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

of **XXX**

concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for cows (holder of authorisation: Volac International Ltd) and repealing Implementing Regulation (EU) 2015/502

(Text with EEA relevance)

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

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concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for cows (holder of authorisation: Volac International Ltd) and repealing Implementing Regulation (EU) 2015/502

(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) 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 an authorisation.
- (2) A preparation of *Saccharomyces cerevisiae* NCYC R404, was authorised for a period of 10 years as a feed additive for dairy cows by Commission Implementing Regulation (EU) 2015/502².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows, requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. 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 18 March 2025³ that the preparation of *Saccharomyces cerevisiae* NCYC R404 remains safe for dairy cows, consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Saccharomyces cerevisiae* NCYC R404, is not irritant to skin or eyes, and it should be considered a potential skin and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of

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

² Commission Implementing Regulation (EU) 2015/502 of 24 March 2015 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows (holder of the authorisation Micro Bio-System Ltd) (OJ L 79, 25.3.2015, pp. 57, ELI: http://data.europa.eu/eli/reg_Impl/2015/502/oj).

³ EFSA Journal. 2025;23:e9342. <https://doi.org/10.2903/j.efsa.2025.9342>.

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the additives. Therefore, it concluded that there is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive in the context of the previous authorisations are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005⁴, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* NCYC R404 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive, Implementing Regulation (EU) 2015/502 should be repealed.
- (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
Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

Article 2
Repeal

Implementing Regulation (EU) 2015/502 is repealed.

Article 3
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.

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 059 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

Done at Brussels,

*For the Commission
The President
Ursula VON DER LEYEN*

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