COMMISSION REGULATION (EC) No 232/2009

of 19 March 2009

concerning the authorisation of a new use of *saccharomyces cerevisiae* NCYC Sc47 as a feed additive for dairy buffaloes (holder of the authorisation Société Industrielle Lesaffre)

(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. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of a new use of the preparation of *Saccharomyces cerevisiae* NCYC Sc47 as a feed additive for dairy buffaloes, to be classified in the additive category 'zootechnical additives'.

(4) The use of the preparation of *Saccharomyces cerevisiae* NCYC Sc47 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 piglets (weaned) 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] and for pigs for fattening by Commission Regulation (EC) No 209/2008 [10].

(5) New data were submitted in support of an application for authorisation for dairy buffaloes. The European Food Safety Authority (hereinafter the Authority) concludes in its opinion of 21 October 2008 [11] that *Saccharomyces cerevisiae* NCYC Sc47, as produced by the applicant Société Industrielle Lesaffre, can be presumed safe for the target species, consumers and the wider environment. In addition, it concludes that its use with dairy buffaloes is not expected to introduce any additional hazards for users. According to that opinion, that preparation can produce a significant effect on increasing milk protein content and its use does not have any treatment-related adverse effects on this additional animal category. 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,

[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] Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of Biosaf Sc47 (*Saccharomyces cerevisiae* NCYC Sc47) as feed additive for diary buffaloes. *The EFSA Journal (2008) 837, 1-10.*

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, 19 March 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

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.									
4b1702	Société Industrielle Lesaffre	*Saccharomyces cerevisiae* NCYC Sc47	Additive composition: Preparation of *Saccharomyces cerevisiae* NCYC Sc47 containing a minimum of 5×10^9 CFU/g Characterisation of active substance: *Saccharomyces cerevisiae* NCYC Sc47 Analytical methods (*): Pour plate method using a chloramphenicol yeast extract agar based on the ISO 7954 method Polymerase chain reaction (PCR)	Dairy buffaloes	—	$5{,}0 \times 10^8$	$1{,}4 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	8 April 2019

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