II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/764
of 14 May 2019
concerning the authorisation of a preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 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 Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 as a feed additive for all animal species to be classified in the additive category ‘technological additives’.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 2 October 2018 (2) that, under the proposed conditions of use, the preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is considered a potential respiratory sensitiser and that no conclusion could be drawn on skin or eyes sensitisation or irritation by the additive. 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. The Authority also concluded that the preparation concerned has the potential to improve the production of silage from easy and moderately difficult to ensile forage materials. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

(2) EFSA Journal 2018; 16(10):5455.
HAS ADOPTED THIS REGULATION:

Article 1

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

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, 14 May 2019.

For the Commission
The President
Jean-Claude JUNCKER
### Technological additives: silage additives

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum content</th>
<th>Minimum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1k20757</td>
<td><em>Lactobacillus hilgardii</em> CNCM I-4785 and <em>Lactobacillus buchneri</em> CNCM I-4323/NCIMB 40788</td>
<td><strong>Additive composition:</strong> Preparation of <em>Lactobacillus hilgardii</em> CNCM I-4785 and <em>Lactobacillus buchneri</em> CNCM I-4323/NCIMB 40788 containing a minimum of $1.5 \times 10^{11}$ CFU/g additive (ratio of 1:1). <strong>Characterisation of the active substance:</strong> Viable cells of <em>Lactobacillus hilgardii</em> CNCM I-4785 and <em>Lactobacillus buchneri</em> CNCM I-4323/NCIMB 40788. <strong>Analytical method (¹)</strong> Enumeration in the feed additive and premixtures: spread plate method on MRS agar: EN 15787. Identification of the feed additive: Pulsed Field Gel Electrophoresis (PFGE).</td>
<td>All animal species</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>4 June 2029</td>
</tr>
</tbody>
</table>

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