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

of **XXX**

**concerning the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as
a feed additive for dairy cows and horses and repealing Regulation (EC) No 1119/2010
(holder of authorisation Prosol SpA)**

(Text with EEA relevance)

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

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concerning the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and repealing Regulation (EC) No 1119/2010 (holder of authorisation Prosol SpA)

(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 and renewing such authorisation.
- (2) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised for 10 years as a feed additive for dairy cows and horses by Commission Regulation (EC) No 1119/2010².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 12 November 2019³ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority concluded that *Saccharomyces cerevisiae* MUCL 39885 remains safe under the authorised conditions of use for the animal health, consumers, and the environment. The Authority also concluded that the additive is considered a potential skin and eye irritant and skin/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.
- (5) The assessment of *Saccharomyces cerevisiae* MUCL 39885 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Regulation (EU) No 1119/2010 of 2 December 2010 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and amending Regulation (EC) No 1520/2007 (holder of the authorisation Prosol SpA) (OJ L 317, 3.12.2010, p. 9).

³ EFSA Journal 2019; 17(11):5915.

satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

- (6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EU) No 1119/2010 should be repealed.
- (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

The authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EU) No 1119/2010 is repealed.

Article 3

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