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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for ruminants and camelids reared for milk production or reared for reproduction, young ruminants for fattening other than calves and lambs, camelid calves for fattening, and Equidae other than horses (holder of authorisation: Lallemand SAS) and amending Implementing Regulation (EU) 2020/149 as regards the terms of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for lambs

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(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 nutrition¹, and in particular Article 9(2) and Article 13(3) 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 an authorisation.
- (2) A preparation of *Saccharomyces cerevisiae* CNCM I-1077 was authorised for a period of 10 years as a feed additive for lambs and horses by Commission Implementing Regulation (EU) 2020/149².
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-1077. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The application concerns the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for ruminants and camelids reared for milk production or reared for reproduction, young ruminants for fattening other than calves and lambs, camelid calves for fattening, and Equidae other than horses, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional groups ‘digestibility enhancers and gut flora stabilisers’.
- (5) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the terms of the authorisation of the preparation

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² 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) (OJ L 33, 5.2.2020, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2020/149/oj).

of *Saccharomyces cerevisiae* CNCM I-1077 as laid down in Implementing Regulation (EU) 2020/149 as regards the use for lambs. That application concerned a request to lower the minimum inclusion level in feed for lambs from 3×10^9 to 1×10^9 CFU/kg of complete feed with a moisture content of 12 %.

- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 October 2024³ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1077 is safe for the target species, consumers and the environment. The Authority also concluded that the preparation of *Saccharomyces cerevisiae* CNCM I-1077, in both formulations, should be considered a skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. The not-coated form of the additive is not irritant to skin or eyes. No conclusion can be drawn on the eye irritation potential of the coated form of the additive due to the lack of data. The Authority further concluded that the preparation of *Saccharomyces cerevisiae* CNCM I-1077 has the potential to be efficacious in all ruminants and camelids reared for milk production or suckling or reproduction at a minimum proposed use level of 5×10^8 CFU/kg of complete feed, all minor (young) ruminant species and camelids for fattening and lambs at 1×10^9 CFU/kg of complete feed, and in all Equidae species other than horses at 3×10^9 CFU/kg of complete feed. It did not consider that there is a need for specific requirements of post-market monitoring.
- (7) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁴, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning the same additive are valid and applicable for the current application.
- (8) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* CNCM I-1077 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for ruminants and camelids reared for milk production or reared for reproduction, young ruminants for fattening other than calves and lambs, camelid calves for fattening, and Equidae other than horses. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (9) In addition, in view of the above, the Commission considers that the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms thereof as regards the use for lambs, by decreasing the minimum content of the additive to 1×10^9 CFU/kg of complete feed. Implementing Regulation (EU) 2020/149 should therefore be amended accordingly.
- (10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 for lambs, it is appropriate to provide for a transitional period for interested

³ EFSA Journal. 2024;22:e9075. <https://doi.org/10.2903/j.efsa.2024.9075>

⁴ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

parties to prepare themselves to meet the new requirements resulting from the modification of the authorisations concerned.

- (11) 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 groups ‘digestibility enhancers and gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2020/149

In the Annex to Implementing Regulation (EU) 2020/149 in the column ‘minimum content’ regarding lambs the value is replaced by ‘ 1×10^9 ’.

Article 3

Transitional measures

1. The feed additive *Saccharomyces cerevisiae* CNCM I-1077, as authorised by Implementing Regulation (EU) 2020/149 and premixtures containing that additive, which are intended for lambs, and which are produced and labelled before [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for lambs, and which are produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned 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,

For the Commission
The President
Ursula VON DER LEYEN