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

of **XXX**

**correcting Implementing Regulation (EU) 2021/422 as regards the authorisation of a
preparation of *Enterococcus faecium* DSM 7134 as a feed additive for laying hens**

(Text with EEA relevance)

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

of **XXX**

correcting Implementing Regulation (EU) 2021/422 as regards the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for laying hens (holder of authorisation: Lactosan GmbH & Co KG)

(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) The use of the preparation *Enterococcus faecium* DSM 7134 as a feed additive was authorised for laying hens by Commission Implementing Regulation (EU) 2021/422² for a 10-year period.
- (2) In the Annex to Implementing Regulation (EU) 2021/422, the wrong identification number of the additive has been inserted in the column ‘Identification number of the additive’.
- (3) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 30 September 2020³ that the additive may be used via water for drinking, as part of the conditions of use subject to the safety and efficacy assessment. The specification deriving from that conclusion was not included in the column ‘Other provisions’ of the Annex to Implementing Regulation (EU) 2021/422, and should therefore be added therein for reasons of legal certainty.
- (4) The Authority’s opinion also indicated that the additive is not a dermal or ocular irritant, but a potential dermal and respiratory sensitiser. The Annex to Implementing Regulation (EU) 2021/422, in the column “Other provisions”, erroneously refers to the use of breathing protection, glasses and gloves as personal protection equipment, while it should instead refer to the use of breathing and skin protection in order to take appropriate account of the Authority’s opinion concerning users’ safety.
- (5) In the Annex to Implementing Regulation (EU) 2021/422, a minor clerical error has been made as regards the name of the authorisation holder.

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Implementing Regulation (EU) 2021/422 of 9 March 2021 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for laying hens (holder of authorisation: Lactosan GmbH & Co KG) (OJ L 83, 10.3.2021, p. 25).

³ EFSA Journal 2020;18(11):6277.

- (6) Implementing Regulation (EU) 2021/422 should therefore be corrected accordingly. For the sake of clarity, it is appropriate to replace the whole Annex to the said Implementing Regulation by the corrected version thereof.
- (7) In order to preserve the legitimate expectations of the interested parties in relation to the terms of the authorisation of the additive, this Regulation should enter into force as a matter of urgency.
- (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

The Annex to Implementing Regulation (EU) 2021/422 is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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