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[...] (2024) **XXX** draft

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

**of XXX**

**concerning the authorisation of a preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 as a feed additive for all poultry species for fattening or reared for laying and ornamental birds (holder of authorisation: Nutrex N.V.)**

(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 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 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 by *Komagataella phaffii* CGMCC 7.19 as a feed additive. 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 by *Komagataella phaffii* CGMCC 7.19 as a feed additive for chickens for fattening, other poultry species for fattening or reared for laying and ornamental birds, 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 30 September 2020<sup>2</sup> that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 in the thermostable granulate formulation and in the granulate formulation is safe for consumers and the environment. The Authority also concluded that the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 in all its formulations, is not a skin or eye irritant and is not dermal sensitiser. However, owing to the proteinaceous nature of the active substance, it should be considered a respiratory sensitiser. The Authority concluded in its opinion of 4 May 2022<sup>3</sup> that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 in the powder formulation and in the liquid formulation is safe for consumers and the environment. It also stated that the preparation of 6-phytase produced by

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

<sup>2</sup> EFSA Journal 2020;18(11):6282.

<sup>3</sup> EFSA Journal 2022;20(6):7343.

*Komagataella phaffii* CGMCC 7.19 in all its formulations is safe for chickens for fattening, other poultry species for fattening or reared for laying and ornamental birds. The Authority further concluded in its opinion of 27 September 2023<sup>4</sup> that the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 has the potential to be efficacious for chickens for fattening, other poultry for fattening or reared for laying and ornamental birds, at the minimum recommended level of 500 FTU/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 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) In view of the above, the Commission considers that the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening or reared for laying 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

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<sup>4</sup> EFSA Journal 2023;21(0):8345.