Commission Implementing Regulation (EU) 2020/995 of 9 July 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM 26372) as a feed additive for lactating sows (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o.o) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/995

of 9 July 2020

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(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 produced by *Aspergillus oryzae* (DSM 26372). That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) as a feed additive for lactating sows, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 3 July 2019[(2)] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) does not have an adverse effect on animal health, consumer safety or the environment. It was also concluded that the additive is considered as a potential respiratory sensitiser and that no conclusion could be drawn on dermal sensitisation potential of the additive. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) showed an effect in improving the apparent faecal digestibility of the energy 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 produced by *Aspergillus oryzae* (DSM 26372) 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 as set out in the 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/995. (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.									
4a1607i	DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o.o	Endo-1,4-beta-xylanase (EC 3.2.1.8)	*Additive composition* Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus oryzae* (DSM 26372) having a minimum activity of: Solid form: 1 000 FXU[a]/g Liquid form: 650 FXU/ml *Characterisation of active substance:* Endo-1,4-beta-	Lactating sows		200 FXU		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures	[X] 30.7.2030

a 1 FXU is the amount of enzyme which liberates 7,8 µmol 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