

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1799**of 30 November 2020****concerning the authorisation of a preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 as a feed additive for laying hens and other laying birds (holder of authorisation: Andrés Pintaluba S.A.)****(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 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. 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 12056 as a feed additive for laying hens and other laying birds to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 May 2020 ⁽²⁾ 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 the health of laying hens and other laying birds, consumer safety or the environment. It was also concluded that the additive should be considered as a potential 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 is efficacious as a zootechnical additive in improving the digestibility of the diets in laying hens and other laying birds. 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.
- (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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(5): 6142.

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, 30 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a31	Andrés Pintaluba S.A.	6-phytase (EC 3.1.3.26)	<p><i>Additive composition</i></p> <p>Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> (CGMCC 12056) having a minimum activity of: Solid form: 20 000 U ⁽¹⁾/g Liquid form: 20 000 U/ml</p> <p><i>Characterisation of the active substance</i></p> <p>6-phytase (EC 3.1.3.26) produced by fermentation with <i>Komagataella phaffii</i> CGMCC 12056</p> <p><i>Analytical method ⁽²⁾</i></p> <p>For the quantification of phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4</p> <p>For the quantification of phytase activity in premixtures: — colorimetric method based on the enzymatic reaction of phytase on the phytate -VDLUFA 27.1.3</p> <p>For the quantification of phytase activity in feed materials and compound feed: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024</p>	laying hens and other laying birds	-	300 U	-	<ol style="list-style-type: none"> 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 potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 	21.12.2030
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⁽¹⁾ One unit is the amount of enzyme which releases one micromole of inorganic phosphate from phytate per minute at pH 5,5 and 37 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>