COMMISSION IMPLEMENTING REGULATION (EU) 2016/104

of 27 January 2016

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for minor ruminant species for fattening and dairy production (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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for minor ruminant species for fattening and dairy production to be classified in the additive category 'zootechnical additives'.

(4) The additive was already authorised for use in piglets by Commission Implementing Regulation (EU) No 170/2011 ([2]), in dairy cows and horses by Commission Implementing Regulation (EU) No 1119/2010 ([3]), in sows by Commission Implementing Regulation (EU) No 896/2009 ([4]) and in cattle for fattening by Commission Implementing Regulation (EU) No 1059/2013 ([5])

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 9 July 2015 ([6]) that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* MUCL 39885 is presumed not to have an adverse effect on animal health, human health or the environment. The Authority considered that the conclusions on efficacy drawn in previous opinions for the major species for fattening and for dairy production can be extrapolated to minor ruminant species for fattening and dairy production. 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.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([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]) 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).

([4]) 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).

([5]) 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) (OJ L 289, 31.10.2013, p. 30)

([6]) *EFSA Journal* 2015; 13(7):4199.

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 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, 27 January 2016.

For the Commission
The President
Jean-Claude JUNCKER

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^{10} CFU/g of additive Solid form *Characterisation of the active substance* Viable cells of *Saccharomyces cerevisiae* MUCL 39885 *Analytical method* (1) Enumeration: Pour plate method using chloramphenicol glucose yeast extract agar (EN 15789:2009) Identification: Polymerase Chain Reaction (PCR) method	Minor ruminants for fattening	—	4×10^9	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For safety: glasses and gloves shall be used during handling.	17 February 2026
				Minor ruminants for dairy production		2×10^9			

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