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COMMISSION

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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**concerning the authorisation of a preparation of *Saccharomyces cerevisiae* DSM 34246  
as a feed additive for dogs and cats (holder of authorisation: ACEL pharma s.r.l.)**

(Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) .../...

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### concerning the authorisation of a preparation of *Saccharomyces cerevisiae* DSM 34246 as a feed additive for dogs and cats (holder of authorisation: ACEL pharma s.r.l.)

(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<sup>1</sup>, 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 *Saccharomyces cerevisiae* DSM 34246. 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 a preparation of *Saccharomyces cerevisiae* DSM 34246 as a feed additive for dogs and cats, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 April 2024<sup>2</sup> that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* DSM 34246 is safe for dogs and cats. Furthermore, it stated that there is no need to perform an assessment of the safety for the consumer or the environment because the additive is intended to be used only in feed for cats and dogs. It also concluded that the preparation of *Saccharomyces cerevisiae* DSM 34246 is not a skin or eye irritant but should be considered a skin and respiratory sensitiser. The Authority further concluded that the preparation of *Saccharomyces cerevisiae* DSM 34246, has the potential to be efficacious as a zootechnical additive for dogs and cats when added to feed at  $5 \times 10^9$  CFU/kg complete feed. It 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 *Saccharomyces cerevisiae* DSM 34246 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should

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

<sup>2</sup> EFSA Journal. 2024;22:e8802.

be authorised for dogs and cats. 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 ‘gut flora stabilisers’, 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.

Done at Brussels,

*For the Commission*  
*The President*  
Ursula VON DER LEYEN