COMMISSION IMPLEMENTING REGULATION (EU) 2020/1034

of 15 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 laying hens (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o.o)

(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) This application concerns the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) as a feed additive for laying hens, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 26 September 2017 ([2]) and 13 November 2019 ([3]) 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 also concluded that the additive is considered as a potential respiratory sensitiser and that no conclusion could be drawn on dermal sensitisation potential by the additive. 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 also concluded that the additive showed an effect in improving laying performance. 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2017;15(10):5020.
([3]) *EFSA Journal* 2019;17(11):5919.

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, 15 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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 (1)/g Liquid form: 650 FXU/ml ***Characterisation of active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus oryzae* (DSM 26372) ***Analytical method*** (2) For quantification of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (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. For quantification of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) in premixtures and feedingstuffs: — colorimetric method measuring water soluble dye released by action of xylanase from dye-labelled oat spelt azo-xylan.	Laying hens	-	100 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 and organisational measures to address potential risks resulting from their 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 skin, eyes and breathing protection.	5.8.2030

(1) 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.
(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