

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1414**of 27 August 2021****correcting Implementing Regulation (EU) 2021/422 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)****(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) The use of the preparation *Enterococcus faecium* DSM 7134 as a feed additive was authorised for laying hens by Commission Implementing Regulation (EU) 2021/422 ⁽²⁾ 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 2020 ⁽³⁾ 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.
- (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 allow feed business operators to adapt the labelling of the additive and feed containing it to the corrected terms of authorisation, a transitional period should be provided for as regards the placing on the market of those products.
- (8) 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.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽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.

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

1. The preparation specified in the Annex and premixtures containing that substance, which are produced and labelled before 1 December 2021 in accordance with the rules applicable before 31 August 2021 may continue to be placed on the market until the existing stocks are exhausted.
2. Feed materials and compound feed containing the preparation and premixtures referred to in paragraph 1 which are produced and labelled before 31 August 2022 in accordance with the rules applicable before 31 August 2021 may continue to be placed on the market until the existing stocks are exhausted.

Article 3

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4b1841	Lactosan GmbH & Co KG	<i>Enterococcus faecium</i> DSM 7134	Additive composition Preparation of <i>Enterococcus faecium</i> DSM 7134 containing a minimum of: Powder: 1×10^{10} CFU/g of additive Granules (microencapsulated): 1×10^{10} CFU/g of additive	Laying hens	-	1×10^9	-	5×10^8	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. For use of the additive in water for drinking the homogenous dispersion of the additive shall be ensured. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or	30.3.2031
			Characterisation of the active substance: Viable cells of <i>Enterococcus faecium</i> DSM 7134								
			Analytical method ⁽¹⁾ For enumeration: Spread plate method using bile esculin azid agar (EN 15788). For identification: Pulsed Field Gel Electrophoresis (PFGE).								

										reduced to a minimum by such procedures and measures, the additive and pre-mixtures shall be used with appropriate personal protective equipment, including breathing and skin protection.'	
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>