## **COMMISSION IMPLEMENTING REGULATION (EU) 2020/166**

# of 5 February 2020

concerning the renewal of the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, weaned piglets, pigs for fattening and sows and repealing Regulation (EC) No 785/2007 (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)

(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) The preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) was authorised for 10 years as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, and sows by Commission Regulation (EC) No 785/2007 (<sup>2</sup>).
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of the preparation of 6-phytase produced by *Schizosac-charomyces pombe* (ATCC 5233) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, weaned piglets, pigs for fattening and sows requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 April 2019 (3) that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.
- (5) The assessment of the preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) 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 the preparation of 6-phytase produced by *Schizosac-charomyces pombe* (ATCC 5233) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 785/2007 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,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(\*)</sup> Commission Regulation (EC) No 785/2007 of 4 July 2007 concerning the authorisation of 6-phytase EC 3.1.3.26 (Phyzyme XP 5000G Phyzyme XP 5000L) as a feed additive (OJ L 175, 5.7.2007, p. 5).

<sup>(3)</sup> EFSA Journal 2019;17(5):5701.

HAS ADOPTED THIS REGULATION:

## Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

### Article 2

Regulation (EC) No 785/2007 is 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, 5 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  Unit of acticomplete feedi moisture con	ngstuff with a	Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1640	Danisco (UK) Ltd, trading as Danisco Ani- mal Nutrition and repre- sented by Genencor In- ternational B. V.		Additive composition Preparation of 6-phytase (EC 3.1.3.26) produced by Schizosaccharomyces pombe (ATCC 5233) having a minimum activity of: 5 000 FTU (¹) /g Solid coated and liquid form  Characterisation of the active substance: 6-phytase (EC 3.1.3.26) produced by Schizosaccharomyces pombe (ATCC 5233)  Analytical method (²) Determination of 6-phytase EC 3.1.3.26 in feed additive: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate. Determination of 6-phytase EC 3.1.3.26 in feed premixtures and feedingstuff: EN ISO 30024: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate (after dilution with heat-treated whole grain flour).	Chickens for fattening Turkeys for fattening Ducks for fattening Laying hens Piglets (weaned) Pigs for fattening Sows	_	250 FTU  150 FTU  250 FTU  500 FTU	— —	<ol> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>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.</li> </ol>	

ANNEX

<sup>(</sup>¹) One FTU is the amount of enzyme which liberates one 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