Commission Regulation (EU) No 221/2011 of 4 March 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by Aspergillus oryzae DSM 14223 as a feed additive for salmonids (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 221/2011

of 4 March 2011

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for salmonids (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o)

(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 the enzyme preparation 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223. That application was accompanied by the particulars and documents required pursuant to 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 *Aspergillus oryzae* DSM 14223 as a feed additive for salmonids, to be classified in the additive category ‘zootechnical additives’.

(4) Its use was also provisionally authorised for salmonids by Commission Regulation (EC) No 521/2005[(2)].

(5) New data were submitted in support of the application for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 for salmonids. The European Food Safety Authority (‘the Authority’) concluded in its opinion of 10 November 2010[(3)] that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus utilisation. 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 European Union Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(6) The assessment of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 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) In the interest of clarity, the entry on 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 in Regulation (EC) No 521/2005 should be deleted.

(8) 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:

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

In Regulation (EC) No 521/2005, Article 2 and Annex II are deleted.

Article 3

This Regulation shall enter into force on the 20th day following 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, 4 March 2011.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 221/2011. (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**	**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									
4a1641(i)	DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o	6-phytase (EC 3.1.3.26)	*Additives composition* Preparation of 6-phytase produced by *Aspergillus oryzae* DSM 14223 having a minimum activity of: liquid form: 20 000 FYT[a]/g *Characterisation of the active substance* 6-phytase produced by *Aspergillus oryzae*	*Swine*	—	750 FYT	—	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 feed containing more than 0,23 % phytin-bound phosphorus. 3. For safety: breathing protection,	25 March 2021

a One FYT is the amount of enzyme that releases 1 μmol of inorganic phosphate from sodium phytate per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and a temperature of 37 °C during 30 minutes incubation.

b Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives