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Assessment of the application for renewal of the authorisation of Calsporin® (*Bacillus velezensis* DSM 15544) as a feed additive for weaned piglets

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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 assessment of the application for renewal of authorisation of Calsporin® (*Bacillus velezensis* DSM 15544) as a zootechnical additive for weaned piglets. The product under assessment is based on viable spores of a strain originally identified as *Bacillus subtilis*. During the course of the current assessment, the active agent has been reclassified as *Bacillus velezensis* DSM 15544. *B. velezensis* is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment. The identity of the active agent was established and the compliance with the other qualifications confirmed. Therefore, *B. velezensis* DSM 15544 is presumed safe for the target species, consumers of products derived from animals fed the additive and the environment. Since no concerns are expected from the other components of the additive, Calsporin® is also considered safe for the target species, consumers of products derived from animals fed the additive and the environment. The additive is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. The present application for renewal of the authorisation did not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

Keywords: Zootechnical additive, gut flora stabiliser, *Bacillus velezensis*, weaned piglets, safety

Requestor: European Commission

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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. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Asahi Calpis Wellness Co., Ltd.[2] for renewal of the authorisation of the product Calsporin® (*Bacillus velezensis* DSM 15544[3]), when used as a feed additive for weaned piglets (category: zootechnical additives; functional group: gut flora stabilisers).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 15 July 2019.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Calsporin® (*Bacillus velezensis* DSM 15544), when used under the proposed conditions of use (see Section 3.1.2).

1.2. Additional information

The additive Calsporin® is a preparation containing viable spores of a strain of *Bacillus velezensis* (DSM 15544), formerly identified as *Bacillus subtilis*.

EFSA has issued several opinions on the safety and efficacy of Calsporin® as a feed additive for different species: chickens for fattening (EFSA, 2006, 2007a; EFSA FEEDAP Panel, 2018a), weaned piglets (EFSA FEEDAP Panel, 2010a), turkeys for fattening, ducks, geese, pigeons and other game birds for meat production, ducks, geese, pigeons, game birds, ornamental and sporting birds for rearing to point of lay, turkeys reared for breeding and chickens reared for laying (EFSA FEEDAP Panel, 2010b), laying hens and avian species for laying (EFSA FEEDAP Panel, 2015a), ornamental fish (EFSA FEEDAP Panel, 2015b), sows and suckling piglets (EFSA FEEDAP Panel, 2017a), dogs (EFSA FEEDAP Panel, 2017b), pigs for fattening (EFSA FEEDAP Panel, 2018b) and all poultry species (EFSA FEEDAP Panel, 2019).

The additive is authorised in the European Union (EU) as a zootechnical additive (functional group: gut flora stabiliser) for use in chickens for fattening,[4] weaned piglets,[5] chickens reared for

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2] Asahi Calpis Wellness Co., Ltd, represented in the EU by Pen & Tec Consulting S.L.U, Pl. Ausias March 1, 4th Floor, D01, 08195 Sant Cugat del Vallès, Spain.

[3] Originally designated as *Bacillus subtilis* DSM 15544.

[4] Commission Implementing Regulation (EU) 2019/893 of 28 May 2019 concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1444/2006 (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office). OJ L 142, 29.05.2019, p. 60 plus amendments.

[5] Commission Regulation (EU) No 333/2010 of 22 April 2010 concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets (holder of authorisation Calpis Co. Ltd. Japan, represented in the European Union by Calpis Co. Ltd. Europe Representative Office). OJ L 102, 23.4.2010, p. 19 plus amendments.

laying, turkeys, minor avian species and other ornamental and game birds,[6] laying hens and ornamental fish,[7] dogs, suckling piglets and in sows,[8] and in pigs for fattening (4b1820).[9]

The applicant has requested the renewal of the authorisation of the additive for weaned piglets.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[10] in support of the authorisation request for the use of Calsporin® (*Bacillus velezensis* DSM 15544) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[11]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Calsporin® (*Bacillus velezensis* DSM 15544) is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018c).

3. Assessment

The additive Calsporin® (*Bacillus velezensis* DSM 15544) is authorised as a zootechnical additive (functional group of gut flora stabilisers) for weaned piglets at a minimum level of 3×10^8 colony forming units (CFU)/kg complete feed.

The applicant is requesting the renewal of the authorisation of the feed additive for weaned piglets.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is a preparation of viable spores of *B. velezensis* DSM 15544. The applicant stated that no changes in the manufacturing process or composition of the additive have been introduced since the first authorisation. [redacted]

[6] Commission Regulation (EU) No 184/2011 of 25 February 2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office). OJ L 53, 26.2.2011, p. 33 plus amendments.

[7] Commission Implementing Regulation (EU) 2016/897 of 8 June 2016 concerning the authorisation of a preparation of Bacillus subtilis (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish (holder of authorisation Asahi Calpis Wellness Co. Ltd) and amending Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011 as regards the holder of the authorisation. OJ L 152, 9.6.2016, p. 7 plus amendments.

[8] Commission Implementing Regulation (EU) 2017/2312 of 13 December 2017 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office), OJ L 331, 14.12.2017, p. 41 plus amendments.

[9] Commission Implementing Regulation (EU) 2018/1081 of 30 July 2018 concerning the authorisation of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for pigs for fattening (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office), OJ L 194, 31.08.2018, p. 137 plus amendments.

[10] FEED dossier reference: FAD-2019-0037.

[11] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2009-0013.pdf

[12] 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.

The additive currently authorised contains viable spores of *B. velezensis* DSM 15544 at the minimum concentration of 1×10^{10} CFU/g additive. Compliance with this specification was demonstrated in three recent batches of the additive (mean count 1.2×10^{10} CFU/g additive, range $1.1–1.3 \times 10^{10}$ CFU/g additive).[13]

Three batches were analysed for chemical and microbiological contamination. The analyses for chemical contaminants included arsenic (0.228–0.299 mg/kg), cadmium (0.133–0.149 mg/kg), lead (0.870–1.05 mg/kg) and mercury (< 0.001 mg/kg, limit of quantification (LOQ)).[14] The results of the analyses for mycotoxins showed values below the corresponding limit of detection (LOD): 15-acetyl deoxynivalenol (< 0.1 mg/kg), 3-acetyl deoxynivalenol (< 0.1 mg/kg), aflatoxins B1, B2, G1 and G2 (< 1 μg/kg), deoxynivalenol (< 0.1 mg/kg), citrinin (< 50 μg/kg), diacetoxyscirpenol (< 20 μg/kg), fumonisin B1, B2, B3 (< 0.1 mg/kg), fusarenon X (< 0.1 mg/kg), HT-2 and T-2 Toxin (< 5 μg/kg), neosolaniol (< 20 μg/kg), nivalenol (< 0.1 mg/kg), ochratoxin A (< 1 μg/kg) and zearalenone (< 12.5 μg/kg).[15] Results of the microbial contaminants analyses also showed values below the LOD: *Escherichia coli* (< 3 CFU/g), Enterobacteriaceae (< 10 CFU/g), coliforms (< 3 CFU/g), filamentous fungi (< 10 CFU/g), yeasts (< 10 CFU/g) and *Bacillus cereus* (< 83 CFU/g). *Salmonella* spp. was not detected in 25g.[16,17]

The above-mentioned impurities/contaminants do not represent a safety concern.

3.1.2. Characterisation of the active agent

The active agent is a non-genetically modified organism that was isolated from the soil in Japan and is deposited in the German Collection of Microorganisms and Cell Cultures with the accession number DSM 15544.[18,19]

The active agent was formerly identified as *Bacillus subtilis* (EFSA, 2006). The data recently provided to support the taxonomic identification allocated the strain to the newly recognised species *B. velezensis*. [redacted][20]

The susceptibility of the strain to the antibiotics recommended to be tested by FEEDAP was investigated by broth microdilution following the method of the Clinical and Laboratory Standards Institute (CLSI) and all of the minimum inhibitory concentration (MIC) values determined fell below the FEEDAP cut-off values (EFSA FEEDAP Panel, 2018c).[21]

The WGS of the active agent was interrogated for the presence of antimicrobial resistance (AMR) genes [redacted][22]

The toxigenic potential of the strain was assessed according to the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018c). No lysis of Vero cells was detected. Therefore, *B. velezensis* DSM 15544 is considered to be non-toxigenic.[23]

The production of aminoglycosides by *B. velezensis* DSM 15544 was analysed in culture supernatants of the active agent by a disk diffusion test. As indicator strains, *Escherichia coli* ATCC 25922; *Pseudomonas aeruginosa* ATCC 27853; *Staphylococcus aureus* ATCC 25923; *Enterococcus faecalis* ATCC 29212 and *Bacillus subtilis* ATCC 6633, were used.[24] None of the reference strains was inhibited, demonstrating the absence of antimicrobial activity in the supernatant of *B. velezensis* DSM 15544.

[13] Technical dossier/Section II/Annex.II.1.3.1.
[14] Technical dossier/Section II/Annex.II.1.4.1, Annex.II.1.4.2 and Annex.II.1.4.3.
[15] Technical dossier/Section II/Annex.II.1.4.4.
[16] Technical dossier/Section II/Annex.II.1.4.1, Annex.II.1.4.2 and Annex.II.1.4.3 and Technical dossier/Supplementary information April 2020/EFSA_SIn_request_12Sep2019_reply. LOD in CFU/g were: 3 for *E. coli* and coliforms and 10 for Enterobacteriaceae, yeasts and moulds.
[17] Technical dossier/Supplementary information August 2020/Annexes/Annex_II_1_4_5.
[18] Technical dossier/Section II/Annex.II.2.1.2.1.
[19] Technical dossier/Supplementary information April 2020/Annexes/Annex_updated_II_2_1_2_1_Conf.
[20] Technical dossier/Supplementary information August 2020/Annexes/Annex_updated_II_2_1_2_7_1_Conf.
[21] Technical dossier/Supplementary information April 2020/Annexes/Annex_updated_II_2_2_2_4.
[22] Technical dossier/Supplementary information April 2020/Annexes/Annex_updated_II_2_2_2_6.
[23] Technical dossier/Supplementary information April 2020/Annexes/Annex_updated_II_2_2_2_1.
[24] Technical dossier/Supplementary information April 2020/Annexes/Annex_updated_II_2_2_2_2.

3.1.3. Conditions of use

The additive is currently authorised for use in feed as a feed additive for weaned piglets at a minimum level of 3×10^8 CFU/kg of complete feed. The authorisation also includes under 'Other provisions' 'For safety: breathing protection, glasses and gloves shall be used during handling'.

The applicant does not propose to modify the conditions of use as authorised.

3.2. Safety

B. velezensis is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007b; EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strain to be conclusively established and evidence provided that it does not show acquired resistance to relevant antimicrobials, that it lacks toxigenic potential and that it does not produce aminoglycosides. In the view of the FEEDAP Panel, the identity of the active agent is established and the compliance with the other qualifications confirmed. Therefore, *B. velezensis* DSM 15544 is presumed safe for the target species, consumers of products derived from animals fed the additive and the environment. Since no concerns are expected from the other components of the additive, the FEEDAP Panel concludes that Calsporin® remains safe for the target species, consumers and the environment.

The safety for the users was evaluated by the FEEDAP Panel in a previous assessment (EFSA, 2006). The Panel concluded that the additive is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. No additional data were provided in the current application.

The applicant stated that no adverse events have been detected under its global monitoring plan.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

3.4. 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[25] and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence that the additive currently in the market complies with the conditions of authorisation.

The active agent has been reclassified as *B. velezensis*. The strain does not show acquired antimicrobial resistance determinants for antibiotics of human and veterinary interest, aminoglycosides production ability, or toxigenic potential. Thus, the Panel concludes that the additive remains safe for the target species, consumer and the environment under the authorised conditions of use. Regarding user safety, the additive is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

5. Documentation as provided to EFSA/Chronology

Date	Event
15/05/2019	Dossier received by EFSA. Calsporin® (*Bacillus subtilis* C-3102, DSM 15544) for piglets (weaned). Submitted by Asahi Calpis Wellness Co. Ltd. represented in the EU by Pen & Tec Consulting S.L.U
06/05/2019	Reception mandate from the European Commission
15/07/2019	Application validated by EFSA – Start of the scientific assessment

[25] 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.

Date	Event
24/09/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
15/10/2019	Comments received from Member States
08/04/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
30/06/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
24/07/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
28/08/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
30/09/2020	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), 2010b. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis*) for turkeys for fattening, ducks, geese, pigeons and other game birds for meat production, ducks, geese, pigeons, game birds, ornamental and sporting birds for rearing to point of lay, turkeys reared for breeding and chickens reared for laying. EFSA Journal 2010;8(10):1867, 13 pp. https://doi.org/10.2903/j.efsa.2010.1867

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Abbreviations

AMR	antimicrobial resistance
CFU	colony forming unit
CLSI	Clinical and Laboratory Standards Institute
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
QPS	qualified presumption of safety
WGS	whole genome sequence