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COMMISSION REGULATION (EC) No 188/2007

of 23 February 2007

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

(Text with EEA relevance)

(OJ L 57, 24.2.2007, p. 3)

Amended by:

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		No	page	date
►**M1**	Commission Regulation (EC) No 897/2009 of 25 September 2009	L 256	8	29.9.2009

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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 dairy goats and dairy sheep to be classified in the additive category 'zootechnical additives'.

(4) The method of analysis included in the application for authorisation in accordance with Article 7(3)(c) of Regulation (EC) No 1831/2003 concerns the determination of the active substance of the feed additive in feed. The method of analysis referred to in the Annex to this Regulation is therefore not to be understood as a Community method of analysis within the meaning of Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([2]).

(5) The use of the preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) was authorised for cattle for fattening by Commission Regulation (EC) No 316/2003 of 19 February 2003 concerning the permanent authorisation of an additive in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs ([3]), for piglets (weaned) by Commission Regulation (EC) No 2148/2004 of 16 December 2004 concerning the permanent and provisional authorisation of certain additives in feedingstuffs and the authorisation of a new use of an additive already authorised in feedingstuffs ([4]), for sows by Commission Regulation (EC) No 1288/2004 of 20 December 2004 concerning the permanent authorisation of certain additives

([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 165, 30.4.2004, as corrected by OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).
([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).

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and the provisional authorisation of a new use of an additive already authorised in feedingstuffs ([1]), for rabbits for fattening by Commission Regulation (EC) No 600/2005 of 18 April 2005 concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives in feedingstuffs ([2]), for dairy cows by Commission Regulation (EC) No 1811/2005 of 4 November 2005 concerning the provisional and permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs ([3]) and for lambs for fattening by Commission Regulation No 1447/2006 of 29 September 2006 concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf SC 47) as a feed additive ([4]).

(6) New data were submitted in support of the application for authorisation for dairy goats and dairy sheep. The European Food Safety Authority (the Authority) concluded in its opinion of 12 July 2006 that the preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) does not have an adverse effect on animal health, human health or the environment ([5]). It further concluded that the preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) does not present any other risk for this additional animal category which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that preparation can improve significantly milk yield in dairy goats and dairy sheep. The Authority does not consider that there is a need for specific requirements of post market monitoring. This opinion also verifies 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 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*.

([1]) 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).
([2]) OJ L 99, 19.4.2005, p. 5. Regulation as amended by Regulation (EC) No 2028/2006 (OJ L 414, 30.12.2006, p. 26).
([3]) OJ L 291, 5.11.2005, p. 12.
([4]) OJ L 271, 30.9.2006, p. 28.
([5]) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product ‘Biosaf Sc 47’, a preparation of *Saccharomyces cerevisiae* as a feed additive for dairy small ruminants. Adopted on 12 July 2006, *The EFSA Journal* (2006) 379, p. 1.

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This Regulation shall be binding in its entirety and directly applicable in all Member States.

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)	Dairy goats and dairy sheep	—	7×10^8	$7{,}5 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended doses: — Dairy goats: 3×10^9 CFU per head per day. — Dairy ewes: 2×10^9 CFU per head per day.	16.3.2017

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/