

Commission Implementing Regulation (EU) 2020/1755 of 24 November 2020 concerning the authorisation of a preparation of *Bacillus coagulans* DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds (holder of authorisation Biochem Zusatzstoffe Handels- und Produktionsges. mbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1755

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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 *Bacillus coagulans* DSM 32016. 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 *Bacillus coagulans* DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds, to be classified in the category ‘zootechnical additives’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 25 May 2020⁽²⁾ that, under the proposed conditions of use, the preparation of *Bacillus coagulans* DSM 32016 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that it is not a skin/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. 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 has the potential to be efficacious as zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of

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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 *Bacillus coagulans* DSM 32016 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 product 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,

HAS ADOPTED THIS REGULATION:

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- (1) [OJ L 268, 18.10.2003, p. 29.](#)
- (2) [EFSA Journal 2020;18\(6\):6158.](#)

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