COMMISSION IMPLEMENTING REGULATION (EU) 2020/1374

of 1 October 2020

concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for calves, all minor ruminant species (for rearing) other than lambs and camelids (for rearing) (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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for calves, all minor ruminant species (for rearing) other than lambs and camelids (for rearing), to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 May 2019 ([2]) that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1077 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that this preparation is considered an eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation has the potential to be efficacious in improving weight gain and feed to gain ratio. The conclusion on efficacy for calves can be extrapolated to minor ruminant species and camelids at the same developmental stage. 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 the preparation 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 use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) 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

Authorisation

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(6):5723.

Article 2

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 October 2020.

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.									
4b1711	Danstar Ferment AG represented in the Union by Lallemand SAS	*Saccharomyces cerevisiae* CNCM I-1077	***Additive composition*** Preparation of *Saccharomyces cerevisiae* CNCM I-1077 containing a minimum of: — 1×10^{10} CFU/g additive (coated form) — 2×10^{10} CFU/g additive (not-coated form) ***Characterisation of active substance*** Viable cells of *Saccharomyces cerevisiae* CNCM I-1077 ***Analytical method*** (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15 789:2009). Identification: polymerase chain reaction (PCR) method (CEN/TS 15 790:2008)	Calves All minor ruminant species (for rearing) other than lambs Camelids (for rearing)	-	1×10^9	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. 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 skin, eyes and breathing protection.	22.10.2030

(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