

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1342

of 30 June 2023

concerning the renewal of the authorisation of a preparation of 6-phytase produced by *Aspergillus oryzae* DSM 33699 as a feed additive for poultry, pigs for fattening, weaned piglets and sows (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.) and repealing Implementing Regulation (EU) No 837/2012

(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 *Aspergillus oryzae* DSM 22594 was authorised for 10 years as a feed additive for poultry, weaned piglets, pigs for fattening and sows by Commission Implementing Regulation (EU) No 837/2012 ⁽²⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of 6-phytase produced by *Aspergillus oryzae* DSM 33699 as a feed additive for poultry, pigs for fattening, weaned piglets and sows in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application requested to change the production strain, substituting the strain *Aspergillus oryzae* DSM 22594 for *Aspergillus oryzae* DSM 33699, and 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 22 November 2022 ⁽³⁾ that new production strain *Aspergillus oryzae* DSM 33699 does not give rise to safety concerns and that, under the proposed conditions of use, the preparation of 6-phytase produced by *Aspergillus oryzae* DSM 33699 is safe for the target species, for consumers and the environment. As regards safety for the users when handling the preparation, due to the absence of data on the final formulations, the Authority could not conclude on the potential of the additive to be irritant to eyes or skin or to be a skin sensitiser but considered that the additive is a respiratory sensitiser. The Authority finally concluded that the additive has the potential to be efficacious in poultry, pigs for fattening, weaned piglets and sows at the minimum recommended level of 500 FYT/kg complete feed.
- (5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) No 837/2012 of 18 September 2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) as feed additive for poultry, weaned piglets, pigs for fattening and sows (holder of authorisation DSM Nutritional Products) (OJ L 252, 19.9.2012, p. 7).⁽³⁾ EFSA Journal 2023;21(1):7698.⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (6) The assessment of the preparation of 6-phytase produced by *Aspergillus oryzae* DSM 33699 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed.
- (7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) As a consequence of the renewal of the authorisation of the preparation of 6-phytase produced by *Aspergillus oryzae* DSM 33699 as a feed additive, Implementing Regulation (EU) No 837/2012 should be repealed.
- (10) 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

Renewal of the authorisation

The authorisation of the preparation of 6-phytase produced by *Aspergillus oryzae* DSM 33699, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in the Annex.

Article 2

Repeal of Implementing Regulation (EU) No 837/2012

Implementing Regulation (EU) No 837/2012 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 23 January 2024 in accordance with the rules applicable before 23 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 23 July 2024 in accordance with the rules applicable before 23 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 June 2023.

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	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

4a18i	DSM Nutritional Products Ltd., represented by DSM Nutritional Products Sp. z o.o.	6-phytase (EC 3.1.3.26)	Additive composition Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Aspergillus oryzae</i> DSM 33699 with a minimum activity of: 10 000 FYT ⁽¹⁾/g in solid form, 20 000 FYT/g in liquid form Characterisation of the active substance 6-phytase (EC 3.1.3.26) produced by <i>Aspergillus oryzae</i> DSM 33699 Analytical method ⁽²⁾ For the quantification of phytase activity in the feed additive: colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4; For the quantification of phytase activity in premixtures: colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.3; For the quantification of phytase activity in compound feeds: colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024.	Poultry Piglets (weaned) Pigs for fattening Sows	—	500 FYT	—	1. In the directions for use of the additive and premixture, the storage temperature, storage life, 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	23 July 2033
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⁽¹⁾ 1 FYT is the amount of enzyme which liberates 1 µmol of inorganic phosphate from phytate per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and 37 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.
