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)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a new use of the micro-organism preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows, to be classified in the additive category 'zootechnical additives'.

(4) The use of the micro-organism preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised without time limit for weaned piglets by Commission Regulation (EC) No 1200/2005 [2], for cattle for fattening by Commission Regulation (EC) No 492/2006 [3] and for dairy cows by Commission Regulation (EC) No 1520/2007 [4].

(5) New data were submitted in support of an application for authorisation for sows. The European Food Safety Authority (the Authority) concludes in its opinion of 3 February 2009 [5] that *Saccharomyces cerevisiae* MUCL 39885 can be considered safe for the target species, consumers and the wider environment. According to that opinion, the preparation can produce a significant beneficial effect on the weight of litters and individual piglets. 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 that preparation shows that the conditions for authorisation, 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.

(7) 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

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, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

---

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 195, 27.7.2005, p. 6.
[3] OJ L 89, 28.3.2006, p. 6.
[4] OJ L 335, 20.12.2007, p. 17.
[5] *The EFSA Journal* (2009) 970, pp. 1-9.

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: powder and granulated form 1×10^9 CFU/g additive Characterisation of the active substance: *Saccharomyces cerevisiae* MUCL 39885 Analytical method (1): Enumeration: pour plate method using chloramphenicol glucose yeast extract agar Identification: polymerase chain reaction (PCR) method	Sows	—	$6{,}4 \times 10^9$	—	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	19 October 2019

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