



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* DBVPG 48 SF as a feed additive for ruminants other than dairy (holder of authorisation: Mazzoleni S.p.A.)

(Text with EEA relevance)

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(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 nutrition¹, 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* DBVPG 48 SF as a feed additive. 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* DBVPG 48 SF as a feed additive for horses, ruminants and all pigs, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’ as regards horses, and in the functional group ‘other zootechnical additives’ as regards ruminants and pigs.
- (4) The preparation of *Saccharomyces cerevisiae* DBVPG 48 SF was authorised for 10 years as a feed additive for horses, dairy ruminants and pigs by Commission Implementing Regulation (EU) 2023/2734².
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 23 March 2023³ and 13 March 2024⁴ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF is safe for the target species, consumers and the environment. It also concluded that the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF is not irritant to the eyes and skin but should be considered a respiratory sensitiser, while it could not conclude on the skin sensitisation potential of the preparation. The Authority further concluded that the

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

² Commission Implementing Regulation (EU) 2023/2734 of 7 December 2023 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* DBVPG 48 SF as a feed additive for horses, dairy ruminants and pigs (holder of authorisation: Mazzoleni S.p.A.) (OJ L, 2023/2734, 8.12.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2734/oj).

³ EFSA Journal 2023;21(4):7971.

⁴ EFSA Journal 2024;22:e8728.

preparation of *Saccharomyces cerevisiae* DBVPG 48 SF has the potential to be efficacious for all ruminants at the proposed condition of use. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 for ruminants other than dairy. Accordingly, the use of that preparation should be authorised for ruminants other than dairy. 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.
- (7) 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 ‘other zootechnical additives’, 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