



Brussels, XXX
SANTE/5278712/2026 CIS
(POOL/G5/2026/5278712/5278712-EN
CIS.docx)
[...] (2026) XXX draft

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

of XXX

concerning the renewal of the authorisation of a preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375 as a feed additive for poultry species, ornamental birds, weaned piglets, pigs for fattening, sows and minor porcine species (holder of authorisation: Kaesler Nutrition GmbH) and repealing Implementing Regulation (EU) 2016/329

(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 and renewing such an authorisation.
- (2) A preparation of 6-phytase produced with *Komagataella phaffii* (formerly *Komagataella pastoris*) DSM 25375, was authorised for 10 years as a feed additive for all avian species and for weaned piglets, pigs for fattening, sows and minor porcine species by Commission Implementing Regulation (EU) 2016/329².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375 as a feed additive for chickens for fattening and reared for laying, all avian species for fattening and reared for laying other than turkeys for fattening and reared for breeding, all avian species for laying, turkeys for fattening and reared for breeding, weaned piglets, pigs for fattening, sows and minor porcine species, requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2026³ that the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375 remains safe for the target animals (all poultry species, weaned piglets,

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

² Commission Implementing Regulation (EU) 2016/329 of 8 March 2016 concerning the authorisation of 6-phytase as a feed additive for all avian species and for weaned piglets, pigs for fattening, sows and minor porcine species (holder of the authorisation Kaesler Nutrition GmbH) (OJ L 62, 9.3.2016, pp. 5, ELI: http://data.europa.eu/eli/reg_impl/2016/329/2017-12-25).

³ EFSA Journal. 2026;24:e10116. <https://doi.org/10.2903/j.efsa.2026.10116>.

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pigs for fattening, sows and minor porcine species), the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375, in its solid formulation is not a skin or eye irritant but is a dermal and respiratory sensitiser. The liquid formulation is considered a skin and eye irritant and a respiratory sensitiser. Exposure of users to both forms of the additive by any route is considered a risk. It also indicated that there is no need to assess the efficacy of the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375, as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation which would have an impact on the efficacy of the additive. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out by the Authority in its opinion of 17 June 2015⁴ regarding the method of analysis of 6-phytase as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁵, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375 as a feed additive, Implementing Regulation (EU) 2016/329 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of 6-phytase produced with *Komagataella phaffii* DSM 25375 for chickens for fattening and reared for laying, all avian species for fattening and reared for laying other than turkeys for fattening and reared for breeding, all avian species for laying, turkeys for fattening and reared for breeding, weaned piglets, pigs for fattening, sows and minor porcine species, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ EFSA Journal 2015;13(7):4159. <https://doi.org/10.2903/j.efsa.2015.4159>.

⁵ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 059 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Implementing Regulation (EU) 2016/329 is repealed.

Article 3

Transitional measures

1. The feed additive 6-phytase produced with *Komagataella pastoris* DSM 25375, as authorised by Implementing Regulation (EU) 2016/329 and premixtures containing that additive, which are intended for all avian species and for weaned piglets, pigs for fattening, sows and minor porcine species, and which are produced and labelled before [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for all avian species and for weaned piglets, pigs for fattening, sows and minor porcine species, and which are produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 4

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