

COMMISSION REGULATION (EC) No 1447/2006

of 29 September 2006

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 lambs for fattening, 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 dairy cows by Commission Regulation (EC) No 1811/2005 of 4 November 2005⁽³⁾ 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, 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⁽⁴⁾, 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⁽⁵⁾, for sows by Commission Regulation (EC) No 1288/2004 of 14 July 2004 concerning the permanent authorisation of certain additives and the provisional authorisation of a new use of an additive already authorised in feedingstuffs⁽⁶⁾ and 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⁽⁷⁾. New data were submitted in support of an application for authorisation for lambs for fattening. In its assessment, the European Food Safety Authority (the Authority) concludes that the safety of this organism (and its growth medium) for the consumer, the user and the environment have already been established and will not be changed by the proposed new use. 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 average daily weight gain in lambs for fattening. The Authority does not consider that there is a need for specific requirements of post-market monitoring. This opinion

⁽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 amended by Commission Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3).

⁽³⁾ OJ L 291, 5.11.2005, p. 12.

⁽⁴⁾ OJ L 46, 20.2.2003, p. 15.

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ OJ L 99, 19.4.2005, p. 5.

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.

- (6) 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*.

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

Done at Brussels, 29 September 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

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 |
|---|-------------------------------------|--|---|-------------------------------|-------------|-------------------|----------------------|--|---|
| Category of zootechnical additives. Functional group: gut flora stabilisers. | | | | | | | | | |
| E 1702 | LEA Lesaffre Feed Additives | <i>Saccharomyces cerevisiae</i> (NCYC Sc 47) (Biosaf Sc 47) | Additive composition: <i>Saccharomyces cerevisiae</i> (NCYC Sc 47) Preparation containing a minimum of 5×10^9 CFU/g of additive Analytical methods ⁽¹⁾ Pour plate method using a chloramphenicol yeast extract agar based on the ISO 7954 method Polymerase chain reaction (PCR) | Lambs for fattening | — | $1,4 \times 10^9$ | $1,4 \times 10^{10}$ | In the directions for use of the additive and the premixture, indicate the storage temperature, storage life and stability to pelleting. (Stable for pellets at a temperature up to 83 °C) | 10 years from the date of entry into force of this Regulation |

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