II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/367

of 1 March 2021

concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for calves for rearing and repealing Regulation (EU) No 883/2010 (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* CNCM I-4407, previously identified as *Saccharomyces cerevisiae* NCYC Sc47, was authorised for 10 years as a feed additive for calves for rearing by Commission Regulation (EU) No 883/2010 ([2]).

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for the renewal of the authorisation for calves for rearing, requesting the additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 May 2020 ([3]) that the applicant has provided evidence that the additive complies with the existing conditions of authorisation. The Authority concluded that the preparation of *Saccharomyces cerevisiae* CNCM I-4407 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that it is not a skin or eye irritant and, in the absence of data, no conclusions can be drawn on the dermal sensitisation potential of the additive. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to users of the additive. 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.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EU) No 883/2010 of 7 October 2010 concerning the authorisation of a new use of Saccharomyces cerevisiae NCYC Sc 47 as a feed additive for calves for rearing (holder of the authorisation Société Industrielle Lesaffre) (OJ L 265, 8.10.2010, p. 1).

([3]) *EFSA Journal* 2020;18(6):6167.

(5) The assessment of a preparation 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.

(6) As a consequence of the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive, Regulation (EU) No 883/2010 should be repealed.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-4407, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the authorisation

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

Article 2

Transitional period

1. The additive specified in the Annex and premixtures containing it, which are produced and labelled before 22 September 2021 in accordance with the rules applicable before 22 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the additive specified in the Annex which are produced and labelled before 22 March 2022 in accordance with the rules applicable before 22 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

Article 3

Repeal

Regulation (EU) No 883/2010 is repealed.

Article 4

Entry into force

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, 1 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

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 containing a minimum 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 Identification: polymerase chain reaction (PCR) method CEN/TS 15790.	Calves for rearing	-	$1{,}5 \times 10^9$	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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.	22.3.2031

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