

ADOPTED: 18 May 2017

doi: 10.2903/j.efsa.2017.4860

Safety and efficacy of *Bacillus amyloliquefaciens* (NCIMB 30229) as a silage additive for all animal species

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Abstract

The additive under assessment is a preparation of *Bacillus amyloliquefaciens* NCIMB 3022 intended for use as a technological additive in forages for all animal species at a proposed minimum dose of 5×10^7 CFU/kg fresh materials. The species *B. amyloliquefaciens* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment. This approach requires the identification of the strain and evidence that it is not toxigenic and does not show acquired resistance to relevant antibiotics. In a previous assessment, the identity and susceptibility to clinically relevant antibiotics of the active agent was established but the lack of toxigenic potential could not be demonstrated. Therefore, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) could not conclude on the safety of the product for target animals, consumers, users or the environment. In the same opinion, the potential of the additive to improve aerobic stability of silages at the proposed dose was not convincingly demonstrated. A new cytotoxicity study was conducted using methanol extracts. The methanol extract was cytotoxic at the inclusion level of 5%, while no cytotoxicity was observed at lower concentrations. The current guidance on *Bacillus* requires absence of toxic effect using the non-concentrated supernatant. Since the applicant was unable to determine the correlation between the methanol extracts and the *Bacillus* supernatant concentrations, the FEEDAP Panel is unable to conclude on the toxigenic potential of the strain based on the current data. An additional efficacy study with a similar protocol to the ones previously assessed was conducted. The study showed an improved aerobic stability when added to forage at the proposed dose. However, the FEEDAP Panel remains unable to conclude on the efficacy of the additive to improve the ensiling process on the basis of a single positive result.

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Keywords: technological additive, silage additive, *Bacillus amyloliquefaciens*, safety, cytotoxicity, methanol extract, efficacy

Requestor: the European Commission

Question number: EFSA-Q-2016-00646

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Note: The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

Suggested citation: 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, Coconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Brozzi R and Saarela M, 2017. Scientific Opinion on the safety and efficacy of *Bacillus amyloliquefaciens* (NCIMB 30229) as a silage additive for all animal species. EFSA Journal 2017;15(6):4860, 2 pp. <https://doi.org/10.2903/j.efsa.2017.4860>

ISSN: 1831-4732

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