COMMISSION IMPLEMENTING REGULATION (EU) 2019/899

of 29 May 2019

concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening and repealing Regulations (EC) No 1447/2006, (EC) No 188/2007, (EC) No 232/2009, (EC) No 186/2007 and (EC) No 209/2008 (holder of authorisation S.I. 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 and renewing such authorisation.

(2) *Saccharomyces cerevisiae* NCYC Sc 47 was authorised for 10 years as a feed additive for lambs for fattening by Commission Regulation (EC) No 1447/2006 ([2]), for horses by Commission Regulation (EC) No 186/2007 ([3]), for dairy goats and dairy sheep by Commission Regulation (EC) No 188/2007 ([4]), for pigs for fattening by Commission Regulation (EC) No 209/2008 ([5]) and for dairy buffaloes by Commission Regulation (EC) No 232/2009 ([6]).

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, applications were submitted by the holder of those authorisations for the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 (formerly NCYC Sc 47) as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, pigs for fattening and horses requesting that additive to be classified in the additive category 'zootechnical additives'. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 June 2018 ([7]) that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.

(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 authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009 should be repealed.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) OJ L 268, 18.10.2003, p. 29.
([2]) 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 (OJ L 271, 30.9.2006, p. 28).
([3]) Commission Regulation (EC) No 186/2007 of 21 February 2007 concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf SC 47) as a feed additive (OJ L 63, 1.3.2007, p. 6).
([4]) 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 (OJ L 57, 24.2.2007, p. 3).
([5]) 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 (OJ L 63, 7.3.2008, p. 3).
([6]) 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) (OJ L 74, 20.3.2009, p. 14).
([7]) *EFSA Journal* 2018;16(7):5339.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' when it is used for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes and pigs for fattening; and to the functional group 'digestibility enhancers' when it is used for horses, is renewed subject to the conditions laid down in that Annex.

Article 2

Saccharomyces cerevisiae NCYC Sc47as feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009, and premixtures and compound feed containing it, labelled in accordance with those Regulations before the entry into force of this Regulation, may be continued to be placed on the market until the existing stocks are exhausted.

Article 3

Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009 are repealed.

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, 29 May 2019.

For the Commission

The President

Jean-Claude JUNCKER

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	S.I. Lesaffre	*Saccharomyces cerevisiae* CNCM I-4407	*Additive composition:* Preparation of *Saccharomyces cerevisiae* CNCM I-4407 with a minimum concentration of 5×10^9 CFU/g. Solid form *Characterisation of the active substance:* Viable dried cells of *Saccharomyces cerevisiae* CNCM I-4407 *Analytical method* (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008.	Lambs for fattening	—	$1{,}4 \times 10^9$	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended doses (CFU/head/day) for: — dairy goats: 3×10^9 — dairy sheep: 2×10^9 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.	23 June 2029
				Dairy goats and dairy sheep		7×10^8			
				Pigs for fattening		$1{,}25 \times 10^9$			
				Dairy buffaloes		5×10^8			

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

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: digestibility enhancers									
4b1702	S.I. Lesaffre	*Saccharomyces cerevisiae* CNCM I-4407	*Additive composition:* Preparation of *Saccharomyces cerevisiae* CNCM I-4407 with a minimum concentration of 5×10^9 CFU/g. Solid form *Characterisation of the active substance:* Viable dried cells of *Saccharomyces cerevisiae* CNCM I-4407 *Analytical method* (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008.	Horses	—	8×10^8	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended doses (CFU/head/day) for: — horses: $1{,}25 \times 10^{10} – 6 \times 10^{10}$ 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.	23 June 2029

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports