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COMMISSION REGULATION (EC) No 209/2008

of 6 March 2008

concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf Sc 47) as a feed additive

(Text with EEA relevance)

(OJ L 63, 7.3.2008, p. 3)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 897/2009 of 25 September 2009	L 256	8	29.9.2009
►**M2**	Commission Implementing Regulation (EU) No 1018/2012 of 5 November 2012	L 307	56	7.11.2012

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concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf Sc 47) as a feed additive

(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 authorisation of a new use of the preparation *Saccharomyces cerevisiae* NCYC Sc 47 (Biosaf Sc 47) as a feed additive for pigs for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The use of the preparation of *Saccharomyces cerevisiae* NCYC Sc 47 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]) and 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]).

([1]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
([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. Regulation as amended by Regulation (EC) No 1980/2005 (OJ L 318, 6.12.2005, p. 3).
([5]) OJ L 243, 15.7.2004, p. 10. Regulation as amended by Regulation (EC) No 1812/2005 (OJ L 291, 5.11.2005, p. 18).
([6]) OJ L 99, 19.4.2005, p. 5. Regulation as last amended by Regulation (EC) No 496/2007 (OJ L 117, 5.5.2007, p. 9).
([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.

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(5) New data were submitted in support of an application for authorisation for pigs for fattening. The European Food Safety Authority (the Authority) concludes in its opinion of 22 November 2007 that the safety of *Saccharomyces cerevisiae* (Biosaf Sc 47) for the consumer, the user and the environment has already been established by its previous opinions ([1]). It further concludes that the use of the preparation does not present a risk for this additional animal category and that the use of that preparation can improve performance parameters in pigs for fattening. 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 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.

([1]) Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the safety and efficacy of Biosaf Sc 47 (*Saccharomyces cerevisiae*) as feed additive for pigs for fattening. *The EFSA Journal* (2007) 585, 1-9.

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ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	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 Sc 47 (►**M1** Actisaf ◄)	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 Analytical methods (1) Pour plate method using a chloramphenicol yeast extract agar based on the ISO 7954 method Polymerase chain reaction (PCR)	Pigs for fattening	—	$1{,}25 \times 10^9$	►**M2** ——— ◄	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	27 March 2018

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