SCIENTIFIC OPINION



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Efficacy of ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) as a feed additive for weaned piglets and minor porcine species

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the efficacy of ZM16 10 for weaned piglets and minor porcine species. The additive is a preparation containing viable spores of a strain of Bacillus amyloliquefaciens (DSM 25840). This product is available in two forms, ZM16 and ZM16 10, which contain the bacterium in concentrations of 1.25×10^9 CFU/q additive and 1.25×10^{10} CFU/g additive, respectively. In a previous opinion, the FEEDAP Panel assessed the safety and the efficacy of the product when used in weaned piglets. The Panel concluded that the active agent fulfils the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety. Consequently, the additive is presumed safe for the target animals, consumers of products from animals fed with the additive and the environment. Regarding the safety for the user, the FEEDAP Panel could not conclude on the potential of the additive to be irritant to skin and eyes or its dermal sensitisation due to the lack of data. However, it concluded that the additive should be considered a potential respiratory sensitiser. The data provided in the previous assessment to support the efficacy of the additive was not sufficient to conclude on the efficacy of the additive in weaned piglets or minor weaned porcine species. The applicant provided supplementary information to complement the data, including a statistical analysis pooling data from different studies. Based on the newly submitted data, the Panel concluded that the additive has a potential to be efficacious as a zootechnical additive in weaned piglets at a level of 5×10^8 CFU/kg complete feed or in water for drinking at 1.7×10^8 CFU/L. This conclusion was extrapolated to minor porcine species at the same developmental stage.

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1. Introduction

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

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

The applicant, Chr. Hansen A/S, is seeking a Community authorisation of *Bacillus amyloliquefaciens* DSM 25840 as a feed additive to be used as a gut flora stabilisers for piglets (weaned) and weaned minor porcine species (Table 1).

Table 1: Description of the substances

Category of additive	Zootechnical additive
Functional group of additive	Gut flora stabilizer
Description	Bacillus amyloliquefaciens DSM 25840
Target animal category	Piglets (weaned) and weaned minor porcine species
Applicant	Chr. Hansen A/S
Type of request	New opinion

On 21 February 2018, the Panel on Additives and Products or Substances use in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the product, could not conclude on the efficacy of *Bacillus amyloliquefaciens* DSM 25840 in piglets (weaned) and weaned minor porcine species, under the condition of use as proposed by the applicant.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of Authority's opinion. The new data have been received on 24 July 2018.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for piglets (weaned) and weaned minor porcine species based on the additional data submitted by the applicant.

1.2. Additional information

The FEEDAP Panel issued an opinion on the safety and efficacy of ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) as a feed additive for weaned piglets and minor porcine species (EFSA FEEDAP Panel, 2018). In that assessment, the Panel could not conclude on the efficacy of the additive due to insufficient data/information.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information to a previous application on the same product.²

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess efficacy of ZM16 10 is in line with the principles laid down in Regulation (EC) No 429/2008³ and the Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and the technical guidance on tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

3. Assessment

The additive is a preparation containing viable spores of a strain of *B. amyloliquefaciens* (DSM 25840). This product is available in two forms, ZM16 and ZM16 10, which contain the bacterium in concentrations

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¹ FEED dossier reference: FAD-2018-0046.

² FEED dossier reference: FAD-2016-0069.

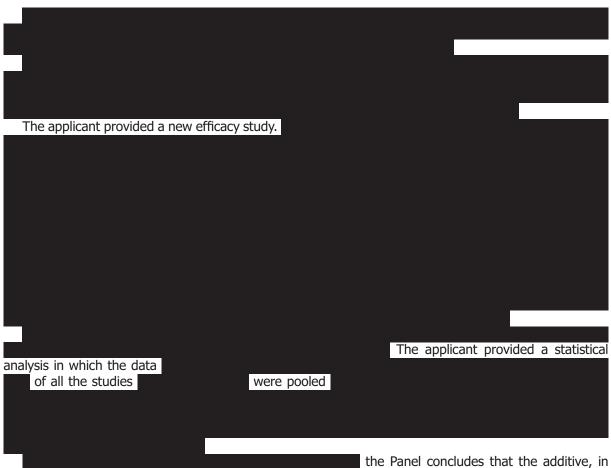
³ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.



of 1.25×10^9 CFU/g additive and 1.25×10^{10} CFU/g additive, respectively. In a previous opinion, the FEEDAP Panel assessed the safety and the efficacy of the product when used in weaned piglets (EFSA FEEDAP Panel, 2018). The Panel concluded that the active agent fulfils the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety. Consequently, the additive is presumed safe for the target animals, consumers of products from animals fed with the additive and the environment. Regarding the safety for the user the FEEDAP Panel could not conclude on the potential of the additive to be irritant to skin and eyes or its dermal sensitisation due to the lack of data. However, it concluded that the additive should be considered a potential respiratory sensitiser. The data provided to support the efficacy of the additive was not sufficient to conclude on the efficacy of the additive in weaned piglets or minor weaned porcine species.

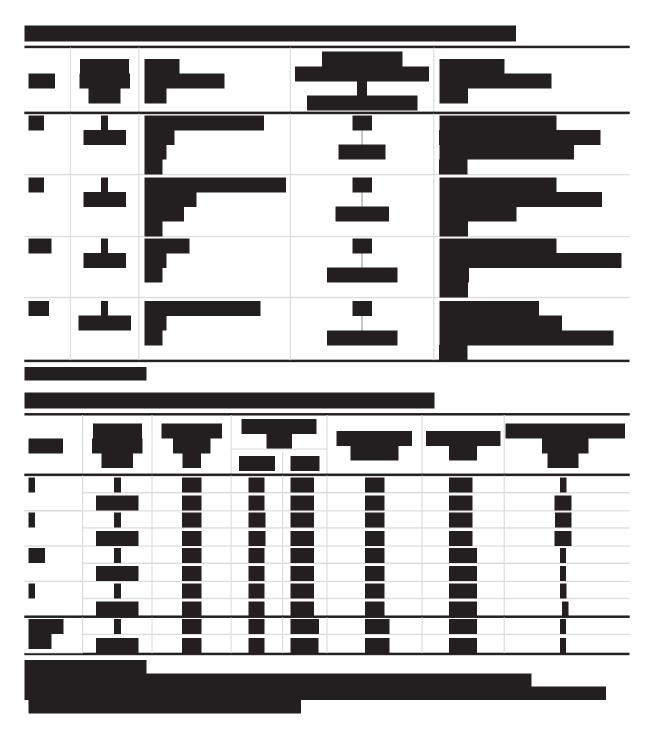
The applicant has provided new data to complement the information available supporting the efficacy of the additive in weaned piglets and minor porcine species. The additive is intended to be used as a zootechnical additive in weaned piglets and minor porcine species (functional group: gut flora stabilisers) at the proposed level of 5 \times 10 8 CFU/kg complete feed or in water for drinking at 1.7 \times 10 8 CFU/L.

3.1. Efficacy for weaned piglets



either form, has a potential to be efficacious as a zootechnical additive in weaned piglets at the recommended level of 5×10^8 CFU/kg complete feed. The conclusions are extended to the use of the additive in water for drinking at 1.7×10^8 CFU/L. These conclusions are extrapolated to minor porcine species in the same developmental stage.





3.2. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation 12 and Good Manufacturing Practice.



Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.



4. Conclusion

The additive ZM16 or ZM16 10 (Bacillus amyloliquefaciens DSM 25840) has a potential to be efficacious as a zootechnical additive in weaned piglets and minor porcine species at the recommended level of 5×10^8 CFU/kg complete feed or at 1.7×10^8 CFU/L drinking water.

Chronology

Date	Event	
23/7/2018	Dossier received by EFSA. ZM16 (<i>Bacillus amyloliquefaciens</i> DSM 25840) for weaned piglets and minor porcine species. Submitted by Chr. Hansen A/S.	
12/2/2019 Reception mandate from the European Commission		
12/2/2019 Application validated by EFSA – Start of the scientific assessment		
11/3/2016 Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation No 1831/2003 – Scientific assessment suspended. <i>Issue: efficacy</i>		
11/6/2019	Clarification teleconference during risk assessment with the applicant according to the 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products'	
13/8/2019	Reception of supplementary information from the applicant - Scientific assessment re-started	
4/10/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment	

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. https://doi.org/10.2903/j.efsa.2011.2175

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Abbreviations

CFU colony forming unit

OPS qualified presumption of safety