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

of XXX

concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for all avian species for fattening other than chickens for fattening and all weaned porcine species and for fattening other than weaned piglets and pigs for fattening (holder of authorisation Berg und Schmidt GmbH Co. KG)

(Text with EEA relevance)

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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) The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) was authorised for 10 years by Commission Implementing Regulation (EU) No 2018/130² for pigs for fattening and by Commission Implementing Regulation (EU) No 2019/929³ for chickens for fattening and weaned piglets.
- (3) 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 (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for all avian species for fattening and all weaned porcine species and for fattening, to be classified in the additive category 'zootechnical additives'.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 July 2019⁴ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive should be regarded as a potential skin and a respiratory sensitiser. Therefore, appropriate protective measures should be taken to

¹ OJ L 268, 18.10.2003, p. 29.

² OJ L 22, 26.1.2018, p.120.

³ OJ L 148, 6.6.2019, p.25.

⁴ EFSA Journal 2019;17(7):5781.

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prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded in its previous opinions⁵ that the additive has the potential to be efficacious improving of the zootechnical performance in chickens for fattening, weaned piglets and pigs for fattening and these conclusions can be extrapolated to the all bird for fattening and ornamental bird and to all weaned porcine species 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.

- (6) The assessment of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) 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,

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

⁵ EFSA Journal 2017;15(2):4707 and EFSA Journal 2018;16(10):5457.