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Safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) for all poultry species

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, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Rosella Brozzi, Jaume Galobart, Gloria López-Gálvez, Lucilla Gregoretti, Maria Vittoria Vettori and Matteo Lorenzo Innocenti

Abstract

The additive Calsporin® is a preparation of viable spores of *Bacillus subtilis* DSM 15544, at a minimum declared concentration of 1×10^{10} colony forming units (CFU)/g additive. The additive is authorised as a zootechnical additive (functional group: gut flora stabiliser) for use in chickens for fattening, weaned piglets, chickens reared for laying, turkeys, minor avian species and other ornamental and game birds, laying hens and ornamental fish, dogs, in sows and in suckling piglets. This opinion concerns a request for a modification of the terms of the authorisation, reducing the minimum content in complete feed for chickens for fattening from the authorised concentration of 5×10^8 CFU/kg feed to a concentration of 3×10^8 CFU/kg feed and for an authorisation for the use of the additive for all poultry species. The active agent fulfils the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Calsporin® is considered safe for the target animals, the consumers and for the environment. The additive is not a dermal/eye irritant or a skin sensitiser but should be considered a potential respiratory sensitiser. The additive has the potential to be efficacious as a zootechnical additive in feedingstuffs for chickens for fattening at the level of 3×10^8 CFU/kg complete feed. Considering that efficacy at the same level has been shown in laying hens and turkeys, this conclusion is extrapolated to all poultry species and categories.

Keywords: zootechnical additive, Calsporin®, *Bacillus subtilis*, chickens for fattening, all poultry species, efficacy

Requestor: European Commission

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Correspondence: feedap@efsa.europa.eu

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

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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 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, and Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Asahi Calpis Wellness Co. Ltd.[2] for modifications of the terms of authorisation and for authorisation of the product Calsporin® (*Bacillus subtilis* DSM 15544), when used as a feed additive for all poultry 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 13(3) (modification of the authorisation of a feed additive) and under Article 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 12/10/2018.

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 subtilis* DSM 15544), when used under the proposed ll conditions of use .

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,b; 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) and pigs for fattening (EFSA FEEDAP Panel, 2018b).

The additive is authorised as a zootechnical additive (functional group: gut flora stabiliser) for use in chickens for fattening,[3] weaned piglets,[4] chickens reared for laying, turkeys, minor avian species and other ornamental and game birds,[5] laying hens and ornamental fish,[6] dogs and sows.[7]

[1] 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, 30.9.20.

[2] Asahi Calpis Wellness Co. Ltd., Japan, represented in Europe by Asahi Calpis Wellness Co. Ltd. Europe Representative Office, 46 rue Paul Valéry, 75116, Paris, France.

[3] 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.

[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 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.

[6] 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.

[7] 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.

The applicant is asking for a modification of the terms of the authorisation, reducing the minimum content in complete feed for chickens for fattening from the authorised concentration of 5×10^8 colony forming units (CFU)/kg feed to a concentration of 3×10^8 CFU/kg feed; in addition, the applicant is asking for an authorisation for the use of the additive for all poultry species. It is noted that, except for chickens for fattening, which are subject of the current opinion, the additive is already currently authorised at 3×10^8 CFU/kg feed for all the remaining poultry species (laying hens and minor laying poultry species, turkeys and minor growing poultry species).

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[8] in support of the authorisation request for the use of Calsporin® (*Bacillus subtilis* 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 substance/agent in animal feed/marker residue in tissues are valid and applicable for the current application.[9]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Calsporin® is in line with the principles laid down in Regulation (EC) No 429/2008, the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and Technical guidance on tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011a,b).

3. Assessment

Calsporin® is a preparation of viable spores of a single strain of *B. subtilis* intended for use as a zootechnical additive (gut flora stabiliser) in all poultry species. The additive is currently authorised for use in laying hens, turkeys, minor avian species and other ornamental and game birds at a minimum content of 3×10^8 CFU/kg feed, and for chickens for fattening and chickens reared for laying at a minimum content of 5×10^8 CFU/kg feed. The applicant is now requesting the reduction of the minimum content in complete feed for chickens for fattening to 3×10^8 CFU/kg feed and the authorisation for the use of the additive for all poultry species.

3.1. Characterisation

The active agent is a *B. subtilis* strain deposited in the German Collection of Microorganisms and Cell Cultures with accession number DSM 15544 and in the National Institute of Advanced Industrial Science and Technology (Japan) with accession number FERM BP-1096. The identity of the strain has been previously demonstrated using molecular methods (full 16S rRNA gene sequencing and pulsed field gel electrophoresis (PFGE)).[10] The PFGE patterns of the strain isolated from one batch of the product from 2015 were identical to those from the strain deposited (DSM 15544), confirming that the strain has not been modified over time (EFSA FEEDAP Panel, 2018a). Susceptibility to relevant antibiotics and lack of toxigenic potential were confirmed in a previous opinion (EFSA FEEDAP Panel, 2015a) and are considered still valid.

The additive is a preparation of viable spores of *Bacillus subtilis* DSM 15544 at a minimum declared concentration of 1×10^{10} CFU/g additive. It has the same formulation ([redacted]) and method of manufacture as that considered in previous opinions (EFSA, 2006; EFSA FEEDAP Panel, 2010a,b, 2015a). Thus, the data pertaining to composition, impurities, physical properties and shelf life still apply.

[8] FEED dossier reference: FAD-2018-0062.
[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2009-0013.pdf
[10] Technical dossier/Supplementary information October 2016/Annexes II.2.1.2.1–II.2.1.2.3.

The stability of the additive and its capacity to homogeneously distribute in feed has also been previously demonstrated in feed for chickens for fattening (EFSA, 2006; EFSA FEEDAP Panel, 2010a,b, 2018a).

Calsporin® is proposed to be used in feeds for all poultry species at a minimum recommended dose of 3×10^8 CFU/kg complete feed.

3.2. Safety

The species *B. subtilis* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to establish safety for the target species, consumers and the environment (EFSA, 2007a,b; EFSA BIOHAZ Panel, 2018). This approach requires the identity of the active agent to be established and the absence of a toxigenic potential and susceptibility to antibiotics of human clinical and veterinary importance to be demonstrated. The identity of the strain Calsporin® (*Bacillus subtilis* DSM 15544) was established and the lack of resistance to relevant antibiotics and of toxigenic potential was demonstrated in a previous assessment (EFSA FEEDAP Panel, 2015a). Accordingly, this strain is considered by EFSA to be suitable for the QPS approach to safety and the additive is presumed safe for the target species, consumers and for the environment.

In the context of the renewal of the authorisation of Calsporin® for chickens for fattening, the FEEDAP Panel concluded that Calsporin is safe for the target species, consumers of products from animals fed the additive and for the environment. The additive is not a dermal/eye irritant or a skin sensitiser but should be considered a potential respiratory sensitiser (EFSA FEEDAP Panel, 2018a).

The proposed reduction in the minimum recommended use level would not impact the conclusions on the safety of the product. Likewise, the extension of use to all poultry species would not introduce hazards other than those already considered in the previous assessments.

Therefore, the FEEDAP Panel concludes that Calsporin®, under the proposed conditions of use is safe for target species, consumers, users and the environment.

3.3. Efficacy

A total of four trials sharing a common design and performed in chickens for fattening were submitted. The studies were conducted in two Member States. The details on the study design are provided in Table 1 and the main results in Table 2. In all trials, 1-day-old male birds (average body weight 44 g) were used. In all trials, a basal diet was either unsupplemented (control) or supplemented with Calsporin® (30 mg/kg feed) to provide 3×10^8 CFU/kg feed (confirmed by analysis). The diets were administered *ad libitum* for 42 days. The health of the birds and mortality were monitored throughout the study and the body weight and feed intake were recorded on days 21 and 42. Feed to gain ratio was calculated. In each study, the data on the zootechnical parameters and the mortality were analysed with an analysis of variance (ANOVA), using the pen as the experimental unit. Statistical significance level was set at 0.05.

Table 1: Trial design and dosages of the efficacy trials performed in chickens for fattening

Trial	Total no of animals (animals × replicate) replicates × treatment	Breed sex (duration)	Composition feed (Form)	Groups (CFU/kg feed)	
				Intended	Analysed§
1(a)	2,560 (40) 16	Ross 308 Males (42 days)	Wheat, barley*, soya bean meal (Mash)	0 3×10^8	– 2.3×10^8
2(b)	2,240 (35) 16	Ross 308 Males (42 days)	Wheat, barley*, soya bean meal (Mash)	0 3×10^8	– 2.6×10^8
3(c)	2,240 (35) 16	Ross 308 Males (42 days)	Wheat, barley*, soya bean meal (Mash)	0 3×10^8	– 3×10^8
4(d)	306 (9) 17	Ross 308 Males (42 days)	Wheat, soya bean meal (Mash)	0 3×10^8	– 2.8×10^8

CFU: colony forming unit.
*: In the grower diets only (days 21–42).
§: Mean of starter and grower diets.
(a): Technical dossier/Section IV/Annex_IV_3_1.
(b): Technical dossier/Section IV/Annex_IV_3_2.
(c): Technical dossier/Section IV/Annex_IV_3_3.
(d): Technical dossier/Section IV/Annex_IV_3_4.

Table 2: Effects of Calsporin® on the performance of chickens for fattening (trials 1, 2 and 3)

Trial	Groups (CFU/kg feed)	Feed intake[1] (kg)	Weight gain[2] (kg)	Feed to gain ratio	Mortality and culling (%)
1	0	4.66	2.39	1.95	6.0
	3×10^8	4.69	2.40	1.96	6.9
2	0	4.26	2.17^b	1.96^a	1.8
	3×10^8	4.29	2.21^a	1.94^b	1.1
3	0	4.53	2.26^b	2.01^a	3.0^a
	3×10^8	4.56	2.30^a	1.98^b	1.4^b
4	0	0.101	0.054	1.85	3.3
	3×10^8	0.099	0.054	1.83	1.3

CFU: colony forming unit.
[a,b]: Mean values within a trial and within a column with a different superscript are significantly different $p < 0.05$.
1: Total feed intake in studies 1, 2 and 3; average daily feed intake in study 4.
2: Total weight gain in studies 1, 2 and 3; average daily weight gain in study 4.

The supplementation of diets for chickens for fattening with Calsporin® supplying 3×10^8 CFU/kg complete feed had a beneficial effect on the total weight gain and feed to gain ratio in two trials (trials 2 and 3) and reduced mortality in trial 3 only. No effects on zootechnical parameters were observed in the other two trials.

The data from the four studies were pooled and analysed statistically.[11] The analysis included the following parameters: weight gain, feed intake, feed to gain ratio and mortality. An ANOVA, which took into account the effect of the treatment, the effect of the trial and their interaction, was performed; differences were considered significant at a level of at least $p < 0.05$. The results showed that the supplementation of the feed with Calsporin® improved significantly the total weight gain (2.27 *vs* 2.30 kg for control and Calsporin®), the feed to gain ratio (1.96 vs 1.94 for control and Calsporin®) and reduced the mortality (3.56% vs 2.85% for control and Calsporin®). Based on the results of the pooled data, the Panel concludes that the additive has the potential to be efficacious in chickens for fattening at the newly proposed minimum content of 3×10^8 CFU/kg compete feed. This conclusion can be extended to chickens reared for laying.

[11] Technical dossier/Section IV/Annex_IV_3_5.

The efficacy of the additive Calsporin® at the same minimum concentration of 3×10^8 CFU/kg complete feed was previously demonstrated in laying hens and turkeys. The conclusions on the efficacy of the additive are therefore extrapolated to all poultry species.

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[12] and Good Manufacturing Practice.

4. Conclusions

The active agent fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Calsporin® is considered safe for the target animals, the consumers and for the environment. The additive is not a dermal/eye irritant or a skin sensitiser but should be considered a potential respiratory sensitiser.

The additive has the potential to be efficacious as a zootechnical additive in feedingstuffs for chickens for fattening at the level of 3×10^8 CFU/kg complete feed. Considering that efficacy at the same level has been shown in laying hens and turkeys, this conclusion is extrapolated to all poultry species and categories.

Documentation provided to EFSA

1) CALSPORIN®. *Bacillus subtilis* C-3102, DSM 15544. 08/2018. Submitted by Asahi Calpis Wellness Co. Ltd.
2) Comments from Member States.

Chronology

Date	Event
14/8/2018	Dossier received by EFSA
31/8/2018	Reception mandate from the European Commission
12/10/2018	Application validated by EFSA – Start of the scientific assessment
12/1/2019	Comments received from Member States
22/1/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

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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. EFSA Journal 2007;5(9):543, 8 pp. https://doi.org/10.2903/j.efsa.2007.543

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EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2018. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 7: suitability of taxonomic units notified to EFSA until September 2017. EFSA Journal 2018;16(1):5131, 43 pp. https://doi.org/10.2903/j.efsa.2018.5131

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[12] 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 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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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 19 pp. https://doi.org/10.2903/j.efsa.2012.2536

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Abbreviations

ANOVA	analysis of variance
CFU	colony forming unit
EURL	European Union Reference Laboratory
PFGE	pulsed field gel electrophoresis
QPS	qualified presumption of safety