



2025/1392

16.7.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1392

of 15 July 2025

concerning the authorisation of a preparation of 3-phytase produced with *Komagataella phaffii* CECT 13171 as a feed additive for poultry species for fattening or reared for laying or for breeding, minor poultry species for breeding, laying hens and pigs for fattening of all Suidae species (holder of authorisation: Fertinagro Biotech S.L.)

(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 ⁽¹⁾, 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 3-phytase produced with *Komagataella phaffii* CECT 13171. 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 the preparation of 3-phytase produced with *Komagataella phaffii* CECT 13171 as a feed additive for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening, minor poultry species for breeding, minor poultry species reared for laying, pigs for fattening and minor porcine species for fattening, 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 opinions of 27 September 2022 ⁽²⁾ and 17 September 2024 ⁽³⁾ that, under the proposed conditions of use, the preparation 3-phytase produced with *Komagataella phaffii* CECT 13171 in its both liquid and solid formulations is considered safe for the target species, consumers and environment. Regarding the safety for the user, the Authority concluded that the preparation 3-phytase produced with *Komagataella phaffii* CECT 13171 in either form is not an irritant to the eyes and skin. It further stated that the liquid formulation of the preparation is not a dermal sensitiser, while its solid formulation is a dermal sensitiser, and that the two formulations should be considered potential respiratory sensitisers. The Authority concluded that the preparation 3-phytase produced with *Komagataella phaffii* CECT 13171 is efficacious at 500 FTU/kg feed in poultry species for fattening or reared for laying or breeding, pigs for fattening and minor porcine species for fattening and at 1 000 FTU/kg feed in laying hens. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive are valid and applicable for the current application.

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

⁽²⁾ EFSA Journal 2022; 20(11):7614, <https://doi.org/10.2903/j.efsa.2022.7614>.

⁽³⁾ EFSA Journal 2024; 22:e9023, <https://doi.org/10.2903/j.efsa.2024.9023>.

⁽⁴⁾ 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 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

- (6) In view of the above, the Commission considers that the preparation of 3-phytase produced with *Komagataella phaffii* CECT 13171 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 poultry species for fattening or reared for laying or for breeding, minor poultry species for breeding, laying hens and pigs for fattening of all Suidae species. 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.
- (7) 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, 15 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a50	Fertinagro Biotech S.L.	3-phytase (EC 3.1.3.8)	<i>Additive composition</i> Preparation of 3-phytase produced with <i>Komagataella phaffii</i> CECT 13171 having a minimum activity of: Solid form: 10 000 FTU ⁽¹⁾ /g Liquid form: 1 000 FTU/mL.	Poultry species for fattening or reared for laying or for breeding	—	500 FTU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and	5 August 2035
			<i>Characterisation of the active substance</i> 3-phytase produced with <i>Komagataella phaffii</i> CECT 13171. <i>Analytical method</i> ⁽²⁾ For the quantification of 3-phytase activity in the feed additive, premixtures and compound feed: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024.	Minor poultry species for breeding Pigs for fattening of all Suidae species		Laying hens			

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
								measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	

(¹) 1 FTU is the amount of enzyme that releases 1 µmol of inorganic phosphate from sodium phytate per minute at 37 °C and pH 5,5.

(²) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.