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Assessment of the application for renewal of authorisation of Bactocell® (*Pediococcus acidilactici* CNCM I-4622) as a feed additive for all fish and shrimps and its extension of use for all crustaceans

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Abstract

Bactocell® is the trade name for a feed additive based on viable cells of a strain of *Pediococcus acidilactici*. 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® in the context of the renewal of the authorisation for shrimps, salmonids and fish other than salmonids. In addition, the applicant requested the extension of use for all crustaceans. The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation. The FEEDAP Panel concludes that Bactocell® Aqua 10 Md/100 Md is safe under the current conditions of authorisation for the target species (all fish, shrimps and all crustaceans), consumers of products from animals fed the additive and the environment. Bactocell® Aqua 10 Md/100 Md is non-irritant to skin and eyes and is not a dermal sensitiser, but should be considered a potential respiratory sensitiser. Exposure of users by inhalation is very likely. There is no need for assessing the efficacy of Bactocell® in the context of the renewal of the authorisation. The Panel concludes that the additive at the minimum inclusion level of 1×10^9 CFU/kg feed has the potential to be efficacious in salmonids and in the new species proposed, i.e. all crustaceans.

Keywords: zootechnical additives, other zootechnical additives, Bactocell®, *Pediococcus acidilactici* CNCM I-4622, safety, fish, shrimps and crustaceans

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Question number: EFSA-Q-2018-00632

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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 one year before the expiry date of the authorisation.

The European Commission received a request from Danstar Ferment AG[2] for renewal of the authorisation of the product Bactocell® (*Pediococcus acidilactici* CNCM I-4622), when used as a feed additive for all fish and shrimps (category: zootechnical additives; functional group: other zootechnical additives) and for authorisation when used as a feed additive for all other crustaceans (category: zootechnical additives; functional group: other zootechnical additives).

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® (*Pediococcus 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 *Pediococcus 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 other zootechnical additives, for use in feed for salmonids, shrimps[3] and fish other than salmonids[4] and 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

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Danstar Ferment AG, Switzerland, represented in the EU by Lallemand SAS, 19 Rue des Briquetiers BP 31702 Blagnac, France.
[3] 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
[4] 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

for laying, chickens for fattening and minor avian species for fattening.[5] The active agent of Bactocell PA (*Pediococcus acidilactici* CNCM MA 18/5M) is also authorised as a silage additive for all animal species.[6]

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[7] in support of the authorisation request for the use of Bactocell® as a feed additive.

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.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Bactocell® is in line with the principles laid down in Regulation (EC) No 429/2008[9] 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).

3. Assessment

Bactocell®[10] is a preparation consisting of viable cells of a strain of *P. acidilactici* CNCM I-4622 intended to be used as a zootechnical additive (other zootechnical additives: favourably affecting growth) in feed for all fin fish and all crustaceans.

This assessment regards the renewal of the authorisation of Bactocell when used in feed for all fish and shrimps, and a new authorisation for use in feed for all crustaceans.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive under assessment (Aqua 10 Md) is a powder [redacted] to reach a minimum declared content of 1×10^{10} CFU of *P. acidilactici* CNCM I-4622[11] per gram of additive.[redacted]

The applicant declares that minor changes have been introduced in the manufacturing process of the additive, [redacted] Results of the analysis of three batches from 2018 support the modification of the composition and compliance with the specifications (average:

[5] 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.

[6] 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.

[7] FEED dossier reference: FAD-2018-0054.

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

[9] 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.

[10] The applicant declares that the additive is also marketed with other trade names: Bactocell PA, Bactocell 10Md, Bactocell Aqua

[11] The strain has also been deposited under the name DSM 11673.

1.3 × 10^{10} CFU/g additive).[13] The applicant also refers to a new formulation that is 10 times more concentrated (1 × 10^{11} CFU/g additive), named as Bactocell® Aqua 100 Md, and provides analysis of three batches from 2018 showing compliance with specifications (average: 1.5 × 10^{11} CFU/g additive).[13] Further demonstration of compliance with specifications was shown in two recent batches (from 2017/2018) of both uncoated forms of the additive (for Aqua 10 Md: 1.2 and 1.6 × 10^{10} CFU/g, and for Aqua 100 Md: 1.7 and 2.6 × 10^{11} CFU/g additive, mean: 1.7 10^{11} CFU/g additive).[14]

Data from these five batches were provided for microbiological control of quality. Measurements included total coliforms and *Escherichia coli* (< 10 CFU/g) and *Salmonella* (absent in 25 g).[15] Three batches of each form of the additive were also subject to the analysis of chemical contaminants. Results showed values of cadmium (0.014–0.08 mg/kg), lead (< 0.02), mercury (< 0.005 mg/kg), arsenic (< 0.05 mg/kg), aflatoxins B1, B2 and G1 (< 0.1 μg/kg) and G2 (< 0.2 μg/kg), dioxins (0.0739–0.0788 ng/kg), dioxin-like polychlorinated biphenyls (PCBs) (0.0395–0.0423 ng/kg) that do not raise safety concerns.[16]

The dusting potential of three recent batches of both forms of the additive measured with Heubach dustometer showed values ranging between 5.3 and 16.8 g/m^3.[17]

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 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.[18]

Identification and taxonomic classification of the active agent have been reconfirmed [redacted]

The susceptibility of the strain to the battery of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2012e) was examined [redacted] All the minimum inhibitory concentration (MIC) values observed were below the cut-off values established, consequently *P. acidilactici* CNCM I-4622 is considered to be susceptible to all relevant antibiotics.

3.1.3. Conditions of use

The additive is currently authorised for use in feed for salmonids at the minimum content of 3 × 10^9 CFU/kg complete feed and for shrimps and all fish, other than salmonids, at the minimum content of 1 × 10^9 CFU/kg complete feed. The applicant proposes to maintain the same conditions of use for shrimps and all fish other than salmonids, and to modify that of salmonids to 1 × 10^9 CFU/kg complete feed.

For the new use with all crustaceans, the applicant proposes also the same minimum inclusion level of 1 × 10^9 CFU/kg complete feed.

The authorisation for salmonids and shrimps includes under other provisions an indication that breathing protection shall be used during handling. In the authorisation for all fish other than salmonids, the same safety protection provision is included plus the requirement that glasses and gloves shall be used during handling.

[13] Technical dossier/Supplementary information February 2019.
[14] Technical dossier/Section II/Annexes II 2b and 2c and Supplementary information February 2019.
[15] Technical dossier/Section II/Annexes II 2b and 2c.
[16] Technical dossier/Supplementary information February 2019/Appendix_1_impurities.
[17] Technical dossier/Section II/Annex II 3d.
[18] Technical dossier/Section II/Annex II 4b.
[redacted]

3.2. Safety

3.2.1. Safety for the target species, 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 established as *P. acidilactici* and the antibiotic resistance qualification has been 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 a request for an extension of use is made.

3.2.2. Safety for the user

The safety for the user has been assessed by the FEEDAP Panel in a former opinion of the same product (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 and identified 147 relevant publications (Appendix A). Although some studies included supplementation levels higher than the minimum recommended use level and assessed some health-related endpoints, none was designed to assess the safety *per se* of the additive. Most of the studies were designed to assess the effects of Bactocell® PA (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 concern 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 the target species, consumers, users and the environment under the authorised conditions of use. The additive Bactocell® PA is considered safe for the target species, including all crustaceans, 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. Exposure of users by inhalation is very likely.

3.3. Efficacy

The additive is currently authorised for use in feed for salmonids at the minimum content of 3×10^9 CFU/kg complete feed and for shrimps and at 1×10^9 CFU/kg complete feed for all fish other than salmonids. The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation for shrimps and all fish other than salmonids that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation for these species.

The applicant is proposing to reduce the authorised minimum inclusion level of the additive in feed for salmonids from 3×10^9 CFU/kg feed to 1×10^9 CFU/kg feed. The efficacy of Bactocell at 1×10^9 CFU/kg feed was already shown in all fish, including salmonids, in a previous opinion (EFSA FEEDAP Panel, 2012a). Therefore, the Panel reiterates its previous conclusion that Bactocell has the potential to reduce bone deformation in developing fish at the dose of 1×10^9 CFU/kg of complete feedingstuffs.

The Panel considers that the conclusion on the efficacy for shrimps established at 1×10^9 CFU/kg complete feed in a previous opinion (EFSA, 2009b) can be extrapolated to all crustaceans when used at the same inclusion level.

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[21] and Good Manufacturing Practice.

4. Conclusions

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

The FEEDAP Panel concludes that Bactocell® Aqua 10 Md/100 Md is safe under the current conditions of authorisation for the target species (all fish and all crustaceans), consumers of products from animals fed the additive and the environment. Bactocell® Aqua 10 Md/100 Md is non-irritant to skin and eyes and is not a dermal sensitiser, but should be considered a potential respiratory sensitiser.

There is no need for assessing the efficacy of Bactocell® in the context of the renewal of the authorisation (all fish except salmonids and shrimps). The Panel concludes that the additive at the minimum inclusion level of 1×10^9 CFU/kg feed has the potential to be efficacious in salmonids and in the new species proposed, i.e. all crustaceans.

Documentation provided to EFSA/Chronology

Date	Event
30/07/2018	Dossier received by EFSA. Bactocell® *Pediococcus acidilactici* CNCM MA 18/5M for - All fish, salmonids (renewal of authorisation), all fish other than salmonids (renewal of authorisation), all crustaceans, shrimps (renewal of authorisation) and all other crustaceans (new). Submitted by Danstar Ferment AG
13/08/2018	Reception mandate from the European Commission
25/09/2018	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*
25/12/2018	Comments received from Member States
11/01/2019	Clarification teleconference during risk assessment with the applicant according to the "EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products"
18/02/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
01/04/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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EFSA (European Food Safety Authority), 2008. Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition. EFSA Journal 2008;6(9):803, 5 pp. https://doi.org/10.2903/j.efsa.2008.803

EFSA (European Food Safety Authority), 2009a. Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of Bactocell PA (*Pediococcus acidilactici*) as feed additive for fish. EFSA Journal 2009;7(4):1037, 13 pp. https://doi.org/10.2903/j.efsa.2009.1037

EFSA (European Food Safety Authority), 2009b. Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of Bactocell PA (*Pediococcus acidilactici*) as feed additive for shrimp. EFSA Journal 2009;7(4):1038, 12 pp. https://doi.org/10.2903/j.efsa.2009.1038

[21] 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 BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Allende A, Bolton D, Chemaly M, Davies R, Girones R, Herman L, Koutsoumanis K, Lindqvist R, Nørrung B, Robertson L, Ru G, Sanaa M, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlstr€om H, Cocconcelli PS, Klein G (deceased), Prieto Maradona M, Querol A, Peixe L, Suarez JE, Sundh I, Vlak JM, Aguilera-Gomez M, Barizzone F, Brozzi R, Correia S, Heng L, Istace F, Lythgo C and Fernández Esc_amez PS, 2017. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. EFSA Journal 2017;15(3):4664, 177 pp. https://doi.org/10.2903/j.efsa.2017.4664

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010a. Scientific Opinion on the safety and efficacy of Bactocell PA 10 (*Pediococcus acidilactici*) as a feed additive for piglets. EFSA Journal 2010;8(7):1660, 10 pp. https://doi.org/10.2903/j.efsa.2010.1660

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, 17 pp. https://doi.org/10.2903/j.efsa.2012.2776

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Scientific Opinion on the safety and efficacy of *Pediococcus acidilactici* (CNCM I-3237, CNCM MA 18/5M—DSM 11673) and *Pediococcus pentosaceus* (DSM 23376, NCIMB 12455, NCIMB 30237 and NCIMB 30168) as silage additives for all species. EFSA Journal 2012;10(6):2733, 15 pp. https://doi.org/10.2903/j.efsa.2012.2733

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012d. 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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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of Bactocell PA (*Pediococcus acidilactici* CNCM MA 18/5M) for pigs for fattening, minor porcine species, chickens for fattening and minor avian species. EFSA Journal 2016;14 (6):4483, 15 pp. https://doi.org/10.2903/j.efsa.2016.4483

Abbreviations

CFU colony-forming unit
EURL European Union Reference Laboratory
MIC minimum inhibitory concentration
PCB polychlorinated biphenyls
QPS Qualified Presumption of Safety

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

Poultry for fattening

Chafai S, Ibrir F, Alloui N, Nouicer F, 2007. Effects of *Pediococcus acidilactici* feed supplementation on broiler chicken performances, immunity and health. World Poultry Science Association, Proceedings of the 16th European Symposium on Poultry Nutrition, Strasbourg, France, 26–30 August, 2007, 4 p.

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Rowghani E, Arab M, Akbarian A, 2007. Effects of a probiotic and other feed additives on performance and immune response of broiler chicks. International Journal of Poultry Science, 6, 261–265.

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Ramdane MS, Guitarni D, 2008. Effets des probiotiques sur 3 germes de la flore intestinale poulet de chair. Bulletin UASVM, Horticulture, 65, 614–620.

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