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)

(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 in accordance with Directive 70/524/EEC as a feed additive without a time limit for use on piglets (weaned) by Commission Regulation (EC) No 1200/2005 ([3]), for cattle for fattening by Commission Regulation (EC) No 492/2006 ([4]). The 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) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was also authorised in accordance with Regulation (EC) No 1831/2003 as a feed additive for 10 years for use in sows by Commission Regulation (EC) No 896/2009 ([5]) and for dairy cows and horses by Commission Regulation (EU) No 1119/2010 ([6]).

(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 *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) 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 6 October 2010 ([7]) that, under the proposed conditions of use, *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect on animal health, human health or on the environment, and that it has the potential to improve the zootechnical performance of the target species. 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.

(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 a new authorisation being granted by this Regulation, the entry for *Saccharomyces cerevisiae* MUCL 39885 in Regulation (EC) No 1200/2005 should be deleted.

(8) Since the modifications to 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 pre-mixtures and compound feed containing this preparation.

(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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 195, 27.7.2005, p. 6.
([4]) OJ L 89, 28.3.2006, p. 6.
([5]) OJ L 256, 29.9.2009, p. 6.
([6]) OJ L 317, 3.12.2010, p. 9.
([7]) *EFSA Journal* 2010; 8(10):1864.

Article 2

In Annex II to Regulation (EC) No 1200/2005, the entry E 1710, additive: *Saccharomyces cerevisiae* MUCL 39885, is deleted.

Article 3

Pre-mixtures 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 the existing 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, 23 February 2011.

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	*Saccharomyces cerevisiae* MUCL 39885	*Additive composition* Preparation of *Saccharomyces cerevisiae* MUCL 39885 containing a minimum of 1×10^9 CFU/g *Characterisation of active substance* Viable cells of *Saccharomyces cerevisiae* MUCL 39885 *Analytical methods* (1) Enumeration: pour plate method using chloramphenicol glucose yeast extract agar Identification: polymerase chain reaction (PCR) method	Piglets (weaned)		3×10^9	—	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. 3. For piglets (weaned) up to 35 kg.	16 March 2021

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