Commission Implementing Regulation (EU) 2020/159 of 5 February 2020
concerning the renewal of the authorisation of Enterococcus faecium
DSM 7134 as a feed additive for weaned piglets and pigs for fattening
and repealing Regulation (EC) No 538/2007 (holder of authorisation
Lactosan Starterkulturen GmbH & Co) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/159
of 5 February 2020

concerning the renewal of the authorisation of Enterococcus faecium DSM 7134 as
a feed additive for weaned piglets and pigs for fattening and repealing Regulation
(EC) No 538/2007 (holder of authorisation Lactosan Starterkulturen GmbH & Co)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 and renewing such
authorisation.

(2) Enterococcus faecium DSM 7134 was authorised for 10 years as a feed additive for

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application
was submitted by the holder of that authorisation for the renewal of the authorisation of
Enterococcus faecium DSM 7134 as a feed additive for weaned piglets and pigs for fattening, requesting that additive to be classified in the additive category
‘zootechnical additives’. That application was accompanied by the particulars and

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of
27 February 2019(3) that the applicant has provided data demonstrating that the
additive complies with the conditions of authorisation. The Authority concluded that
Enterococcus faecium DSM 7134 remains safe under the authorised conditions of
use for the target animals, consumers, users and the environment. The Authority also
concluded that the additive is considered a potential skin and respiratory sensitiser.
Therefore the Commission considers that appropriate protective measures should be
taken to prevent adverse effects on human health, in particular as regards the users of
the additive.
(5) The assessment of Enterococcus faecium DSM 7134 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of Enterococcus faecium DSM 7134 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 538/2007 should be repealed.

(7) 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 authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is renewed subject to the conditions laid down in that Annex.

Article 2
Regulation (EC) No 538/2007 is repealed.

Article 3
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, 5 February 2020.

For the Commission
The President
Ursula VON DER LEYEN
### ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive of authorisation</th>
<th>Additive composition</th>
<th>Species category</th>
<th>Minimum content CFU/kg of complete feedingstuff with a moisture content of 12%</th>
<th>Maximum content CFU/kg of complete feedingstuff with a moisture content of 12%</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4b1841 Lactosan Starterkulturen GmbH &amp; Co</td>
<td>Preparation of <em>Enterococcus faecium</em> DSM 7134 containing a minimum of: Powder: $1 \times 10^{10}$ CFU/g of additive Granules (microencapsulated): $1 \times 10^{10}$ CFU/g of additive</td>
<td>Piglets (weaned)</td>
<td>$0,5 \times 10^9$</td>
<td>$4 \times 10^9$</td>
<td>1.</td>
<td>26 February 2030</td>
</tr>
</tbody>
</table>

**Characterisation of the active substance:**

Viable cells of *Enterococcus faecium* DSM 7134

**Analytical method:**

For enumeration: spread

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*a* 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
<table>
<thead>
<tr>
<th>Method</th>
<th>Pigs for fattening</th>
<th>Minimum level</th>
<th>Maximal level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plate method using bile esculin azide agar (EN 15788)</td>
<td></td>
<td>0.2 x 10^9</td>
<td>1 x 10^9</td>
</tr>
</tbody>
</table>

*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](https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports)*
Commission Implementing Regulation (EU) 2020/159 of 5 February 2020 concerning the renewal of...

Status: Point in time view as at 05/02/2020

Changes to legislation: There are currently no known outstanding effects for the
Commission Implementing Regulation (EU) 2020/159. (See end of Document for details)


(3) EFSA Journal 2019; 17(3):5650.
**Status:**
Point in time view as at 05/02/2020.

**Changes to legislation:**
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/159.