

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1006**of 15 June 2017****amending Implementing Regulation (EU) No 1206/2012 as regards the change of the production strain of the preparation of endo-1,4-beta-xylanase, produced by *Aspergillus oryzae* (DSM 10287) as feed additive for poultry for fattening, weaned piglets and pigs for fattening (holder of authorisation DSM Nutritional Products Ltd)****(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) The use of the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287), belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for poultry for fattening, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 1206/2012 ⁽²⁾.
- (2) 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 the preparation concerned by requesting for a change in the production strain, from *Aspergillus oryzae* (DSM 10287) to *Aspergillus oryzae* (DSM 26372). The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').
- (3) The Authority concluded in its opinion of 14 July 2016 ⁽³⁾ that the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) does not have any adverse effects on animal health, human health and the environment. The Authority further concluded that the additive has the potential to be efficacious as a zootechnical additive in poultry species for fattening, weaned piglets and 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.
- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Implementing Regulation (EU) No 1206/2012 should therefore be amended accordingly.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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 1206/2012 is replaced by the text set out in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 347, 15.12.2012, p. 12.

⁽³⁾ EFSA Journal 2016; 14(8):4564.

Article 2

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 6 January 2018 in accordance with the rules applicable before 6 July 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 15 June 2017.

For the Commission

The President

Jean-Claude JUNCKER

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									
4a1607i	DSM Nutritional Products Ltd	Endo-1,4-beta-xylanase EC 3.2.1.8	Additive composition	Poultry for fattening	—	100FXU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended maximum dose per kilogram of complete feedingstuff for: — poultry for fattening: 200 FXU; — piglets (weaned): 400 FXU; — pigs for fattening: 400 FXU. 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. 4. For use in weaned piglets up to approximately 35 kg.	4 January 2023
			Preparation of endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM 26372) having a minimum activity of: Solid form: 1 000 FXU ⁽¹⁾ /g Liquid form: 650 FXU/ml	Weaned piglets		200FXU			
			Solid form: 1 000 FXU ⁽¹⁾ /g Liquid form: 650 FXU/ml <i>Characterisation of the active substance</i> endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM 26372) <i>Analytical method</i> ⁽²⁾ For quantification of endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM 26372) in a feed additive: — colorimetric method measuring coloured compound produced by the dinitro salicylic acid (DNSA) and the xylosylic moieties released by the action of xylanase on arabinoxylan.	Pigs for fattening		200FXU			

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 %			
			For quantification of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM26372) in premixtures and feedingstuffs: — colorimetric method measuring water soluble dye released by action of xylanase from dye-labelled oat spelt azo-xylan.						

(¹) 1 FXU is the amount of enzyme which liberates 7,8 micromole of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °C.

(²) 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>.