

COMMISSION IMPLEMENTING REGULATION (EU) No 334/2012

of 19 April 2012

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for rabbits for fattening and non food-producing rabbits and amending Regulation (EC) No 600/2005 (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:

- (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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.
- (2) The preparation of *Saccharomyces cerevisiae* NCYC Sc47 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on rabbits for fattening by Commission Regulation (EC) No 600/2005⁽³⁾. That preparation was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of *Saccharomyces cerevisiae* CNCM I-4407, formerly NCYC Sc47, as a feed additive for rabbits for fattening and, in accordance with Article 7 of that Regulation, for a new use for non food-producing rabbits, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 December 2011⁽⁴⁾ that, under the proposed conditions of use, *Saccharomyces cerevisiae* CNCM I-4407 does not have an adverse effect on animal health, consumer health or the environment, and that it has a potential to reduce mortality in rabbits 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of *Saccharomyces cerevisiae* CNCM I-4407 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.
- (6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on *Saccharomyces cerevisiae* NCYC Sc47 contained in Regulation (EC) No 600/2005 should be deleted.
- (7) Since the modifications on the conditions of the authorisation of the feed additive are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed, as authorised by Regulation (EC) No 600/2005.
- (8) 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

The entry for E 1702 in Annex III to Regulation (EC) No 600/2005 is deleted.

Article 3

The preparation of *Saccharomyces cerevisiae* NCYC Sc47, as authorised by Regulation (EC) No 600/2005, and premixtures and compound feed containing it, labelled in accordance with Directive 70/524/EEC before the entry into force of this Regulation may continue to be placed on the market and used until the existing stocks are exhausted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ OJ L 99, 19.4.2005, p. 5.

⁽⁴⁾ EFSA Journal 2012; 10(1):2531.

Article 4

This Regulation shall enter into force on the twentieth 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.

Done at Brussels, 19 April 2012.

For the Commission
The President
José Manuel BARROSO

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	<i>Saccharomyces cerevisiae</i> CNCM I-4407	<i>Additive composition</i> Preparation of dried cells of <i>Saccharomyces cerevisiae</i> CNCM I-4407 containing a minimum of 5 × 10 ⁹ CFU/g <i>Characterisation of active substance</i> <i>Saccharomyces cerevisiae</i> CNCM I-4407 <i>Analytical methods</i> ⁽¹⁾ Enumeration: Pour plate method using a yeast extract dextrose chloramphenicol (CGYE) agar — EN 15789. Identification: polymerase chain reaction (PCR) method).	Rabbits for fattening and non food-producing rabbits	—	5 × 10 ⁹	—	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	11 May 2022

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx