Commission Implementing Regulation (EU) No 1206/2012 of 14 December 2012 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM 10287) as a feed additive for poultry for fattening, weaned piglets and pigs for fattening and amending Regulations (EC) No 1332/2004 and (EC) No 2036/2005 (holder of the authorisation DSM Nutritional Products) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1206/2012

of 14 December 2012

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) as a feed additive for poultry for fattening, weaned piglets and pigs for fattening and amending Regulations (EC) No 1332/2004 and (EC) No 2036/2005 (holder of the authorisation DSM Nutritional Products)

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) A preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus oryzae* (DSM 10287) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening, turkeys for fattening and piglets by Commission Regulation (EC) No 1332/2004[(3)] and authorised for four years for pigs for fattening and ducks by Commission Regulation (EC) No 2036/2005[(4)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus oryzae* (DSM 10287), as a feed additive for chickens and turkeys for fattening, weaned piglets, pigs for fattening and ducks and, in accordance with Article 7 of that Regulation, for a new use for all poultry species for fattening, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1206/2012. (See end of Document for details)*

by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 June 2012[(5)] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus oryzae* (DSM 10287), does not have an adverse effect on animal health, human health or the environment, and that it has a potential to favourably affect animal performance in chickens for fattening, turkeys for fattening and ducks for fattening. This conclusion can be extrapolated to all minor poultry species for fattening. It is also concluded that the additive has the potential to favourably affect animal performance in 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.

(5) The assessment of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus oryzae* (DSM 10287) 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) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC) No 1332/2004 and (EC) No 2036/2005 should therefore be amended accordingly.

(7) 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.

(8) 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

Authorisation

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

Amendments to Regulation (EC) No 1332/2004

Regulation (EC) No 1332/2004 is amended as follows:

(1) Article 1 is replaced by the following:

Article 1

The preparation belonging to the group "Enzymes", as set out in Annex II, is authorised for use without a time limit as additive in animal nutrition under the conditions laid down in that Annex.;

(2) Annex I is deleted.

Article 3

Amendment to Regulation (EC) No 2036/2005

In Annex III to Regulation (EC) No 2036/2005, the entry for No 5, Endo-1,4-beta-xylanase EC 3.2.1.8, is deleted.

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 4 July 2013 in accordance with the rules applicable before 4 January 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1206/2012. (See end of Document for details)*

[F1ANNEX

Textual Amendments

F1 Substituted by 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).

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* Preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) having a minimum activity of: Solid form: 1 000 FXU[a] / g	Poultry for fattening	—	100FXU	—	1. the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. maximum dose per kilogram of complete	4 January 2023
				Weaned piglets		200FXU			
				Pigs for fattening		200FXU			Recommended

a 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.

b 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.]