COMMISSION IMPLEMENTING REGULATION (EU) 2019/857

of 27 May 2019

concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for dairy sheep and dairy goats and repealing Regulation (EC) No 226/2007 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)

(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-1077 was authorised for 10 years as a feed additive for dairy goats and dairy sheep by Commission Regulation (EC) No 226/2007 ([2]).

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for dairy goats and dairy sheep, requesting that 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 Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 July 2018 ([3]) that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.

(5) The assessment of *Saccharomyces cerevisiae* CNCM I-1077 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-1077 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 226/2007 should be repealed.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,

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', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 226/2007 is repealed.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Regulation (EC) No 226/2007 of 1 March 2007 concerning the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive (OJ L 64, 2.3.2007, p. 26).
([3]) *EFSA Journal* 2018;16(7):5385.

Article 3

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, 27 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 (CFU /kg of complete feedingstuff with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1711	Danstar Ferment AG represented by Lallemand SAS	*Saccharomyces cerevisiae* CNCM I-1077	*Additive composition* Preparation of *Saccharomyces cerevisiae* CNCM I-1077 with a minimum concentration of: — 1×10^{10} CFU/g of additive (coated form); — 2×10^{10} CFU/g of additive (not-coated form); *Characterisation of the active substance* Viable dried cells of *Saccharomyces cerevisiae* CNCM I-1077 *Analytical method* (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008	Dairy goats Dairy sheep	—	5×10^8 $1{,}2 \times 10^9$	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. In the label of feed additive the following shall be indicated: '*Recommended dose for dairy goats and dairy sheep: 4×10^9 CFU/head/day*' 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.	17 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