

COMMISSION IMPLEMENTING REGULATION (EU) 2020/172

of 6 February 2020

concerning the renewal of the authorisation of 3-phytase produced by *Aspergillus niger* (CBS 101.672) as a feed additive for piglets (weaned), pigs for fattening, sows, chickens for fattening, turkeys for fattening, laying hens, ducks and all other minor avian species, ornamental birds and the new authorisation for chickens reared for laying or for breeding purposes, turkeys reared for breeding or breeding hens and suckling piglets and repealing Regulations (EC) No 243/2007, (EC) No 1142/2007, (EC) No 165/2008, (EC) No 505/2008 and (EU) No 327/2010 (holder of authorisation BASF SE)

(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 and renewing such authorisation.
- (2) 3-phytase produced by *Aspergillus niger* (CBS 101.672) was authorised for 10 years as a feed additive for piglets (weaned), pigs for fattening and chickens for fattening by Commission Regulation (EC) No 243/2007 ⁽²⁾, for laying hens and turkeys for fattening by Commission Regulation (EC) No 1142/2007 ⁽³⁾, for ducks by Commission Regulation (EC) No 165/2008 ⁽⁴⁾, for sows by Commission Regulation (EC) No 505/2008 ⁽⁵⁾, and for minor avian species, other than ducks, and for ornamental birds by Commission Regulation (EU) No 327/2010 ⁽⁶⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation for the renewal of the authorisation of 3-phytase produced by *Aspergillus niger* (CBS 101.672) as a feed additive for piglets (weaned), pigs for fattening, sows, chickens for fattening, laying hens, turkeys for fattening, ducks and other minor avian species and ornamental birds, and for a new use for chickens reared for laying or for breeding purposes, turkeys reared for breeding or breeding hens and suckling piglets requesting that additive to be classified in the additive category 'zootechnical additives' That application was accompanied by the particulars and documents required under Articles 7(3) and 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 February 2019 ⁽⁷⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority also concluded that the additive does not have adverse effect on animal health and the environment. It was also concluded that the additive is a respiratory sensitiser and should be considered as a potential skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effect on human health, in particular as regards the users of feed additives. The Authority also concluded

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 243/2007 of 6 March 2007 concerning the authorisation of 3-phytase (Natuphos) as a feed additive (OJ L 73, 13.3.2007, p. 4).

⁽³⁾ Commission Regulation (EC) No 1142/2007 of 1 October 2007 concerning the authorisation of a new use of 3-phytase (Natuphos) as a feed additive (OJ L 256, 2.10.2007, p. 20).

⁽⁴⁾ Commission Regulation (EC) No 165/2008 of 22 February 2008 concerning the authorisation of a new use of 3-phytase (Natuphos) as a feed additive (OJ L 50, 23.2.2008, p. 8).

⁽⁵⁾ Commission Regulation (EC) No 505/2008 of 6 June 2008 concerning the authorisation of a new use of 3-phytase (Natuphos) as a feed additive (OJ L 149, 7.6.2008, p. 33).

⁽⁶⁾ Commission Regulation (EU) No 327/2010 of 21 April 2010 concerning the authorisation of a new use of 3-phytase as a feed additive for all minor avian species, other than ducks, and for ornamental birds (holder of authorisation BASF SE), (OJ L 100, 22.4.2010, p. 3).

⁽⁷⁾ EFSA Journal 2019;17(3):5640.

that the additive is efficacious in improving digestibility of feed for chickens reared for laying or for breeding purposes, turkeys reared for breeding or breeding hens and suckling piglets. 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 3-phytase produced by *Aspergillus niger* (CBS 101.672) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of 3-phytase produced by *Aspergillus niger* (CBS 101.672) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 243/2007, (EC) No 1142/2007, (EC) No 165/2008, (EC) No 505/2008 and (EU) No 327/2010 should be repealed.
- (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

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers' is authorised and renewed as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Regulations (EC) No 243/2007, (EC) No 1142/2007, (EC) No 165/2008, (EC) No 505/2008 and (EU) No 327/2010 are repealed.

Article 3

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, 6 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	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									
4a1600	BASF SE	3-phytase EC 3.1.3.8	<i>Additive composition</i> 3-phytase produced by <i>Aspergillus niger</i> (CBS 101.672) having a minimum activity of: Solid form: 5 000 FTU ⁽¹⁾ /g Liquid form: 5 000 FTU/ml <i>Characterisation of the active substance</i> 3-phytase produced by <i>Aspergillus niger</i> (CBS 101.672) <i>Analytical method</i> ⁽²⁾ Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate.	Piglets (suckling and weaned) Sows	-	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 and skin protection.	27.2.2030
				Pigs for fattening	-	100 FTU			
				Chickens for fattening Chickens reared for laying/breeding	-	375 FTU			
				Laying hens Turkeys for fattening Turkeys reared for breeding and breeding hens Ornamental birds and all minor avian species, other than ducks	-	250 FTU			
				Ducks	-	300 FTU			

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