COMMISSION IMPLEMENTING REGULATION (EU) 2021/508

of 23 March 2021

concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for weaned piglets and repealing Regulation (EU) No 170/2011 (holder of authorisation: Prosol S.p.A.)

(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 ([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 and renewing such authorisation.

(2) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised for 10 years as a feed additive for weaned piglets by Commission Regulation (EU) No 170/2011 ([2]).

(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 the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for weaned piglets, requesting the 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 that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 ([3]) that the applicant has provided evidence that the additive complies with the existing conditions of authorisation. The Authority further concluded that the preparation of *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the 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 to users of the additive. 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.

(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) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.

(6) As a consequence of the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive, Regulation (EU) No 170/2011 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,

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EU) No 170/2011 of 23 February 2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA) (OJ L 49, 24.2.2011, p. 8).

([3]) *EFSA Journal* 2020;18(11):6284.

HAS ADOPTED THIS REGULATION:

Article 1

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

Regulation (EU) No 170/2011 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, 23 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1710	Prosol S.p.A.	*Saccharomyces cerevisiae* MUCL 39885	**Additive composition** Preparation of *Saccharomyces cerevisiae* MUCL 39885 containing a minimum of 1×10^9 CFU/g **Characterisation of the active substance:** Viable cells of *Saccharomyces cerevisiae* MUCL 39885 **Analytical method** (1) Enumeration: pour plate method using yeast extract glucose chloramphenicol agar (CGYE) (EN 15789) Identification: polymerase chain reaction (PCR) method	Weaned piglets	-	3×10^9	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	13.4.2031

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports