



Brussels, **XXX**
SANTE/4223473/2024 CIS
(POOL/G5/2024/4223473/4223473-EN
CIS.docx)
[...] (2024) **XXX** draft

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

of **XXX**

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for cattle for fattening (holder of authorisation: S.I. Lesaffre) and amending Regulation (EC) No 316/2003

(Text with EEA relevance)

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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) 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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) The preparation of *Saccharomyces cerevisiae* CNCM I-4407 (previously taxonomically identified as *Saccharomyces cerevisiae* NCYC Sc 47) was authorised without a time limit pursuant to Directive 70/524/EEC as a feed additive for cattle for fattening by Commission Regulation (EC) No 316/2003³. 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-4407 as a feed additive for cattle for fattening. The applicant requested the additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’. The application was 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 22 January 2019⁴ and 13 March 2024⁵ that, under the proposed conditions of use, the

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 316/2003 of 19 February 2003 concerning the permanent authorisation of an additive in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 46, 20.2.2003, p. 15, ELI: <http://data.europa.eu/eli/reg/2003/316/oj>).

⁴ EFSA Journal 2019;17(3):5600.

⁵ EFSA Journal 2024;22:e8727.

preparation of *Saccharomyces cerevisiae* CNCM I-4407 is considered safe for cattle for fattening, consumers and the environment. Regarding the safety for the user, in the absence of data, the Authority could not conclude on the potential of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 to be irritant to eyes or its dermal sensitisation potential due to the lack of data but concluded that that additive is not a skin irritant and that inhalation exposure is unlikely. The Authority concluded that the preparation of *Saccharomyces cerevisiae* CNCM I-4407 is efficacious as a zootechnical additive in cattle for fattening at the concentration of 4×10^9 CFU/kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* CNCM I-4407 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 for use in cattle for fattening. Accordingly, the use of that preparation should be authorised for cattle for fattening. 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.
- (6) 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-4407, 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.
- (7) As a consequence of the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for cattle for fattening, Regulation (EC) No 316/2003 should be amended accordingly.
- (8) 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 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 **Amendment to Regulation (EC) No 316/2003**

Regulation (EC) No 316/2003 is amended as follows:

- (1) Article 1 is deleted;
- (2) Annex I is deleted.

Article 3 **Transitional measures**

1. The feed additive *Saccharomyces cerevisiae* NCYC Sc 47 (E 1702), as authorised by Regulation (EC) No 316/2003, and premixtures containing that additive, which are

intended for cattle for fattening, and which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the OP] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the OP] 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 cattle for fattening, and which are produced and labelled before [12 months after the date of entry into force of this Regulation – Date to be inserted by the OP] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the OP] 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