Commission Implementing Regulation (EU) No 1404/2013 of 20 December 2013 concerning 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 pigs for fattening (holder of authorisation BASF SE) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1404/2013

of 20 December 2013

concerning 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 pigs for fattening (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 a new use 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). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a new use 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 pigs for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that preparation was authorised for 10 years 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)].

(5) The European Food Safety Authority (‘the Authority’) in its opinion of 18 June 2013[(4)] confirmed its previous conclusions that, under the proposed conditions of use, the

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1404/2013. (See end of Document for details)*

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) does not have an adverse effect on animal health, human health or the environment. The Authority concluded that it has the potential to be efficacious in pigs for fattening. 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 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 that 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 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, 20 December 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1404/2013. (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 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: 5 600 TXU[a] and 2 500 TGU[b]/g. *Analytical method*[c] For the determination of endo-1,4-beta-xylanase activity: spectrophotometric method measuring the release of reducing sugars from wheat arabinoxylan at pH 3,5 and 55 °C. For the determination of endo-1,4-beta-glucanase activity: spectrophotometric method measuring the release of reducing sugars from barley beta-glucan at pH 3,5 and 40 °C.	Pigs for fattening	—	560 TXU 250 TGU	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. Recommended doses per kilogram of complete feedingstuffs: 560-840 TXU/250 - 375 TGU. 3. For safety: breathing protection, glasses	12 January 2024

a 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 TGU is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-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: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx