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 Micron Bio-Systems Ltd, represented by FF Chemicals BV) (Text with EEA relevance)

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 **[**F1Micron Bio-Systems Ltd, represented by FF Chemicals BV**]**)

(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 a preparation of *Saccharomyces cerevisiae* NCYC R404. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 11 September 2014(2) that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* NCYC R404 does not have an adverse effect on animal health, human health or the environment. It was also concluded that the additive has the potential to improve milk production of dairy cows. 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.

(5) The assessment of the preparation of *Saccharomyces cerevisiae* NCYC R404 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/502. (See end of Document for details)*

(6) 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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/1095 of 24 July 2020 amending Implementing Regulation (EU) 2015/502 concerning the authorisation of the preparation of Saccharomyces cerevisiae NCYC R404 as a feed additive for dairy cows (Text with EEA relevance).

Article 1

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

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/502. (See end of Document for details)*

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 group: gut flora stabilisers									
4b1871	[F1Micron Bio-Systems Ltd, represented by FF Chemicals BV.]	*Saccharomyces cerevisiae* NCYC R404	*Additive composition* Preparation of *Saccharomyces cerevisiae* NCYC R404 containing a minimum of: solid form 1 × 10^{10} CFU/g additive *Characterisation of the active substance* *Saccharomyces cerevisiae* NCYC R404 *Analytical method*[a] Identification: Polymerase Chain Reaction (PCR) —	Dairy cows	—	4,4 × 10^{8}	—	1. the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. dose of the additive: 1 × 10^{10} CFU/ head/ day. 3. safety: breathing and skin protection shall be used during handling.	14 In April 2025 Recommended For

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports