COMMISSION IMPLEMENTING REGULATION (EU) 2020/162

of 5 February 2020

concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for turkeys for fattening (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-1079. 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-1079 as a feed additive for turkeys for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The preparation of *Saccharomyces cerevisiae* CNCM I-1079 was already authorised as a feed additive by Commission Implementing Regulation (EU) 2017/1905 (²) for chickens for fattening and for minor poultry species for fattening and by Commission Implementing Regulation (EU) 2018/347 (³) for piglets and sows.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 (') that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1079 does not have an adverse effect on animal health, consumer safety or the environment, and when used in feed for turkeys, it is efficacious in reducing carcass contamination with *Salmonella* spp. It also concluded that the not-coated form of the additive should be considered a respiratory sensitiser. 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 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.
- (6) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 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.
- (7) 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 Implementing Regulation (EU) 2017/1905 of 18 October 2017 concerning an authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for chickens for fattening and for minor poultry species for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 269, 19.10.2017, p. 30).

⁽³⁾ Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 67, 9.3.2018, p. 21).

⁽⁴⁾ EFSA Journal 2019;17(4):5693.

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 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 5 February 2020.

For the Commission The President Ursula VON DER LEYEN

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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: other zootechnical additives (reduction of Salmonella spp. contamination on carcasses through its decrease in faeces)										
4d1703	Danstar Ferment AG represented by Lallemand SAS	Saccharomy- ces cerevisiae CNCM I- 1079	Additive composition Preparation of Saccharomyces cerevisiae CNCM I-1079 containing a minimum of: 2 × 10 ¹⁰ CFU/g of additive (not-coated form) 1 × 10 ¹⁰ CFU/g of additive (coated form) Characterisation of the active substance Viable cells of Saccharomyces cerevisiae CNCM I-1079 Analytical method (¹) Enumeration: pour plate method using chloramphenicol destrose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method (CEN/TS 15790:2008)		-	1 × 10°		 In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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 breathing protection. 	26 February 2030	

ANNEX

⁽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