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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 chickens for fattening and weaned piglets (holder of authorisation Berg and 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 nutrition<sup>1</sup>, 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 (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.
- (3) The 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 chickens for fattening and weaned piglets to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 25 January 2017<sup>2</sup> and 2 October 2018<sup>3</sup> 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 was also concluded that the additive may have a skin and respiratory sensitisation potential. 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 concluded that the additive is considered efficacious in improving final body weight and feed to gain ratio in chickens for fattening and weaned piglets. 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.

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OJ L 268, 18.10.2003, p. 29.

<sup>&</sup>lt;sup>2</sup> EFSA Journal 2017;15(2):4707

<sup>&</sup>lt;sup>3</sup> EFSA Journal 2018;16(10):5457.

(5)

- (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 Jean-Claude JUNCKER