

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1170

of 15 June 2023

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for dairy cows, cattle for fattening, minor ruminant species for fattening and camelids for fattening (holder of the authorisation: Danstar Ferment AG represented by Lallemand SAS) and repealing Regulation (EC) No 1200/2005

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of *Saccharomyces cerevisiae* CNCM I-1077 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for dairy cows and cattle for fattening by Commission Regulation (EC) No 1200/2005 ⁽³⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted for the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for dairy cows and cattle for fattening. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for the authorisation of a new use of that preparation as a feed additive for minor ruminant species and camelids. Those applications requested that additive to be classified in the additive category 'zootechnical additives' and in the functional groups 'digestibility enhancers' and 'gut flora stabilisers' and were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 4 July 2017 ⁽⁴⁾ and 29 June 2022 ⁽⁵⁾ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1077 is safe for the target animals, the consumers and the environment. It also concluded that the preparation is not a skin irritant or sensitiser but is an eye irritant, and that inhalation exposure is unlikely. The Authority concluded that the preparation has a potential to improve the performance of cattle for fattening when supplied at a minimum dose approximating to 6×10^8 CFU/kg complete feed, while also noting that two *in vivo* studies showed a positive effect on the growth performance of the cattle supplied with the additive at a minimum dose of 5×10^8 CFU/kg complete feed. It extended this conclusion to minor ruminant species and camelids reared for meat production. The Authority could not conclude, based on the data provided by the applicant, on the efficacy of that additive for dairy cows, but noted that the preparation showed a positive effect on performance in dairy cows in three studies. The Authority also verified the report on the methods 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⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 195, 27.7.2005, p. 6).⁽⁴⁾ EFSA Journal 2017;15(7):4944.⁽⁵⁾ EFSA Journal 2022;20(7):7431.

- (5) The applicant withdrew the application on 24 February 2023 for the authorisation of the preparation under the functional group 'digestibility enhancers' and for its use for minor dairy ruminant species and dairy camelids.
- (6) Considering the overall data provided, the already demonstrated capacity of the additive to improve the performance parameters in other dairy ruminants, namely dairy goats and dairy sheep, and the long-standing history of marketing and use of that preparation, the Commission considers that the conditions for the demonstration of the efficacy are met for cattle for fattening, minor ruminant species and camelids reared for meat production supplied with the additive at a minimum dose of 5×10^8 CFU/kg complete feed, and for dairy cows supplied with the additive at a minimum dose of 4×10^8 CFU/kg complete feed.
- (7) The assessment of the additive 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. 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.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation concerned which are intended for dairy cows and cattle for fattening, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) 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.

Article 2

Repeal of Regulation (EC) No 1200/2005

Regulation (EC) No 1200/2005 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that substance, which are intended for dairy cows and cattle for fattening and are produced and labelled before 6 January 2024 in accordance with the rules applicable before 6 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are intended for dairy cows and cattle for fattening and are produced and labelled before 6 July 2024 in accordance with the rules applicable before 6 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

*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, 15 June 2023.

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 groups: 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) Identification: polymerase chain re action (PCR) method CEN/TS 15790	Cattle for fattening All minor ruminant species for fattening Camelids for fattening	-	5 × 10 ⁸	-	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 by such procedures and measures, the additive and premixtures shall be used with personal eye protective equipment.	6 July 2033
				Dairy cows		4 × 10 ⁸			

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en