



2023/2644

29.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2644

of 28 November 2023

concerning the authorisation of lactic acid produced by *Weizmannia coagulans* DSM 32789 as a feed additive for all animal species except all aquatic animals and ruminants without a functional rumen

(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 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of lactic acid produced by *Weizmannia coagulans* (synonym *Bacillus coagulans*) DSM 32789. 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 lactic acid produced by *Weizmannia coagulans* DSM 32789 as a feed additive for all animal species except for fish, requesting that additive to be classified in the category 'technological additives' and in the functional group 'preservatives'.
- (4) The applicant requested the additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of technological additives for use in water for drinking. Therefore, the use of the additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 24 March 2022 ⁽²⁾ and of 22 March 2023 ⁽³⁾ that, under the proposed conditions of use, lactic acid produced by *Weizmannia coagulans* DSM 32789 is safe for the target species except for pre-ruminants and is safe for the consumers and the environment. It also concluded that lactic acid produced by *Weizmannia coagulans* DSM 32789 is corrosive to the skin, eyes and mucous membranes. The Authority further concluded that since lactic acid is used in food as a preservative it is reasonable to expect that the effect seen in food will be observed in feed when it is used at comparable concentrations and conditions. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory set up by Regulation (EC) No 1831/2003, which considered that the evaluation report issued on 21 February 2012 related to lactic acid authorised by Commission Implementing Regulation (EU) 2022/415 ⁽⁴⁾ including an addendum issued on 1 June 2021, is valid and applicable for the current application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2022;20(4):7268.

⁽³⁾ EFSA Journal 2023;21(4):7965.

⁽⁴⁾ Commission Implementing Regulation (EU) 2022/415 of 11 March 2022 concerning the authorisation of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for all animal species (OJ L 85, 14.3.2022, p. 6).

- (6) In view of the above, the Commission considers that lactic acid produced by *Weizmannia coagulans* DSM 32789 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that additive should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (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 substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'preservatives', 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, 28 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi- fication 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
					mg/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: preservatives								
1a270i	Lactic acid	Additive composition Lactic acid ≥ 74 % (w/w) Liquid form Characterisation of the active substance Lactic acid: D-lactic acid ≤ 3 % L-lactic acid ≥ 97 % C ₃ H ₆ O ₃ CAS no 79-33-4 Produced by fermentation of: <i>Weizmannia coagulans</i> DSM 32789 Method of Analysis ⁽¹⁾ For the determination of lactic acid in the feed additive, premixtures and compound feed: Ion Chromatography with Conductivity Detection, IC-CD (EN 17294)	All animal species other than pigs, rumi- nants and all aquatic ani- mals	—	—	20 000	1. The mixture of different sources of lactic acid shall not exceed the permitted max- imum levels in complete feedingstuffs for related species. 2. In the directions for use of the additive, premixture and related feed for food-pro- ducing animals, the following shall be in- dicated: ‘The simultaneous use of differ- ent organic acids or their salts is contra- indicated where one or more of them is used at or near the maximum permitted content.’ 3. For users of the additive and premixtures, feed business operators shall establish op- erational procedures and appropriate or- ganisational measures to address the po- tential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the ad- ditive and premixtures shall be used with personal skin, eye and breathing protec- tive equipment.	19 December 2033
			Pigs and ruminants with a functional rumen			50 000		

⁽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