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

of **XXX**

concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cattle for fattening (holder of authorisation: Prosol SPA) and repealing Commission Implementing Regulation (EU) No 1059/2013

(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 and renewing such an authorisation.
- (2) A preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised for 10 years as a feed additive for cattle for fattening by Commission Implementing Regulation (EU) No 1059/2013².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive. 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 13 March 2024³ that the applicant has provided evidence that the preparation of *Saccharomyces cerevisiae* MUCL 39885 remains safe for the target species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Saccharomyces cerevisiae* MUCL 39885 is not irritant to skin and eyes, but it should be considered a skin and respiratory sensitiser. It also indicated that there is no need for assessing the efficacy of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of

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

² Commission Implementing Regulation (EU) No 1059/2013 of 29 October 2013 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cattle for fattening and amending Regulation (EC) No 492/2006 (holder of the authorisation Prosol SpA) (OJ L 289, 31.10.2013, p. 30; ELI: http://data.europa.eu/eli/reg_impl/2013/1059/oj).

³ *EFSA Journal*. 2024;22:e8720.

the additive. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005⁴, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* MUCL 39885 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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) As a consequence of the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive, Implementing Regulation (EU) No 1059/2013 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) 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

Renewal of the authorisation

The authorisation of the preparation 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

Repeal of Implementing Regulation (EU) No 1059/2013

Implementing Regulation (EU) No 1059/2013 is repealed.

⁴ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8; ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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