**]**