# COMMISSION IMPLEMENTING REGULATION (EU) 2022/1382

## of 8 August 2022

## concerning the authorisation of a preparation of *Propionibacterium freudenreichii* DSM 33189 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 an authorisation.

(2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Propionibacterium freudenreichii* DSM 33189 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 *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856 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 26 January 2022 ([2]) that, under the proposed conditions of use, the preparation of *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is not irritant for eyes and skin but should be considered a respiratory sensitiser and no conclusions could be drawn on the skin sensitisation potential of 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 preservation of nutrients in silage prepared with easy and moderately difficult to ensile material. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the 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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2022;20(2):7151.

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, 8 August 2022.

*For the Commission*
*The President*
Ursula VON DER LEYEN

*ANNEX*

| Identification number of the additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | CFU of additive/kg of fresh material | | | |
| **Category: technological additives**<br>**Functional group: silage additives** | | | | | | | | |
| 1k1801 | *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856 | *Additive composition*<br>Preparation of *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856 containing a minimum of $5 \times 10^{11}$ CFU/g additive, with a ratio of 1:4 ($1\times10^{11}$ CFU *P. freudenreichii* DSM 33189/g and $4\times10^{11}$ CFU *L. buchneri* DSM 12856/g)<br>Solid form<br>*Characterisation of the active substance*<br>Viable cells of *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856<br>*Analytical method* (1)<br>For the identification of *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* DSM 12856:<br>— Pulsed-Field Gel Electrophoresis (PFGE) or DNA sequencing methods<br>For the enumeration of *Lentilactobacillus buchneri* DSM 12856 in the feed additive:<br>— Spread plate method on MRS agar (EN 15787)<br>For the enumeration of *Propionibacterium freudenreichii* DSM 33189 in the feed additive:<br>— Pour plate method on caseine peptone, yeast extract, sodium lactate and L-cysteine agar | All animal species | - | - | - | 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.<br>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: $1\times10^{8}$ CFU/kg of easy and moderately difficult to ensile fresh material (2).<br>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection. | 29 August 2032 |

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

(2) Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in the fresh material in accordance with Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).