COMMISSION IMPLEMENTING REGULATION (EU) 2019/1324

of 5 August 2019

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-27588 as a feed additive for chickens for fattening or reared for laying, turkeys for fattening or reared for breeding, minor poultry species for fattening or reared for laying or for breeding, weaned piglets, pigs for fattening and minor porcine species (holder of authorisation Puratos)

(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, applications were submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-27588). Those applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) Those applications concern the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-27588 as a feed additive for chickens for fattening or reared for laying, turkeys for fattening or reared for breeding, minor poultry species for fattening or reared for laying or for breeding, weaned piglets, pigs for fattening and minor porcine species, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 6 July 2017 ([2]) and of 23 January 2019 ([3]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-27588 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 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 improvements of zootechnical performance in chickens for fattening, turkeys for fattening or reared for breeding, weaned piglets and pigs for fattening. The Authority considered that these conclusions can be extrapolated to chickens reared for laying, minor growing poultry species and minor porcine species weaned and 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 produced by *Bacillus subtilis* LMG S-27588 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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2017;15(7):4941.
([3]) *EFSA Journal* 2019;17(2):5609; *EFSA Journal* 2019;17(2):5610.

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.

Done at Brussels, 5 August 2019.

For the Commission

The President

Jean-Claude JUNCKER

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.									
4a30	Puratos	Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition:* Preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-27588 having a minimum activity of: 500 ADXU (1)/g Solid form and liquid form *Characterisation of the active substance:* Endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-27588 *Analytical method* (2) For the quantification of endo-1,4-beta-xylanase activity in the feed additive: — colorimetric method measuring reducing sugars released by action of endo-1,4-beta-xylanase on beechwood xylan substrate in the presence of 3,5-dinitrosalicylic acid (DNS). For the quantification of endo-1,4-beta-xylanase activity in premixtures and feedingstuffs: — colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked arabinoxylan substrates.	Chickens for fattening or reared for laying Turkeys for fattening or reared for breeding Minor poultry species for fattening or reared for laying or breeding Weaned piglets Pigs for fattening Minor porcine species for fattening	—	100 ADXU	—	1. In the directions for use of the additive and premixtures, 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 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 and skin protection.	26 August 2029

(1) One ADXU is the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalent) per minute from beechwood xylan at pH 6,0 and 70 °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