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Safety and efficacy of a feed additive consisting of *Bacillus velezensis* DSM 15544 (Calsporin[®]) for piglets (suckling and weaned), pigs for fattening, sows in order to have benefit in piglets, ornamental fish, dogs and all avian species (Asahi Biocycle Co.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of *Bacillus velezensis* DSM 15544 (Calsporin[®]) when used as a feed additive for piglets (suckling and weaned), pigs for fattening, sows in order to have benefit in piglets, ornamental fish, dogs and all avian species. The additive is authorised for use in sows, suckling and weaned piglets, pigs for fattening, chickens for fattening, laying hens, ornamental fish and dogs. With this application the company requested a new authorisation for all avian species and the modification of the current authorisations as regards the strain taxonomy from *Bacillus subtilis* DSM 15544 to *B. velezensis* DSM 15544. The FEEDAP Panel concluded that the active agent of Calsporin[®] should be taxonomically designated as *Bacillus velezensis* DSM 15544. The Panel also concluded that Calsporin[®] is presumed safe for the target species, consumers and the environment. Calsporin[®] is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. Calsporin[®] when supplemented at 3×10^8 CFU/kg complete feed has the potential to be efficacious in all avian species for rearing, fattening, laying and breeding purposes.

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Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference.....	4
1.2. Additional information.....	4
2. Data and methodologies.....	5
2.1. Data.....	5
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. Characterisation.....	5
3.1.1. Characterisation of the additive.....	5
3.1.2. Conditions of use.....	6
3.2. Safety.....	6
3.3. Efficacy for all avian species for rearing, fattening, laying and breeding purposes.....	6
3.4. Post-market monitoring.....	7
4. Conclusions.....	7
5. Documentation provided to EFSA/Chronology.....	7
References.....	8
Abbreviations.....	9

1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from (Asahi Biocycle Co. Ltd represented in the EU by Pen & Tec Consulting SLU)² for the authorisation of the additive consisting of *Bacillus velezensis* DSM 15544 (Calsporin®), when used as a feed additive for piglets, pigs for fattening, sows in order to have benefit in piglets, ornamental fish, dogs and all avian species (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 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 13(3) (modification of the authorisation of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 4 May 2021.

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 feed additive consisting of *Bacillus velezensis* DSM 15544 (Calsporin®), 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 single strain of *Bacillus subtilis* DSM 15544.

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, 2020), 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 as a zootechnical additive (functional group: gut flora stabiliser, 4b1820) for use in sows,³ suckling and weaned piglets,⁴ pigs for fattening,⁵ chickens for fattening,⁶ laying hens,

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 Asahi Biocycle Co. Ltd represented in the EU by Pen & Tec Consulting SLU, Plaza Ausias March 1, ES-08195, Sant Cugat del Vallès, Spain.

³ 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.

⁴ 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.

⁵ 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, 31.7.2018, p. 137.

⁶ Commission Regulation (EC) No 1444/2006 of 29 September 2006 concerning the authorisation of *Bacillus subtilis* C-3102 (Calsporin) as a feed additive. OJ L 271, 30.9.2006, p. 19 plus amendments.

ornamental fish⁷ and dogs.⁴ The authorisation of Calsporin® for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds expired on 18 March 2021.⁸

With this application the company is requesting a new authorisation of the additive for chickens reared for laying, for breeding, turkeys for rearing, fattening, breeding and laying, minor poultry species and all other avian species for rearing, fattening, laying and breeding.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁹ in support of the authorisation request for the use of *B. velezensis* DSM 15544 (Calsporin®) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the active agent in animal feed are valid and applicable for the current application.¹⁰

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of active substance (Calsporin®) is in line with the principles laid down in Regulation (EC) No 429/2008¹¹ and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017d), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018c) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018d).

3. Assessment

The subject of the assessment is a product containing viable spores of a single strain of *B. velezensis* with trade name Calsporin®, currently authorised as a zootechnical additive (functional group: gut flora stabilisers) in sows, suckling and weaned piglets, pigs for fattening, chickens for fattening, laying hens, ornamental fish and dogs. With the current application the applicant is seeking the:

- authorisation of Calsporin® in chickens reared for laying, chickens reared for breeding, turkeys for rearing, fattening, breeding and laying, minor poultry species and all other avian species for rearing, fattening, laying and breeding, and the
- modification of the strain taxonomy in all Calsporin® authorisations from *Bacillus subtilis* DSM 15544 to *Bacillus velezensis* DSM 15544.

3.1. Characterisation

3.1.1. Characterisation of the additive

Calsporin® is a powder with a minimum declared content of 1×10^{10} colony forming units (CFU) of *B. velezensis* DSM 15544 per gram of additive.

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.

⁸ 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.

⁹ FEED dossier reference: FAD-2021-0024.

¹⁰ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2009-0013.pdf>

¹¹ 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.

It has the same formulation [REDACTED] and method of manufacture as that considered in the most recent opinion adopted by the FEEDAP Panel in 2020. Thus, the data pertaining to composition, impurities, physical properties and shelf-life described in that opinion (EFSA FEEDAP Panel, 2020) apply to the current assessment.

The batch-to-batch variation of seven recent batches of the additive (2018–2020) showed compliance with the minimum specifications (mean 1.2×10^{10} CFU/g, with a range of 1.1 – 1.3×10^{10} CFU/g).¹²

In that same opinion, the active agent originally identified as *Bacillus subtilis* was reclassified as *Bacillus velezensis* and was fully characterised as per the requirements of the FEEDAP guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b). Therefore, the active agent of Calsporin® should be taxonomically designated as *Bacillus velezensis* DSM 15544.

The stability and capacity of the additive to be homogeneously mixed with feed and premixtures for poultry were also established in previous opinions (EFSA FEEDAP Panel, 2010a, 2010b, 2018a). The FEEDAP Panel is of the opinion that these existing data are sufficient to establish the stability and capacity to be homogeneously mixed in premixtures and feeds for the new target species for which authorisation is sought.

3.1.2. Conditions of use

Calsporin® is intended for use in feed for piglets (suckling and weaned), pigs for fattening, sows in order to bring benefits to piglets, ornamental fish, dogs and all avian species at the proposed level of 3×10^8 CFU/kg complete feed.

3.2. Safety

The species *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, 2021). 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 a previous opinion (EFSA FEEDAP Panel, 2020) the identity of the active agent was established and the compliance with the other qualifications confirmed. Accordingly, *B. velezensis* DSM 15544 was 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® was also presumed safe for the target species, consumers and the environment.

The safety for the users was evaluated by the FEEDAP Panel in a previous opinion (EFSA FEEDAP Panel, 2018a). 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 use of the additive with all avian species for rearing, fattening, laying and breeding purposes is considered unlikely to introduce hazards for users of the product not already considered as part of the previous assessment. Therefore, the conclusions reached in the previous assessment apply to the current application.

3.3. Efficacy for all avian species for rearing, fattening, laying and breeding purposes

The efficacy Calsporin® for laying hens and for chickens for fattening was established in previous opinions (EFSA FEEDAP Panel, 2015a, 2018a). Since the applicant proposes the use of the same level (3×10^8 CFU/kg complete feed) for all avian species for rearing, fattening, laying and breeding, the conclusions reached in laying hens and chickens for fattening can be extended/extrapolated to these avian species/categories at the same use level.

¹² Technical dossier/Section II/Annex II.1.3.1.

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 Regulation¹³ and Good Manufacturing Practice.

4. Conclusions

The active agent of Calsporin® should be taxonomically designated as *Bacillus velezensis* DSM 15544.

Calsporin® is presumed safe for the target species, consumers and the environment.

Calsporin® is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser.

Calsporin® when supplemented at 3×10^8 CFU/kg complete feed has the potential to be efficacious in all avian species for rearing, fattening, laying and breeding purposes.

5. Documentation provided to EFSA/Chronology

Date	Event
09/03/2021	Dossier received by EFSA. CALSPORIN® <i>Bacillus velezensis</i> DSM 15544. Zootechnical feed additive, functional group: gut flora stabiliser. Submitted by Asahi Biocycle Co. Ltd represented by Pen & Tec Consulting SLU
18/03/2021	Reception mandate from the European Commission
04/05/2021	Application validated by EFSA – Start of the scientific assessment
05/08/2021	Comments received from Member States
29/09/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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¹³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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Abbreviations

CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
QPS	Qualified presumption of safety