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)

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 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 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) was authorised for 10 years 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 ([2]).

(3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of that preparation by reducing its minimum content from 560 TXU/kg to 280 TXU/kg and from 250 TGU/kg to 125 TGU/kg of the complete feedingstuff as regards the use on chickens reared for laying, and all avian species for laying. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority ('the Authority').

(4) The Authority concluded in its opinion of 20 October 2016 ([3]) that, under the new proposed conditions of use, 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) has the potential to be efficacious at the requested minimum doses of 280 TXU/kg and 125 TGU/kg of complete feedingstuff on chickens reared for laying, and all avian species for laying. 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 *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.

(6) Implementing Regulation (EU) No 1068/2011 should therefore be amended accordingly.

(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 Annex to Implementing Regulation (EU) No 1068/2011 is replaced by the Annex to this Regulation.

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

([2]) 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).

([3]) *EFSA Journal* 2016; 14(11):4626.

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, 2 June 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

'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									
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 a minimum activity of: Solid form: 5 600 TXU (1) and 2 500 TGU (2)/g Liquid form: 5 600 TXU and 2 500 TGU/g *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* (DSM 18404)	Minor poultry species for fattening (other than ducks for fattening) and ornamental birds Chickens reared for laying, and all minor avian species for laying Turkeys for breeding purposes and turkeys reared for breeding	—	280 TXU 125 TGU 280 TXU 125 TGU 560 TXU 250 TGU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended doses per 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.	11.11.2021

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 %			
			Analytical method (3) For quantification of endo-1,4-beta-xylanase activity: 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. For quantification of endo-1,4-beta-glucanase activity: 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.					3. 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 and skin protection.	

(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) 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.
(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

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