Commission Implementing Regulation (EU) No 840/2012 of 18 September 2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by Schizosaccharomyces pombe (ATCC 5233) as a feed additive for all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens (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) No 840/2012

of 18 September 2012

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens (holder of authorisation **[**[F1]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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233). The 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 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens, to be classified in the additive category ‘zootechnical additives’.

(4) The use of preparations of 6-phytase EC 3.1.3.26 was authorised for 10 years for chickens for fattening, turkeys for fattening, laying hens, piglets (weaned), ducks for fattening, pigs for fattening and sows by Commission Regulations (EC) No 785/2007[(2)] and (EC) No 379/2009[(3)].

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 840/2012. (See end of Document for details)*

(5) New data were submitted in support of the application for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) for use as feed additive to all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens. The European Food Safety Authority ('the Authority') concluded in its opinion of 7 March 2012[(4)] that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus utilisation in all target 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.

(6) The assessment of 6-phytase (EC 3.1.3.26) 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 use of this 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/221 of 6 February 2019 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives (Text with EEA relevance).

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 840/2012. (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 Units 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	[F1Danisco (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 *Saccharomyces cerevisiae* (ATCC 5233) containing a minimum activity of: Liquid and solid form: 5 000 FTU/g *Characterisation of the active substance* 6-phytase (EC	All species and categories	—	250 FTU		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in compound feed containing more than 0,23 % phytin-bound phosphorus. 3. Maximum recommended dose: 1 000	9 October 2022
				All species and categories other than laying hens		150 FTU			

a 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.

b Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx