COMMISSION IMPLEMENTING REGULATION (EU) 2020/1377

of 1 October 2020

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) as a feed additive for suckling piglets, all minor porcine species other than reproductive animals (holder of authorisation Beldem, a division of Puratos NV)

(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 *Bacillus subtilis* (LMG S-15136). This 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 *Bacillus subtilis* (LMG S-15136) as a feed additive for all porcine species, to be classified in the additive category 'zootechnical additives'.

(4) The additive was authorised for 10 years by Commission Implementing Regulation (EU) 2017/211 ([2]) for poultry, weaned piglets and pigs for fattening.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 October 2019 ([3]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) 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, in its previous opinion ([4]), concluded that the additive showed improvements of zootechnical performance in weaned piglets and pig for fattening and this conclusion can be extrapolated to all porcine species from suckling to slaughter, but efficacy has not been demonstrated for sows or other porcine species for reproduction. 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.

(6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) 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.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) 2017/211 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Bacillus subtilis (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007 (holder of authorisation Beldem, a division of Puratos NV). OJ L 33, 8.2.2017, p. 23.

([3]) EFSA Journal 2019;17(11):5892.

([4]) EFSA Journal 2016;14(9):4562.

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, subject to the conditions laid down in that 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, 1 October 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
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1606i	Beldem a division of Puratos NV	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-15136 having a minimum activity of: 400 IU (1)/g Solid form and liquid form **Characterisation of the active substance:** Endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-15136 **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 birchwood 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.	Suckling piglets Minor porcine specis other than reproductive animals	-	10 IU	-	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.	22.10.2030

(1) One IU is the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalent) per minute from birchwood xylan at pH 4,5 and 30 °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