SCIENTIFIC OPINION

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Assessment of the application for renewal of authorisation of Bactocell® (*Pediococcus acidilactici* CNCM I-4622) as a feed additive for weaned piglets, pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying and its extension of use to all growing pigs and all avian 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, Montserrat Anguita, Jaume Galobart, Paola Manini, Fabiola Pizzo, Jordi Tarrés-Call and Orsolya Holczknecht

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 Bactocell® (*Pediococcus acidilactici* CNCM I-4622) in the context of the renewal of the authorisation for weaned piglets, pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying when used as a zootechnical feed additive (gut flora stabiliser) in feed or in water for drinking. In addition, the applicant requested the extension of use for suckling piglets, minor pig species (growing/for fattening), chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species (including non-food producing/ornamental birds) reared for laying/breeding purposes and for breeding purposes when used as in feed or in water for drinking. The applicant has provided evidence that the additive currently on the market complies with the conditions of authorisation. The additive is safe for the target species, consumers and the environment as well. The additive is non-irritant to skin and eyes and is not a dermal sensitiser but should be considered a respiratory sensitiser. Considering the high dusting potential of the formulations, exposure of users by inhalation is very likely. The additive, at the level of 1×10^9 CFU/kg feed (5×10^8 when delivered in water), has the potential to be efficacious in the new species proposed: chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species reared for laying/breeding purposes and for breeding purposes (including non-food producing/ornamental birds) and in suckling piglets and minor porcine species (growing/for fattening).

Keywords: zootechnical additive, Bactocell, *Pediococcus acidilactici*, pigs, poultry, safety, efficacy

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Question number: EFSA-Q-2018-00641

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

The European Commission received a request from Danstar Ferment AG, Switzerland[2] for renewal of the authorisation of the product Bactocell® (*Pediococcus acidilactici* CNCM I-4622),[3] when used as a feed additive in feed or in water for drinking for weaned piglets, pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying (category: zootechnical additives; functional group: gut flora stabilisers) and for authorisation when used as a feed additive in feed or in water for drinking for suckling piglets, minor pig categories (growing/for fattening), chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species (including non-food producing/ornamental birds) reared for laying/breeding purposes and for breeding purposes (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 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 25 September 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 Bactocell® (*P. acidilactici* CNCM I-4622), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive Bactocell® is a preparation based on a strain of *P. acidilactici* CNCM I-4622. EFSA issued four opinions on the safety and efficacy of Bactocell PA 10 when used in feed for salmonids (EFSA, 2009a), shrimps (EFSA, 2009b), weaned piglets (EFSA FEEDAP Panel, 2010a) and laying hens (EFSA FEEDAP Panel, 2010b) and one on the efficacy for all fish (EFSA FEEDAP Panel, 2012a). A further opinion on the safety and efficacy of Bactocell when used in water for drinking for weaned piglets, pigs for fattening, laying hens and chickens for fattening was adopted in 2012 (EFSA FEEDAP Panel, 2012b). In 2016, the Panel re-evaluated the product for pigs for fattening and chickens for fattening and further assessed it for minor porcine species and minor avian species (EFSA FEEDAP Panel, 2016). An opinion on the safety and efficacy of the same active agent when used as a silage additive was adopted in 2012 (EFSA FEEDAP Panel, 2012c).

The additive is currently authorised as a zootechnical additive, under the functional group gut flora stabilisers in feed and water for drinking for weaned piglets, minor weaned porcine species, pigs for fattening, minor porcine species for fattening, laying hens, minor avian species for laying, chickens for fattening and minor avian species for fattening,[4] under the functional group other zootechnical

[1] 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.
[2] Danstar Ferment AG, Switzerland, represented in the EU by Lallemand SAS, 19 Rue des Briquetiers BP 31702 Blagnac, France.
[3] Previously deposited as *Pediococcus acidilactici* CNCM MA 18/5M.
[4] Commission Implementing Regulation (EU) 2017/2299 of 12 December 2017 concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, minor poultry species for fattening and minor poultry species for laying, the authorisation of that feed additive for use in water for drinking and amending Regulations (EC) No 2036/2005, (EC) No 1200/2005 and Implementing Regulation (EU) No 413/2013 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 329, 13.12.2017, p. 33.

additives, for use in feed for salmonids, shrimps[5] and fish other than salmonids.[6] The active agent of Bactocell is also authorised as a silage additive for all animal species.[7]

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 Bactocell® (*P. acidilactici* CNCM I-4622) 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.

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.[9]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Bactocell® (*P. acidilactici* CNCM I-4622) is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012d), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013), Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008), Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2012e) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

Bactocell®[11] is a preparation consisting of viable cells of a strain of *P. acidilactici* CNCM I-4622 intended to be used as a zootechnical additive, functional group 'gut flora stabilisers', in feedingstuffs or in water for drinking for weaned piglets, pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying.

This assessment regards the renewal of the authorisation of the product Bactocell® (*P. acidilactici* CNCM I-4622) for the authorised species and a new authorisation for use in feed or in water for drinking for suckling piglets, minor pig species (growing/for fattening), chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species (including non-food producing/ornamental birds) reared for laying/breeding purposes and for breeding purposes.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is currently authorised as a preparation of *P. acidilactici* CNCM I-4622 as solid non-coated and coated forms, with a minimum content of the active agent of 1×10^{10} colony forming unit (CFU)/g.

[5] Commission Regulation (EC) No 911/2009 of 29 September 2009 concerning the authorisation of a new use of the preparation *of Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for salmonids and shrimps (holder of authorisation Lallemand SAS). OJ L 257, 30.9.2009, p. 10.

[6] Commission Implementing Regulation (EU) No 95/2013 of 1 February 2013 concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for all fish other than salmonids (holder of authorisation Lallemand SAS). OJ L 33, 2.2.2013, p. 19.

[7] Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species. OJ L 330, 30.11.2012, p. 14.

[8] FEED dossier reference: FAD-2018-0055.

[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2013-0031-Bactocell.pdf

[10] 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.

[11] The applicant declares that the additive is also marketed with other trade names: Bactocell, Fermaid. Both trade names can be found with or without additional acronyms: PA, ME, 10 ME, 10 Md.

The applicant stated that the main production steps of the additive are unchanged.[12] The freeze-dried bacteria is mixed with feed materials and technological additives to obtain the commercial preparations that contain the active agent at a concentration of 1×10^{10} CFU/g. The composition of the three commercial preparations (one microencapsulated (ME) and two non-coated (10 Md)) has been provided. [redacted][12]

Compliance with specifications was shown in five batches of an uncoated preparation (Bactocell 10Md'b') (three produced in 2017 and two in 2018), with the following results, range: 1.28–1.72 $\times$ 10^{10} CFU/g, mean: 1.50 $\times$ 10^{10} CFU/g; and of a coated preparation (Bactocell 10ME) (three produced in 2017 and two in 2018), with the following results, range: 1.39–1.77 $\times$ 10^{10} CFU/g, mean: 1.55 $\times$ 10^{10} CFU/g.[13]

The same batches were analysed for microbiological control of quality. Total coliforms were < 10 CFU/g, *Escherichia coli* was < 10 CFU/g and *Salmonella* was absent in 25 g of all batches tested.

No data were provided on the chemical impurities.

The additive is presented in powder form. Particle size distribution (analysed by laser diffraction) and dusting potential (by Stauber–Heubach method) were tested in three batches of the three preparations described above.[14] Measurements indicated that 0.88%, 2.73% and 0% of the particles were < 1 μm; 9.04%, 11.4% and 2.73% < 10 μm; 25.42%, 17.26% and 5.31% < 50 μm; 38.08%, 25.20% and 6.05% < 100 μm in the three Bactocell preparations ME, Md'a' and Md'b' respectively. The average dusting potential for the three preparations were 61.1 g/m^3 (ME), 26.4 g/m^3 (Md'a') and 46.4 g/m^3 (Md'b').

3.1.2. Characterisation of the active agent

The active agent consists of viable cells of a *P. acidilactici* strain isolated from grass pasture. The strain has not been genetically modified. The strain was originally deposited in the Collection Nationale de Cultures de Micro-organismes with the accession number CNCM MA 18/5M. In 2012, the deposition of the strain was converted into a deposition under the 'Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure' and accordingly, the strain was assigned the new accession number CNCM I-4622.[15]

Identification and taxonomic classification of the active agent has been re-confirmed [redacted] All the minimum inhibitory concentration (MIC) values observed were below the cut-off values established in that guidance and no further investigation was required.

3.1.3. Conditions of use

The additive is currently authorised as a zootechnical additive, functional group 'gut flora stabilisers', for pigs for fattening, piglets (weaned), minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying at a minimum content of 1×10^9 CFU/kg feedingstuffs and at a minimum content of 5×10^8 CFU/L water for drinking. The applicant proposes to keep the same conditions.

[12] Technical dossier/Supplementary information January 2019.
[13] Technical dossier/Section II/Annex II.2.
[14] Technical dossier/Section II/Annex II.3.
[15] Technical dossier/Section II/Annex II.4.
[redacted]

In addition, the applicant is proposing the extension of use to suckling piglets, minor pig species (growing/for fattening), chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species (including non-food producing/ornamental birds) reared for laying/breeding purposes and for breeding purposes in feed and in water for drinking with the same minimum content, respectively.

3.2. Safety

3.2.1. Safety for the target animals, consumers and the environment

The species *P. acidilactici* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2017). This approach requires the identity of the strain to be conclusively established and evidence that it does not show resistance to antibiotics of human and veterinary importance. The identity of the active agent was confirmed as *P. acidilactici* and the antibiotic susceptibility qualification was met. Accordingly, this strain is presumed safe for the target species, consumers and the environment. Since the additive does not contain other components of concern, Bactocell is also considered safe for target animals, consumers and the environment. This conclusion applies as well to the new target species/categories for which an extension of use if made.

3.2.2. Safety for the user

The safety for the user has been assessed by the FEEDAP Panel in a former opinion (EFSA FEEDAP Panel, 2016). The Panel concluded that the additive is non-irritant to skin and eyes and is not a dermal sensitiser but should be considered a respiratory sensitiser. The Panel does not expect that the use of the excipients listed raise additional safety concerns. The data submitted indicate high dusting potential; therefore, exposure of users by inhalation is very likely.

3.2.3. Further evidence

The applicant conducted a literature search on the safety of Bactocell® using several databases: CAB Abstracts, Agris, Scopus, Google Scholar, Bielefeld Academic Search Engine (BASE) and the Liège University library. The search included terms such as: CNCM MA 18/5 M, CNCM I-4622, Bactocell, feed, incompatibilities, interactions and terms referring to safety (e.g. toxicity, tolerance, adverse effects, epidemiology). The search covered the period 2007–2018. The search identified 147 relevant publications (Appendix A). Although some studies included supplementation levels higher than the minimum recommended use level and assessed some health-related end points, none was designed to assess the safety per se of the additive. Most of the studies were designed to assess the effects of Bactocell® (alone or in combination with other additives or products) on the performance of animals, immunity or the effects on the intestinal microbiota (e.g. *Salmonella, E. coli*). None of these studies reported any safety concerns with the additive under assessment.

3.2.4. Conclusions on safety

Considering all the above and the fact that the manufacturing process has not been significantly modified and the conditions of use are the same, the FEEDAP Panel concludes that there is no new evidence that would lead the Panel to reconsider its previous conclusions on the safety of the product for target species, consumers, users and the environment under the authorised conditions of use. The additive Bactocell® is considered safe for the target species, consumers and the environment. The additive is non-irritant to skin and eyes and is not a dermal sensitiser but should be considered a respiratory sensitiser. Considering the high dusting potential of the formulations, exposure of users by inhalation is very likely.

3.3. Efficacy

The efficacy of the additive has been established at the level of 1×10^9 CFU/kg feed (5×10^8 CFU/L when delivered in water) in chickens for fattening, laying hens, weaned piglets and pigs for fattening (EFSA FEEDAP Panel, 2010a,b, 2012b) and minor porcine/poultry species (EFSA FEEDAP Panel, 2016). The conditions of use for these target species have not been modified and therefore no further assessment is needed for the renewal of the authorisation.

The applicant has requested to extend the use of the additive at the level of 1×10^9 CFU/kg feed (5×10^8 CFU/L when delivered in water) to the following species and categories: suckling piglets, minor pig species (growing/for fattening), chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species (including non-food producing/ornamental birds) reared for laying/breeding purposes and for breeding purposes.

The efficacy data from chickens for fattening and laying hens can be extended to chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes and extrapolated to turkeys and minor avian species reared for laying/breeding purposes and for breeding purposes (including non-food producing/ornamental birds). Similarly, the efficacy data from weaned piglets can be extended to include the suckling piglets and extrapolated to minor porcine species (growing/for fattening). Therefore, the Panel considers that the additive has the potential to be efficacious in these species and categories under the proposed conditions of use.

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[1] and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence that Bactocell® (*P. acidilactici* CNCM I-4622) currently on the market complies with the conditions of authorisation.

The FEEDAP Panel concludes that Bactocell® under the authorised/proposed conditions of use is considered safe for the target species (suckling piglets, weaned piglets, pigs for fattening, minor porcine species (growing/for fattening), chickens for fattening, laying hens, minor avian species for fattening and for laying, chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species (including non-food producing/ornamental birds) reared for laying/breeding purposes and for breeding purposes), consumers and the environment.

The additive is non-irritant to skin and eyes and is not a dermal sensitiser but should be considered a respiratory sensitiser. Considering the high dusting potential of the formulations, exposure of users by inhalation is very likely.

There is no need for assessing the efficacy of Bactocell® (*P. acidilactici* CNCM I-4622) in the context of the renewal of the authorisation. The additive, at the level of 1×10^9 CFU/kg feed (5×10^8 CFU/L when delivered in water) has the potential to be efficacious in the new species proposed, i.e. in chickens reared for laying, chickens reared for breeding purposes, chickens for breeding purposes, turkeys and minor avian species reared for laying/breeding purposes and for breeding purposes (including non-food producing/ornamental birds) and in suckling piglets and minor porcine species (growing/for fattening).

Documentation provided to EFSA/Chronology

Date	Event
30/7/2018	Dossier received by EFSA. *Pediococcus acidilactici* CNCM MA 18/5M for all birds/avian species and categories and all growing pigs/Suidae species and categories. Submitted by Lallemand SAS (on behalf of Danstar Ferment AG, Switzerland)
21/8/2018	Reception mandate from the European Commission
2/10/2018	Application validated by EFSA – Start of the scientific assessment
21/12/2018	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*
2/1/2019	Comments received from Member States
11/1/2019	Clarification conference during risk assessment
23/1/2019	Reception of supplementary information from the applicant – Scientific assessment re-started
2/4/2019	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), 2010b. Scientific Opinion on Bactocell PA 10 (*Pediococcus acidilactici*) as a feed additive for laying hens. EFSA Journal 2010;8 (10):1865, 9 pp. https://doi.org/10.2903/j.efsa.2010.1865

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Scientific Opinion on the efficacy of Bactocell (*Pediococcus acidilactici*) when used as a feed additive for fish. EFSA Journal 2012;10(9):2886, 6 pp. https://doi.org/10.2903/j.efsa.2012.2886

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Scientific Opinion on the safety and efficacy of Bactocell (*Pediococcus acidilactici*) as a feed additive for use in water for drinking for weaned piglets, pigs for fattening, laying hens and chickens for fattening. EFSA Journal 2012;10 (7):2776, 23 pp. https://doi.org/10.2903/j.efsa.2012.2776

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Abbreviations

CFU	colony forming unit
CNCM	Collection Nationale de Cultures de Micro-organismes
EURL	European Union Reference Laboratory

FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
MIC	minimum inhibitory concentration
QPS	Qualified Presumption of Safety

Appendix A – List of references retrieved from the literature search provided by the applicant to support the safety of the additive

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