



Brussels, XXX
SANTE/7830903/2025 CIS
(POOL/G5/2025/7830903/7830903-EN
CIS.docx)
[...] (2025) XXX draft

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

of XXX

concerning the authorisation of a preparation of 6-phytase produced with *Komagataella phaffii* CGMCC 7.370 as a feed additive for porcine species, poultry and ornamental birds (holder of authorisation: Victory Enzymes GmbH)

(Text with EEA relevance)

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

of **XXX**

concerning the authorisation of a preparation of 6-phytase produced with *Komagataella phaffii* CGMCC 7.370 as a feed additive for porcine species, poultry and ornamental birds (holder of authorisation: Victory Enzymes GmbH)

(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 an 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 with *Komagataella phaffii* CGMCC 7.370. 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 6-phytase produced with *Komagataella phaffii* CGMCC 7.370 as a feed additive for all avian species and ornamental, exotic and game birds and all pigs, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 November 2022² that, under the proposed conditions of use, the preparation of 6-phytase produced with *Komagataella phaffii* CGMCC 7.370 is safe for all Suidae and all avian species, as well as for the consumers and the environment. The Authority also concluded that the additive in both formulations, powder and liquid, is considered to be non-irritant to skin or eyes but should be considered a skin and respiratory sensitiser. Furthermore, it concluded that the additive has the potential to be efficacious in laying hens at 1,000 U phytase/kg complete feed and this conclusion can be extrapolated to other birds for egg production or breeding. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 26 June 2025³ that the additive has a potential to be efficacious as a zootechnical additive for all poultry for fattening and reared for laying/breeding and for reproductive porcine

¹ OJ L 268, 18.10.2003, p. 29. ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² EFSA Journal 2022;20(12):7701. <https://doi.org/10.2903/j.efsa.2022.7701>.

³ EFSA Journal. 2025;23:e9556. <https://doi.org/10.2903/j.efsa.2025.9556>.

Feltkode ændret

species at 500 U phytase/kg complete feed and for all porcine species for fattening and reared for reproduction at 750 U phytase/kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) In view of the above, the Commission considers that the preparation of 6-phytase produced with *Komagataella phaffii* CGMCC 7.370 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for porcine species, poultry and ornamental birds. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (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

Authorisation

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

Entry into force

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