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

of **XXX**

concerning the authorisation of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094 as a feed additive for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding (holder of authorisation: Fertinagro Biotech S.L.)

(Text with EEA relevance)

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(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 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, two applications were submitted for the authorisation of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the extension of use of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094 as a feed additive for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding, 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 January 2020² and 28 January 2020³ that, under the proposed conditions of use, 3-phytase produced by *Komagataella phaffii* CECT 13094 does not have an adverse effect on the health of pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding, consumers safety or the environment. It was also concluded that both formulations of the additive should be considered as a respiratory sensitiser and the solid formulation as a 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 concluded that the additive is efficacious as a zootechnical additive in improving the digestibility of the diets in for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding. The Authority does not consider that there is a need

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2020;18(7):6205.

³ EFSA Journal 2020;18(6):6015.

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 3-phytase shows that the conditions for authorisation of 3-phytase produced by *Komagataella phaffii* CECT 13094, 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,

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