REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/144

of 28 January 2019

concerning the authorisation of a preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094) as a feed additive for chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding (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 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 by *Komagataella pastoris* (CECT 13094). 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 3-phytase produced by *Komagataella pastoris* (CECT 13094) as a feed additive for chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding to be classified in the additive category 'zootechnical additives'.

(4) The preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094) belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for chickens for fattening and laying hens by Commission Implementing Regulation (EU) 2017/895 ([2]).

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 February 2018 ([3]) that, under the proposed conditions of use, 3-phytase produced by *Komagataella pastoris* (CECT 13094) does not have an adverse effect on animal health, human health or the environment. It has also concluded that the additive has a potential to be efficacious in improving phosphorus retention in chickens for fattening and that conclusion can be extended to chickens reared for laying. Since the mode of action can reasonably be assumed to be the same in poultry species, the Authority has extrapolated the conclusion on the efficacy to minor poultry species for fattening and reared for laying or breeding purposes. 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.

(6) The assessment of the 3-phytase shows that the conditions for authorisation of 3-phytase produced by *Komagataella pastoris* (CECT 13094), 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.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Implementing Regulation (EU) 2017/895 of 24 May 2017 concerning the authorisation of a preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094) as a feed additive for chickens for fattening and laying hens (holder of authorisation Fertinagro Nutrientes S.L.) (OJ L 138, 25.5.2017, p. 120).
([3]) *EFSA Journal* 2018;16(3):5203.

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.

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, 28 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a25	Fertinagro Nutrientes S.L.	3-phytase EC 3.1.3.8	*Additive composition:* Preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094) having a minimum activity of: 1 000 FTU (1)/ml Liquid form *Characterisation of the active substance:* 3-phytase (EC 3.1.3.8) produced by *Komagataella pastoris* (CECT 13094) *Analytical method* (2) For the quantification of 3-phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate For the quantification of 3-phytase activity in feedingstuffs: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024	Chickens reared for laying Minor 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 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.	20 February 2029

(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate 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