EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for poultry for laying or reproduction, piglets of porcine species, porcine species for fattening and porcine species reared for reproduction (holder of authorisation: Novonesis)

(Text with EEA relevance)

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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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737. That 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 the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry, all *Suidae* and all fin fish requesting the additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 February 2024[2] that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 is safe for all poultry, all *Suidae* and all fin fish at the highest proposed use level of 4000 FYT/kg complete feed, as well as for the consumers and the environment. The Authority also concluded that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737, in the final formulations of the additive, is not a skin irritant. The two liquid formulations of the additive are not eye irritants, while the two solid ones are considered eye irritants. The Authority was not able to conclude on the skin sensitisation of the final formulations of the additive. Due to the proteinaceous nature of the active substance (6-phytase), the additive is considered a respiratory sensitiser. However, exposure by inhalation is considered unlikely. The Authority further concluded that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 has the potential to be efficacious in all poultry for fattening and reared for laying or breeding and in all reproductive *Suidae* at the minimum proposed use

[1] OJ L 268, 18.10.2003, p. 29. ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[2] *EFSA Journal.* 2024;22:e8663. https://doi.org/10.2903/j.efsa.2024.8663.

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level of 200 FYT/kg complete feed and in all fin fish at the minimum proposed use level of 1 000 FYT/kg complete feed and an authorisation for use in feed for these species was granted by Commission Implementing Regulation (EU) 2024/2177[3]. Due to the lack of sufficient data, the Authority was not able to conclude on the efficacy for laying and reproductive poultry, and for Suidae for fattening or reared for reproduction. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 18 September 2025[4] that the additive has the potential to be efficacious in all poultry and all porcine species at the minimum proposed use level of 200 FYT/kg complete feed. The Authority did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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) In view of the above, the Commission considers that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for poultry for laying or reproduction, piglets of porcine species and porcine species for fattening or reared for reproduction. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(6) 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 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
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.

[3] Commission Implementing Regulation (EU) 2024/2177 of 2 September 2024 concerning the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding, sows of all Suidae species and all fin fish (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.) (OJ L, 2024/2177, 3.9.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2177/oj).

[4] *EFSA Journal.* 2025;23:e9696. https://doi.org/10.2903/j.efsa.2025.9696.

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Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN