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# Scientific opinion on the presence of viable cells in a feed additive consisting of lactic acid produced by *Weizmannia coagulans* DSM 32789 (Jungbunzlauer SA)

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## Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on lactic acid produced by fermentation using a strain of *Weizmannia coagulans* (DSM 32789). The additive is intended to be used as a technological additive, functional group preservatives, in complete feed and water for drinking for all animal species except for fish. In a previous opinion, the FEEDAP Panel concluded that the production strain qualified for the qualified presumption of safety (QPS) approach for safety assessment. Uncertainty remained concerning the possible presence of viable cells and/or spores of the production strain in the final product, however, the presence of viable cells of a QPS strain would not raise safety concerns for the target species, humans, and the environment. The applicant has provided additional information in the form of a scientific report to support the absence of viable cells and/or spores in the final product. Based on the data provided, the FEEDAP Panel concluded that the final product contains no viable cells and/or spores of the production microorganism.



**Keywords:** technological additives, preservatives, lactic acid, *Weizmannia coagulans*, DSM 32789, safety, QPS

**Requestor:** European Commission

**Question number(s):** EFSA-Q-2022-00625

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**Declarations of interest:** If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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# 1. Introduction

## 1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant Jungbunzlauer SA is seeking a Community authorisation of Lactic acid produced using *Weizmannia coagulans* (*Bacillus coagulans*) DSM 32789 as feed additive to be used as preservative for all animal species[2] (Table 1).

**Table 1:** Description of the substances

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|---|---|
| **Category of additive** | Technological additive |
| **Functional group of the additive** | Preservatives |
| **Description** | Lactic acid produced using *Weizmannia coagulans* (*Bacillus coagulans*) DSM 32789 |
| **Target animal category** | All animal species |
| **Applicant** | Jungbunzlauer SA |
| **Type of request** | New opinion |

On 23 March 2022, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA) could not conclude on the safety and efficacy of the additive in its opinion.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 18 January 2023 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks EFSA to deliver a new opinion on Latic acid produced using *Weizmannia coagulans* (*Bacillus coagulans*) DMS 32789 as a feed additive for all animal species based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

## 1.2. Additional information

Lactic acid produced by *W. coagulans* DSM 32789 is not authorised as a feed additive in the EU. The FEEDAP Panel has adopted an opinion on the safety and efficacy of the additive under assessment (EFSA FEEDAP Panel, 2022).

# 2. Data and Methodologies

## 2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[3] to a previous application on the same product.[4] The dossier was received on 7/10/2022 and the general information and supporting documentation available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00625.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] In the previous assessment the applicant decided to withdraw the use of the additive in fish feed.
[3] Dossier reference: EFSA-Q-2022-00625.
[4] Dossier reference: FAD-2018-0092.
[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

concerning transparency and confidentiality,[6] a non-confidential version of the supplementary information has been published on Open.EFSA.

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of the microbial strain producing lactic acid is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

## 3. Assessment

The lactic acid under assessment is produced by fermentation by a non-genetically modified strain of *W. coagulans* (DSM 32789) and it is intended to be used as a technological additive (functional group: preservatives) in feed and in water for drinking for all animal species except fish.

The additive is an aqueous brown viscous liquid with a pH $< 2$. It contains by specification $\geq 74\%$ lactic acid on 'as is' basis, and about 13% of water. Proposed use levels in complete feed are 50,000 mg/kg in feed for pigs and functional ruminants, and 20,000 mg/kg complete feed for poultry and all other species and animal categories. When used in water for drinking, a unique concentration of 15,000 mg/L is proposed for pigs, functional ruminants, poultry and all other animal species and categories.

The additive under assessment and the production strain were characterised in a previous opinion (EFSA FEEDAP Panel, 2022). In that assessment, the data provided did not allow to conclude on the potential presence of viable cells and/or spores of the production strain in the additive. However, considering that the production strain *W. coagulans* DSM 32789 qualifies for the qualified presumption of safety (QPS) approach to safety assessment, the Panel concluded that the potential presence of its viable cells and/or spores in the final product would be of no safety concern for target species, humans, and the environment.

The applicant has provided new information in the form of a study report to exclude the presence of viable cells and/or spores of the production strain in the final product.[8]

The presence of viable cells and/or spores of *W. coagulans* DSM 32789 was tested in three independent batches of the final product (three replicates/batch).[9] For each batch, 10 g of the additive were [redacted] with or without a heat treatment at 60°C for 30 min. Then, 0.1 mL of the incubation medium was spread on a carbonate medium plate and incubated at 50°C for 48 h. Afterwards, colonies were counted. As a positive control, the additive [redacted] was spiked with one inoculation loop of the production strain and processed as described above. The positive control performed as expected.

No viable cells and/or spores of the production microorganism could be detected in the final product.

## 4. Conclusions

The final product contains no viable cells and/or spores of the production microorganism.

## References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

[6] Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[7] 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.

[8] Annex I.

[9] Annex II.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Azimonti G, Bampidis V, Bastos ML, Christensen H, Dusemund B, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Prieto Maradona M, Anguita M, Galobart J, Pettenati E and Tarrés-Call J, 2022. Scientific Opinion on the safety and efficacy of a feed additive consisting of lactic acid produced by *Weizmannia coagulans* (synonym *Bacillus coagulans*) DSM 32789 for all animal species except for fish (Jungbunzlauer SA). EFSA Journal 2022;20(4):7268, 17 pp. https://doi.org/10.2903/j.efsa.2022.7268

## Abbreviations

| | |
|---|---|
| CFU | colony forming unit |
| DSM | Deustche Sammlung von Mikroorganismen |
| FEEDAP | EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed |