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

(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 a new use of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20, Levucell SC10 ME), as a feed additive for dairy goats and dairy sheep, to be classified in the additive category 'Zootechnical additives'.

(4) The use of *Saccharomyces cerevisiae* CNCM I-1077 was authorised without a time limit for dairy cows and cattle for fattening by Commission Regulation (EC) No 1200/2005 [2].

(5) New data were submitted in support of an application for authorisation for dairy goats and dairy sheep. The European Food Safety Authority (the Authority) concluded in its opinion of 15 June 2006 that *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20, Levucell SC10 ME) does not have an adverse effect on animal health, human health or the environment. It further concluded that *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20, Levucell SC10 ME) does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of the preparation does not have an adverse effect on these additional animal categories. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) 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.

(7) 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 twentieth day following its publication in the *Official Journal of the European Union*.

[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 195, 27.7.2005, p. 6. Regulation as amended by Regulation (EC) No 1445/2006 (OJ L 271, 30.9.2006, p. 22).

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

Done at Brussels, 1 March 2007.

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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1711	LALLEMAND SAS	*Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20, Levucell SC10 ME)	**Additive composition:** Solid form: Preparation of *Saccharomyces cerevisiae* CNCM I-1077 of viable dried cells with a guaranteed minimal concentration of 2×10^{10} CFU/g Coated form: Preparation of *Saccharomyces cerevisiae* CNCM I-1077 of viable dried cells with a guaranteed minimal concentration of 1×10^{10} CFU/g **Characterisation of the active substance:** *Saccharomyces cerevisiae* CNCM I-1077: 80 % of viable dried cells and 14 % of not viable cells **Analytical method** (1) Pour plate method and molecular identification (PCR)	Dairy goats Dairy sheep	—	5×10^8 $1{,}2 \times 10^9$	3×10^9 $1{,}2 \times 10^9$	1. In the directions for use of the additive and premixtures, indicate the storage temperature, storage life, and stability to pelleting. 2. In complementary feedingstuffs, do not exceed 50 °C with Levucell SC20 and 80 °C with Levucell SC10ME. 3. Coated form, only for inclusion through a pelleted feed. 4. Recommended dose for dairy goats and dairy sheep: 4×10^9 CFU/head/day. 5. If the product is handled or mixed in a confined atmosphere, it is recommended to use safety glasses and masks for mixing if the mixers are not equipped with exhaust systems.	22 March 2017

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