

## REGULATIONS

## 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)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

cows and horses by Commission Regulation (EU) No 1119/2010<sup>(5)</sup>, and for weaned piglets by Commission Regulation (EU) No 170/2011<sup>(6)</sup>.

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<sup>(1)</sup>, 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 authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC<sup>(2)</sup>.
- (2) A preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on cattle for fattening by Commission Regulation (EC) No 492/2006<sup>(3)</sup>. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was also authorised for 10 years for sows by Commission Regulation (EC) No 896/2009<sup>(4)</sup>, for dairy

- (4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that preparation as a feed additive for cattle for fattening, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 March 2013<sup>(7)</sup> that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect on animal health, human health or the environment and it has the potential to improve the final body weight, the feed to gain ratio and the average daily gain. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) 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 use of that preparation should be authorised as specified in the Annex to this Regulation.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> Commission Regulation (EC) No 492/2006 of 27 March 2006 concerning the provisional and permanent authorisation of certain additives in feedingstuffs (OJ L 89, 28.3.2006, p. 6).

<sup>(4)</sup> Commission Regulation (EC) No 896/2009 of 25 September 2009 concerning the authorisation of a new use of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows (holder of the authorisation Prosol SpA) (OJ L 256, 29.9.2009, p. 6).

<sup>(5)</sup> 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).

<sup>(6)</sup> 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).

<sup>(7)</sup> EFSA Journal 2013; 11(4):3174.

- (7) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on *Saccharomyces cerevisiae* MUCL 39885 contained in Regulation (EC) No 492/2006 should be deleted. Regulation (EC) No 492/2006 should therefore be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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*

In Annex II to Regulation (EC) No 492/2006 the entry on E 1710, *Saccharomyces cerevisiae* MUCL 39 885 is deleted.

*Article 3*

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 19 May 2014 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 4*

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, 29 October 2013.

*For the Commission*  
*The President*

José Manuel BARROSO

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## 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 %			
<b>Category of zootechnical additives. Functional group: gut flora stabilisers</b>									
4b1710	Prosol SpA	<i>Saccharomyces cerevisiae</i> MUCL 39885	<p><i>Additive composition</i></p> <p>Preparation of <i>Saccharomyces cerevisiae</i> MUCL 39885</p> <p>containing a minimum of:</p> <p>Powder: <math>1 \times 10^9</math> CFU/g of additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Saccharomyces cerevisiae</i> MUCL 39885</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>Enumeration: pour plate method using chloramphenicol glucose yeast extract agar (EN15789:2009)</p> <p>Identification: polymerase chain reaction (PCR) method</p>	Cattle for fattening	—	$4 \times 10^9$	—	<p>1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.</p> <p>2. Minimum recommended content of additive for head per day: <math>3,6 \times 10^{10}</math> CFU.</p> <p>3. For safety: glasses and gloves shall be used during handling.</p>	19 November 2023

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: [http://irmm.jrc.ec.europa.eu/EURLs/EURL\\_feed\\_additives/Pages/index.aspx](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)