COMMISSION IMPLEMENTING REGULATION (EU) 2020/150

of 4 February 2020

concerning the authorisation of the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 as a feed additive for chickens for fattening, chickens reared for laying and for breeding and minor poultry species for fattening or reared for laying or for breeding purposes (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 produced by *Komagataella phaffii* CGMCC 12056. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of a preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding purposes to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 ([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 animal health, consumer safety or the environment. It also concluded that the additive may have respiratory sensitisation potential. 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. It concluded that the additive has the potential to improve the utilisation of the phosphorus. 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* 2019; 17(4):5692.

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, 4 February 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 Unit of activity/kg of complete feedingstuff with a moisture content of 12 %		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a31	Andrés Pintaluba S.A.	6-phytase EC 3.1.3.26	**Additive composition** Preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella phaffii* CGMCC 12056, having a minimum activity of: Solid form: 20 000 U (1)/g Liquid form: 20 000 U/ml **Characterisation of the active substance** 6-phytase produced by *Komagataella phaffii* CGMCC 12056 **Analytical method** (2) 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; For the quantification of phytase activity in premixtures: colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.3; For the quantification of phytase activity in feedingstuffs: colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024.	Chickens for fattening Chickens reared for laying and breeding Minor poultry species for fattening or reared for laying or for breeding purposes	-	250 U		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.	25 February 2030

(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