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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136 as feed additive for lactating sows (holder of the authorisation Beldem, division of Puratos NV)

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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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 nutrition¹, 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. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* LMG-S 15136 as a feed additive for lactating sows to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 7 October 2019² and 27 January 2021³ 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. The Authority concluded that that additive should be considered a respiratory sensitiser and a potential dermal sensitiser. 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 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 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.

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2019;17(11):5892.

³ EFSA Journal 2021;19(3):6456.

- (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, 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,

For the Commission
The President
Ursula VON DER LEYEN