



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...] (2026) **XXX** draft

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

of **XXX**

**concerning the authorisation of a preparation of *Saccharomyces cerevisiae* NCYC R618
as a feed additive for poultry for fattening and poultry reared for laying (holder of
authorisation: Global Nutritech Biyoteknoloji Ltd. Sti, represented in the Union by
Regal B.V.)**

(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.
- (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 R618. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R618 as a feed additive for chickens for fattening and other poultry species for fattening and reared for laying, requesting the additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 17 September 2024² that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* NCYC R618 is safe for the target species, as well as for consumers and the environment. The Authority also concluded that the additive should be considered a skin and respiratory sensitiser and any exposure through the skin and respiratory tract should be considered a risk. It could not conclude on the eye irritation potential due to the lack of data. Furthermore, due to the lack of sufficient data, the Authority could not conclude on the efficacy of the additive for poultry species for fattening or reared for laying. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 10 March 2026³ that the additive has the potential to be efficacious in chickens for fattening when included at 4×10^9 CFU/kg of complete feed. This conclusion was extended to chickens reared for laying

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

² EFSA Journal. 2024;22:e9050. <https://doi.org/10.2903/j.efsa.2024.9050>.

³ EFSA Journal. 2026;24:e10035. <https://doi.org/10.2903/j.efsa.2026.10035>.

and extrapolated to other poultry species for fattening or reared for laying. The Authority 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 additive 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* NCYC R618 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for poultry for fattening and poultry reared for laying. 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) 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 group ‘gut flora stabilisers’, 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,

For the Commission
The President
Ursula VON DER LEYEN