Commission Implementing Regulation (EU) 2020/164 of 5 February 2020 concerning the authorisation of 6-phytase produced by Schizosaccharomyces pombe (ATCC 5233) as a feed additive for all avian species and all swine species and repealing Regulation (EC) No 379/2009 (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/164

of 5 February 2020

concerning the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species and all swine species and repealing Regulation (EC) No 379/2009 (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) 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 379/2009[(2)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, in conjunction with Article 7 of that Regulation, an application was submitted by the holder of that authorisation for the renewal of the authorisation of 6-phytase produced by Schizosaccharomyces pombe (ATCC 5233) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows, requesting that additive to be classified in the additive category ‘zootechnical additives’ and for a new use for all avian species for fattening other than chickens, turkeys and ducks and all avian species for laying other than hens and for all avian species reared for laying and breeding, suckling piglets and minor porcine species. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 April 2019[3] that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. It was also concluded that the additive 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. The Authority concluded that the additive is efficacious in improving digestibility of feed for all avian species for fattening, for laying, reared for laying or for breeding purposes, and for all swine species. 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 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 for use 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 6-phytase produced by Schizosaccharomyces pombe (ATCC 5233) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 379/2009 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

Authorisation

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 as additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Repeal of Regulation (EC) No 379/2009

Regulation (EC) No 379/2009 is repealed.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/164. (See end of Document for details)*

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/164. (See end of Document for details)*

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 Unit of activity/kg of complete feedingstuff with a moisture content of 12 %	Maximum content	Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1640	Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.	6-phytase EC 3.1.3.26	**Additive composition** Preparation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) having a minimum activity of:10 000 FTU [a] / g Liquid and solid coated form --- **Characterisation of the active substance:** 6-phytase (EC 3.1.3.26)	All avian species other than laying birds	—	250 FTU	—	1. 2.	26 February 2030
				All avian species for laying	—	150 FTU	—		
				Piglets (weaned) Pigs for fattening	—	250 FTU	—		
				All porcine species other than weaned piglets and pigs for fattening	—	500 FTU	—		

1. Conditions 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

a 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.

b 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.