EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae for fattening other than weaned piglets, all suidae for reproduction purposes other than sows, and dogs (holder of authorisation: Prosol S.p.A.)

(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 *Saccharomyces cerevisiae* MUCL 39885. 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 *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae for fattening other than weaned piglets, all suidae for reproduction purposes other than sows, and dogs, to be classified in the category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 June 2021[2,3] that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* MUCL 39885 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that this preparation is considered as a potential skin and eye irritant and a skin and respiratory sensitiser. Therefore, 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. The Authority also concluded that the preparation has the potential to be efficacious as a zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of postmarket monitoring. It 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.

(5) The assessment of the preparation of *Saccharomyces cerevisiae* MUCL 39885 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC)

[1] OJ L 268, 18.10.2003, p. 29.
[2] EFSA Journal 2021;19(7):6698.
[3] EFSA Journal 2021;19(7):6699.

No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(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

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

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