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

of **XXX**

concerning the authorisation of a preparation of 6-phytase, produced by *Komagataella phaffii* (CGMCC 12056) as feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species (suckling and weaned) (holder of the authorisation Andrés Pinaluba S.A)

(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) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of 6-phytase, produced by *Komagataella phaffii* (CGMCC 12056). That 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 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) as a feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 7 October 2019² that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) 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 respiratory 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 showed improvements on the phosphorus utilisation and content. This conclusion can be extended to turkeys reared for breeding. 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.

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2019;17(11)5893 and EFSA Journal 2019;17(11)5894.

- (5) The assessment of the preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) 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.
- (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