II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 883/2010

of 7 October 2010

concerning the authorisation of a new use of Saccharomyces cerevisiae NCYC Sc 47 as a feed additive for calves for rearing (holder of the authorisation Société industrielle Lesaffre)

(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:

- Regulation (EC) No 1831/2003 provides for the au-(1) thorisation 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 pursuant to Article 7(3) of Regulation (EC) No 1831/2003.
- The application concerns the authorisation of Sacchar-(3) omyces cerevisiae NCYC Sc 47 as a feed additive for calves for rearing, to be classified in the additive category 'zootechnical additives'.
- The use of that preparation was authorised for dairy cows by Commission Regulation (EC) No 1811/2005 (2), for cattle for fattening by Commission Regulation (EC) No 316/2003 (3), for weaned piglets by Commission Regulation (EC) No 2148/2004 (4), for sows by Commission Regulation (EC) No 1288/2004 (5), for

rabbits for fattening by Commission Regulation (EC) No 600/2005 (6), for horses by Commission Regulation (EC) No 186/2007 (7), for dairy goats and dairy sheep by Commission Regulation (EC) No 188/2007 (8), for lambs for fattening by Commission Regulation (EC) No 1447/2006 (9), for pigs for fattening by Commission Regulation (EC) No 209/2008 (10) and for dairy buffaloes by Commission Regulation (EC) No 232/2009 (11).

- (5) New data were submitted in support of the application for the authorisation of the preparation for calves for rearing. The European Food Safety Authority (the Authority) concluded in its opinion of 7 April 2010 (12) that Saccharomyces cerevisiae NCYC Sc 47, under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that its use improves the average daily weight gain 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.
- The assessment of Saccharomyces cerevisiae NCYC Sc 47 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.
- 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 291, 5.11.2005, p. 12.

⁽³⁾ OJ L 46, 20.2.2003, p. 15.

⁽⁴⁾ OJ L 370, 17.12.2004, p. 24. (5) OJ L 243, 15.7.2004, p. 10.

⁽⁶⁾ OJ L 99, 19.4.2005, p. 5.

⁽⁷⁾ OJ L 63, 1.3.2007, p. 6. (8) OJ L 57, 24.2.2007, p. 3.

⁽⁹⁾ OJ L 271, 30.9.2006, p. 28. (10) OJ L 63, 7.3.2008, p. 3.

⁽¹¹⁾ OJ L 74, 20.3.2009, p. 14.

⁽¹²⁾ EFSA Journal (2010); 8(4):1576.

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, 7 October 2010.

For the Commission The President José Manuel BARROSO

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		End of period of
						CFU/kg of complete feedingstuff with a moisture content of 12 %			authorisation
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1702	Société Industrielle Lesaffre	Saccharomyces cerevisiae NCYC Sc 47	Additive composition Preparation of Saccharomyces cerevisiae NCYC Sc 47 containing a minimum of 5 × 10 ⁹ CFU/g Characterisation of active substance Saccharomyces cerevisiae NCYC Sc 47	Calves for rearing	_	1,5 × 10 ⁹	_	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	28.10.2020
			Analytical methods (1)						
			Pour plate method using a chlor-amphenicol yeast extract agar based on the ISO 7954 method.						

ANNEX

Polymerase chain reaction (PCR)

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