

COMMISSION IMPLEMENTING REGULATION (EU) 2020/149**of 4 February 2020****concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for lambs and horses and repealing Regulations (EC) No 1293/2008 and (EC) No 910/2009 (holder of authorisation Danstar Ferment AG represented in the Union 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 lambs by Commission Regulation (EC) No 1293/2008 ⁽²⁾ and as a feed additive for horses by Commission Regulation (EC) No 910/2009 ⁽³⁾.
- (3) 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 lambs and horses, 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 26 February 2019 ⁽⁴⁾ that the applicant has provided data demonstrating that the additive complies with the conditions for authorisation. The Authority concluded that *Saccharomyces cerevisiae* CNCM I-1077 remains safe under the authorised conditions of use for the target animals, consumers, users and the environment. The Authority also concluded that the additive is considered an eyes 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.
- (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, Regulations (EC) No 1293/2008 and (EC) No 910/2009 should be repealed.
- (7) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the preparation of *Saccharomyces cerevisiae* CNCM I-1077, which are in conformity with the provisions applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until they are exhausted.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 1293/2008 of 18 December 2008 concerning the authorisation of a new use of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive (OJ L 340, 19.12.2008, p. 38).

⁽³⁾ Commission Regulation (EC) No 910/2009 of 29 September 2009 concerning the authorisation of a new use of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for horses (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS) (OJ L 257, 30.9.2009, p. 7).

⁽⁴⁾ EFSA Journal 2019;17(3):5639.

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 groups 'gut flora stabilisers' for lambs and 'digestibility enhancers' for horses, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulations (EC) No 1293/2008 and (EC) No 910/2009 are repealed.

Article 3

Saccharomyces cerevisiae CNCM I-1077, as set out in Regulation (EC) No 910/2009, premixtures and compound feed containing that substance, which are produced and labelled before 25 February 2020 in accordance with the rules applicable before 25 February 2020 may continue to be placed on the market and used until the existing stock are exhausted.

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, 4 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

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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: digestibility enhancers									
4b1711	Danstar Ferment AG represented by Lallemand SAS	<i>Saccharomyces cerevisiae</i> CNCM I-1077	<p><i>Additive composition:</i></p> <p>Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-1077 containing a minimum of:</p> <ul style="list-style-type: none"> — 1×10^{10} CFU/g of additive (coated form); — 2×10^{10} CFU/g of additive (not-coated form); <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1077</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009)</p> <p>Identification: polymerase chain reaction (PCR) method (CEN/TS 15790:2008)</p>	Horses	-	$3,0 \times 10^9$	-	<ol style="list-style-type: none"> 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 eye protection. 	25.2.2030

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 by Lallemand SAS	<i>Saccharomyces cerevisiae</i> CNCM I-1077	<p><i>Additive composition</i></p> <p>Preparation of <i>Saccharomyces cerevisiae</i> CNCMI-1077 containing a minimum of:</p> <ul style="list-style-type: none"> — 1 × 10¹⁰ CFU/g of additive (coated form); — 2 × 10¹⁰ CFU/g of additive (not-coated form); <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1077</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009)</p> <p>Identification: polymerase chain reaction (PCR) method (CEN/TS 15790:2008)</p>	Lambs	-	3,0 × 10 ⁹		<ol style="list-style-type: none"> 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 eye protection. 	25.2.2030

⁽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>