

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)

(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 such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.

(2) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised as a feed additive for 10 years for use on sows by Commission Regulation (EC) 896/2009⁽³⁾. In accordance with Directive 70/524/EEC, it was authorised without a time limit for use on weaned piglets by Commission Regulation (EC) No 1200/2005⁽⁴⁾, on cattle for fattening by Commission Regulation (EC) No 492/2006⁽⁵⁾ and on dairy cows by Commission Regulation (EC) No 1520/2007⁽⁶⁾. That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) 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 *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and, in accordance with Article 7 of that Regulation, for a new use on horses, requesting that

additive to be classified in the additive category 'zootechnical additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 22 June 2010⁽⁷⁾ concerning the use as a feed additive for dairy cows that, under the proposed conditions of use, *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect on animal health, consumer health or the environment, and that it has a potential to increase milk production in dairy cows. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The Authority concluded in its opinion of 22 June 2010⁽⁸⁾ concerning the use as a feed additive for horses that the use of that preparation can improve the apparent fibre digestibility in the target species.

(6) 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 satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(7) As a consequence of the granting of a new authorisation under Regulation (EC) 1831/2003, the provisions on *Saccharomyces cerevisiae* MUCL 39885 contained in Regulation (EC) No 1520/2007 should be deleted.

(8) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed.

(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,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ OJ L 256, 29.9.2009, p. 6.

⁽⁴⁾ OJ L 195, 27.7.2005, p. 6.

⁽⁵⁾ OJ L 89, 28.3.2006, p. 6.

⁽⁶⁾ OJ L 335, 20.12.2007, p. 17.

⁽⁷⁾ EFSA Journal 2010; 8(7):1662.

⁽⁸⁾ EFSA Journal 2010; 8(7):1659.

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 Regulation (EC) No 1520/2007, Article 1 and Annex I are deleted.

Article 3

Premixtures and compound feed containing *Saccharomyces cerevisiae* MUCL 39885 labelled in accordance with Directive 70/524/EEC may continue to be placed on the market and used until stocks are exhausted.

Article 4

This Regulation shall enter into force on the 20th day following 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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

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 SpA	<i>Saccharomyces cerevisiae</i> MUCL 39885	<i>Additive composition</i> Preparation of <i>Saccharomyces cerevisiae</i> MUCL 39885 containing a minimum of 1×10^9 CFU/g <i>Characterisation of active substance</i> Viable cells of <i>Saccharomyces cerevisiae</i> MUCL 39885 <i>Analytical methods</i> ⁽¹⁾ Enumeration: pour plate method using chloramphenicol glucose yeast extract agar Identification: polymerase chain reaction (PCR) method	Dairy cows	—	2×10^9	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For safety: glasses and gloves shall be used during handling.	23 December 2020
				Horses	—	3×10^9	—		

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives