Commission Implementing Regulation (EU) 2020/1371 of 1 October 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for lactating sows (holder of the authorisation BASF SE) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1371

of 1 October 2020

concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for lactating sows (holder of the 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 a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase. That 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 a 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 18 404 as a feed additive for lactating sows 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 29 January 2020[(2)] that, under the proposed conditions of use, the 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 18 404 does not have an adverse effect on animal health, consumer safety or the environment. It was also concluded that the additive should 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 concluded that the additive is efficacious as a zootechnical additive in improving the digestibility of the diets in lactating sows. 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 (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 18 404 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,

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, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1371. (See end of Document for details)*

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) 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 18 404 having a minimum activity of 5 600	Lactating cows		560 TXU [a] 250 TGU [b]		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.	22 October 2030

a 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.

b 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.

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

			TXU[a] and 2 500 TGU[b]/ 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 18 404					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
			Analytical method[c] For quantification of endo-1,4-beta-xylanase in the feed						

a 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.

b 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.

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