EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 as a feed additive for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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concerning the authorisation of a preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 as a feed additive for all animal species

(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 *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856. 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 *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 as a feed additive for all animal species, requesting that additive to be classified in the category 'technological additives' and in the functional group 'silage additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 October 2024[2] that the additive consisting of a preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 is safe for all animal species, consumers and the environment. It also concluded that the additive is not an irritant to the skin but should be considered as a potential skin and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk. The latter conclusion would apply to any preparations containing the active agents. The Authority further concluded that the addition of the additive at a minimum level of 1×10^8 CFU/kg fresh plant material has the potential to improve the aerobic stability of silage from fresh plant material, with a dry matter range between 32% and 65%.

(5) In view of the above, the Commission considers that the preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. In addition, the Commission

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

[2] EFSA Journal, 22(11), e9070. https://doi.org/10.2903/j.efsa.2024.9070.

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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 ‘technological additives’ and to the functional group ‘silage additives’, 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