SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 10 November 2021

doi: 10.2903/j.efsa.2022.6984

Safety and efficacy of a feed additive consisting of *Bacillus velezensis* DSM 15544 (Calsporin®) for dairy cows and other dairy ruminants (Asahi Biocycle Co. Ltd.)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Montserrat Anguita, Jaume Galobart, Jordi Ortuño, Maria Vittoria Vettori and Rosella Brozzi

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 Calsporin® (*Bacillus velezensis* DSM 15544) as a zootechnical additive for dairy cows and other dairy ruminants. The product under assessment is based on viable spores of *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 compliance with the applicable 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 FEEDAP Panel is not in the position to conclude on the efficacy of Calsporin® for dairy cows or other dairy ruminants based on the data provided.

Keywords: Zootechnical additive, gut flora stabiliser, Bacillus velezensis, Calsporin®, safety, QPS, efficacy

Requestor: European Commission

Question number: EFSA-Q-2021-00206

Correspondence: feedap@efsa.europa.eu

Panel members: Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, de Lourdes Bastos M, Christensen H, Dusemund B, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Anguita M, Galobart J, Ortuño J, Vettori MV and Brozzi R, 2022. Scientific Opininon on the Safety and efficacy of a feed additive consisting of *Bacillus velezensis* DSM 15544 (Calsporin®) for dairy cows and other dairy ruminants (Asahi Biocycle Co. Ltd.). EFSA Journal 2022;20(1):6984, 9 pp. https://doi.org/10.2903/j.efsa.2022.6984

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Table of contents

1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] 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.

The European Commission received a request from Asahi Biocycle Co. Ltd., Japan, represented in the EU by Pen & Tec Consulting SLU[2] for the authorisation of the additive consisting of *Bacillus velezensis*[3] DSM 15544 (Calsporin®) when used as a feed additive for dairy cows and other dairy ruminants (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). The particulars and documents in support for the application were considered valid by EFSA as of 12 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 subject of the assessment is the feed additive consisting of viable spores of a strain of *Bacillus velezensis* (DSM 15544), intended for use as a zootechnical additive (functional group: gut flora stabiliser) for dairy cows and other dairy ruminants.

The European Food Safety Authority (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), all poultry species (EFSA FEEDAP Panel, 2019a) and for piglets (suckling and weaned), pigs for fattening, sows in order to have benefit in piglets, ornamental fish, dogs and all avian species (EFSA FEEDAP Panel, 2021).

The additive is authorised in the European Union (EU) as a zootechnical additive (functional group: gut flora stabiliser) for use in feed for 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 the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2] Asahi Biocycle Co. Ltd., Japan, represented in the EU by Pen & Tec Consulting SLU. Pl. Ausias March 1, 4th Floor, D01, 08195 Sant Cugat del Vallès, Spain.

[3] Formerly *Bacillus subtilis*.

[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 sows[8] and pigs for fattening[9] (4b1820).

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 for the authorisation request for the use of Calsporin® (*B. 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 regarding the methods used for the control of the active agent in animal feed are valid and applicable for the current application.[11]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *B. velezensis* DSM 15544 (Calsporin®) is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/ workers (EFSA FEEDAP Panel, 2012); Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c); Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017d); Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017e); Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018c); Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018d); Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019b).

3. Assessment

The subject of the assessment is a product containing viable spores of a single strain of *Bacillus velezensis* intended for use as a zootechnical additive (functional group: gut flora stabiliser) in feed for dairy cows and other dairy ruminants. The additive will be hereafter referred to as Calsporin® (its tradename).

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.

[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-2021-0026.

[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.

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 batches of the additive showed compliance with the minimum specifications (mean 1.2×10^{10} CFU/g, with a range of $1.1–1.3 \times 10^{10}$ CFU/g).[13]

In that same opinion, the active agent originally identified as *Bacillus subtilis* was reclassified as *B. velezensis* and fully characterised as per the requirements of the FEEDAP guidance on the characterisation of microorganisms used as feed additives or as production organisms.

The stability and homogeneous distribution of the additive when mixed with premixtures for poultry and pigs were also established in previous opinions (EFSA FEEDAP Panel, 2010a,b, 2018a). The FEEDAP Panel is of the opinion that these existing data are sufficient to establish the homogeneity of Calsporin® when mixed in premixtures for the new target species for which authorisation is sought.

No data have been produced to support the stability and capacity of the additive to homogeneously disperse in feed for dairy ruminants.

3.1.2. Conditions of use

The additive is intended for use in feed for dairy cows and other dairy ruminants at a proposed minimum daily dose of 3×10^9 CFU/head. No inclusion level in CFU/kg feed was provided.

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 applicable 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 applicant conducted a trial aimed to evaluate the possible presence of *B. velezensis* DSM 15544 in milk from dairy cows fed diets supplemented with Calsporin®.[14] For this purpose, 40 lactating dairy cows were divided into two groups and fed the same basal total mixed ration plus a concentrate not supplemented (control), or supplemented with Calsporin® to reach a daily dose of 6×10^9 CFU/head. Cows were under study for 28 days and milk and faecal samples were collected and analysed for *Bacillus* spp. and *B. velezensis* DSM 15544 counts. Milk and faecal samples from 10 animals per treatment were collected at different time points (0, 14 and 28 days) and samples from the milk tanks (one for control and one for Calsporin group) were obtained on days 0, 7, 14, 21 and 28. No significant differences in *Bacillus* spp. counts were observed between treatment groups in any type of sample. No *B. velezensis* DSM 15544 colonies were detected in milk samples from the Calsporin® or control group. The cows receiving the additive had higher counts of *B. velezensis* DSM 15544 in faeces compared to control. These results may indicate that the exposure of the consumers to the active agent under assessment in milk from cows receiving the additive is unlikely.

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 in dairy cows and other dairy ruminants 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.

[13] Technical dossier/Section II/Annex II.1.3.1.
[14] Technical dossier/Section III/Annexes_III_2_1.

3.3. Efficacy

3.3.1. Efficacy for dairy cows

Three efficacy studies with dairy cows were submitted. However, none could be further considered for the assessment due to substantial flaws in the experimental design and reporting, including: housing and feeding conditions not fully reported (study 1),[15] feed intake not (studies 1 and 3[16]) or insufficiently (study 2)[17] recorded/reported, experimental groups not comparable at baseline on differences in days in milk and number of lactations (study 2), non-compliance with guidance provision that efficacy studies in dairy cows should start at 4–8 weeks after calving (studies 2 and 3) or the information at that regard is not reported (study 1).

Therefore, the Panel is not in the position to conclude on the efficacy of Calsporin® for dairy cows based on the data provided.

3.3.2. Efficacy for other dairy ruminants

In the absence of evidence of efficacy in dairy cows, no conclusions can be drawn on the efficacy of Calsporin® for other dairy ruminants.

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[18] and Good Manufacturing Practice.

4. Conclusions

Calsporin® is considered safe for the target species, consumers of products derived from animals fed the additive and the environment.

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

The FEEDAP Panel is not in the position to conclude on the efficacy of Calsporin® for dairy cows or other dairy ruminants based on the data provided.

5. Documentation provided to EFSA/Chronology

Date	Event
15/03/2021	Dossier received by EFSA. CALSPORIN® *Bacillus velezensis* DSM 15544. Zootechnical feed additive for dairy cows and other dairy ruminants, functional group: gut flora stabiliser. Submitted by Asahi Biocycle Co. Ltd represented by Pen & Tec Consulting SLU
23/03/2021	Reception mandate from the European Commission
12/05/2021	Application validated by EFSA – Start of the scientific assessment
28/09/2021	Comments received from Member States
10/11/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EFSA (European Food Safety Authority), 2006. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the safety and efficacy of the product "Calsporin", a preparation of *Bacillus subtilis*, as a feed additive for chickens for fattening in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2006;4(3):336, 15 pp. https://doi.org/10.2903/j.efsa.2006.336

[15] Technical dossier/Section IV/Annex_IV_3_1.
[16] Technical dossier/Section IV/Annex Souza, 2017.
[17] Technical dossier/Section IV/Annex_IV_3_2.
[18] 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.

EFSA (European Food Safety Authority), 2007a. Scientific Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product Calsporin®, a preparation of *Bacillus subtilis*, as a feed additive for chickens for fattening in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2007;5(9):543, 8 pp. https://doi.org/10.2903/j.efsa.2007.543

EFSA (European Food Safety Authority), 2007b. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. EFSA Journal 2007;587, 16 pp. https://doi.org/10.2903/j.efsa.2007.587

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K, Allende A, Alvarez-Ordonez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Hilbert F, Lindqvist R, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Cocconcelli PS, Fernandez Escamez PS, Maradona MP, Querol A, Sijtsma L, Suarez JE, Sundh I, Vlak J, Barizzone F, Hempen M and Herman L, 2021. Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 13: suitability of taxonomic units notified to EFSA until September 2020. EFSA Journal 2021;19(1):6377, 32 pp. https://doi.org/10.2903/j.efsa.2021.6377

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010a. Scientific Opinion on the safety and efficacy of Calsporin® (Bacillus subtilis) as a feed additive for piglets on request from the European Commission. EFSA Journal 2010;8(1):1426, 11 pp. https://doi.org/10.2903/j.efsa.2010.1426

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 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

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015a. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) as a feed additive for laying hens and avian species for laying. EFSA Journal 2015;13(9):4231, 10 pp. https://doi.org/10.2903/j.efsa.2015.4231

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015b. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) as a feed additive for ornamental fish. EFSA Journal 2015;13(11):4274, 10 pp. https://doi.org/10.2903/j.efsa.2015.4274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, De Lourdes BM, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Brozzi R and Saarela M, 2017a. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) for sows and suckling piglets. EFSA Journal 2017;15(4):4761, 9 pp. https://doi.org/10.2903/j.efsa.2017.4761

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, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Brozzi R and Saarela M, 2017b. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) as a feed additive for dogs. EFSA Journal 2017;15(4):4760, 9 pp. https://doi.org/10.2903/j.efsa.2017.4760

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, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Dujardin B, Galobart J and Innocenti ML, 2017c. Guidance on the assessment of the safety of feed additives for the consumer. EFSA Journal 2017;15(10)5022, 15 pp. https://doi.org/10.2903/j.efsa.2017.5022

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, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J and Innocenti ML, 2017d. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal, 2017;15(10):5023, 42 pp. https://doi.org/10.2903/j.efsa.2017.5023

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, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2017e. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 34 pp. https://doi.org/10.2903/j.efsa.2017.5021

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018a. Scientific Opinion on the assessment of the application for renewal of authorisation of Calsporin® (*Bacillus subtilis* DSM 15544) for chickens for fattening. EFSA Journal 2018;16(7):5340, 9 pp. https://doi.org/10.2903/j.efsa.2018.5340

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018b. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) as a feed additive for pigs for fattening. EFSA Journal 2018;16(3):5219, 9 pp. https://doi.org/10.2903/j.efsa.2018.5219

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, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018c. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

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, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Karenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018d. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kouba M, Kos Durjava M, Lopez-Alonso M, López Puente S, Marcon F, Mayo B, Pechova A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brozzi R, Galobart J, Lopez-Gálvez G, Gregoretti L, Vettori MV and Innocenti ML, 2019a. Safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) for all poultry species. EFSA Journal 2019;17(3):5605, 9 pp. https://doi.org/10.2903/j.efsa.2019.5605

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Bastos M, Christensen H, Dusemund B, Kouba M, Kos Durjava M, Lopez-Alonso M, Lopez Puente S, Marcon F, Mayo B, Pechova A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brock T, de Knecht J, Kolar B, van Beelen P, Padovani L, Tarres-Call J, Vettori MV and Azimonti G, 2019b. Guidance on the assessment of the safety of feed additives for the environment. EFSA Journal 2019;17(4):5648, 32 pp. https://doi.org/10.2903/j.efsa.2019.5648

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fasmon Durjava M, Kouba M, Lopez-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Cocconcelli PS, Glandorf B, Herman L, Maradona MP, Saarela M, Anguita M, Galobart J, Holczknecht O, Manini P, Pizzo F, Tarrés-Call J and Pettenati E, 2020. Scienti fic Opinion on the assessment of the application for renewal of the authorisation of Calsporin® (Bacillus velezensis DSM 15544) as a feed additive for weaned piglets. EFSA Journal 2020;18(11):6283, 9 pp. https://doi.org/10.2903/j.efsa.2020.6283

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fasmon Durjava M, Kouba M, Lopez-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Galobart J, Vettori MV and Brozzi R, 2021. Scientific Opinion on the 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.). EFSA Journal 2021;19(10):6903, 9 pp. https://doi.org/10.2903/j.efsa.2021.6903

Abbreviations

CFU	colony-forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed