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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of *Bacillus velezensis* ATCC PTA-6737 (PB6) for the renewal of the authorisations in weaned piglets, weaned minor porcine species and sows and the extension of use to all *Suidae* (Kemin Europe N.V)

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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 *Bacillus velezensis* ATCC PTA-6737 as a zootechnical additive (functional group: gut flora stabilisers) in regard to the renewal of the authorisation for weaned piglets, weaned minor porcine species, sows and minor reproductive *Suidae* species, and its extension of use for all *Suidae*. The applicant provided evidence that the additive currently in the market complies with the conditions of the authorisation. The Panel concluded that there is no new evidence that would lead it to reconsider the previous conclusions; the additive is safe for the target species, consumers and the environment under the authorised conditions of use. This conclusion also applies to the target species/categories for which a request for an extension of use is made. The Panel concluded that *B. velezensis* ATCC PTA-6737 is not irritant to skin or eyes but should be considered a respiratory sensitiser due to its proteinaceous nature. No conclusions could be drawn on the skin sensitisation potential of the additive. The Panel concluded that the additive has the potential to be efficacious in all growing *Suidae* (suckling, weaned and fattening *Suidae*) at the minimum inclusion level of 1×10^7 CFU/kg of complete feed and in sows and minor reproductive *Suidae* species at 1×10^8 CFU/kg complete feed.

KEYWORDS

Bacillus velezensis ATCC PTA-6737, digestibility enhancers, efficacy, PB6, pigs, renewal, zootechnical additives

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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 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. In addition, 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 Kemin Europa N.V.[2] for the renewal of the authorisation of the additive consisting of *Bacillus velezensis* ATCC PTA-6737 (*Bacillus velezensis* PB6), when used in feed for weaned piglets, weaned *Suidae* and sows and for the extension of authorisation for its use in feed for all *Suidae* (category: zootechnical additive; functional group: gut-flora stabiliser).

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). 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 30 September 2022.

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 the agent *Bacillus velezensis* ATCC PTA-6737 when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The additive under assessment is a preparation consisting of viable cells of *Bacillus velezensis* ATCC PTA-6737.

EFSA has issued several opinions on the safety and efficacy of *Bacillus subtilis*[3] ATCC PTA-6737 (*Bacillus subtilis* PB6) as a feed additive for different species: chickens for fattening (EFSA FEEDAP Panel, 2009), chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (EFSA FEEDAP Panel, 2011), weaned piglets and weaned minor porcine species (EFSA FEEDAP Panel, 2012a), turkeys for fattening and turkeys reared for breeding (EFSA FEEDAP Panel, 2013), laying hens, other minor laying poultry birds (EFSA FEEDAP Panel, 2015) and sows (EFSA FEEDAP Panel, 2017a).

An opinion on the compatibility of *Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) with coccidiostats was also published in 2010 (EFSA FEEDAP Panel, 2010) and recently, an opinion with the modification of the strain designation from *Bacillus subtilis* ATCC PTA-6737 to *Bacillus velezensis* ATCC PTA-6737 (EFSA FEEDAP Panel, 2022).

The Panel also adopted an opinion on the renewal of the authorisation of the additive when used in chickens for fattening, chickens reared for laying, minor poultry species (except for laying purposes), ornamental, sporting and game birds (EFSA FEEDAP Panel, 2020).

The additive is currently authorised for use in feed for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes and ornamental birds,[4] turkeys for fattening and reared for breeding,[5] laying hens, minor poultry species for laying,[6] weaned piglets and weaned *Suidae* other than *Sus scrofa domesticus*[7] and sows[8] (4b1823). The taxonomic identification of the active agent was amended in all the authorisations as per Commission implementing regulation (EU) 2023/366.

[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]Kemin Europe N.V. Toekomstlaan 42, 2200, Herentals, Belgium.

[3]The active agent of this additive was formerly identified as *Bacillus subtilis*.

[4]Commission Implementing Regulation (EU) 2023/366 of 16 February 2023 concerning the renewal of the authorisation of a preparation of Bacillus velezensis ATCC PTA-6737 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes, its authorisation for ornamental birds, amending Implementing Regulation (EU) No 306/2013, Implementing Regulation (EU) No 787/2013, Implementing Regulation (EU) 2015/1020, Implementing Regulation (EU) 2017/2276 and repealing Regulation (EU) No 107/2010 and Implementing Regulation (EU) No 885/2011 (holder of authorisation Kemin Europa N.V.).

[5]Commission Implementing Regulation (EU) No 787/2013 of 16 August 2013 concerning the authorisation of a preparation of Bacillus subtilis (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Kemin Europa N.V.). OJ L 220, 17.8.2013, p. 15.

[6]Commission Implementing Regulation (EU) 2015/1020 of 29 June 2015 concerning the authorisation of the preparation of Bacillus subtilis (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying. OJ L 163, 30.6.2015, p. 22.

[7]Commission Implementing Regulation (EU) No 306/2013 of 2 April 2013 concerning the authorisation of a preparation of Bacillus subtilis (ATCC PTA-6737) for weaned piglets and weaned Suidae other than *Sus scrofa domesticus*. OJ L 91, 3.4.2013, p. 5.

[8]Commission Implementing Regulation (EU) 2017/2276 of 8 December 2017 concerning the authorisation of the preparation of Bacillus subtilis (ATCC PTA-6737) as a feed additive for sows. OJ L 326, 9.12.2017, p. 50.

This assessment regards the request for the renewal of the authorisation for the use of the additive in weaned piglets, weaned *Suidae* other than *Sus scrofa domesticus*, and sows, and the extension of its use to all *Suidae*.

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[9] in support of the authorisation request for the use of *Bacillus velezensis* ATCC PTA-6737 as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[10] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[11] a non-confidential version of the dossier has been published on Open.EFSA.[12]

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[13] EFSA carried out a public consultation on the non-confidential version of the application from 14 November 2023 to 05 December 2023 for which no comments were received.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, 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 agent in animal feed are valid and applicable for the current application.[14]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of active substance (trade name of the product) is in line with the principles laid down in Regulation (EC) No 429/2008[15] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), EFSA Journal Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

The subject of the assessment is currently authorised as *B. velezensis*[16] ATCC PTA-6737 (zootechnical additive; functional group: gut flora stabilisers) and the current assessment deals with the renewal of the authorisation for the use in weaned piglets, weaned *Suidae* other than *Sus scrofa* domesticus and sows, and the extension of use to all *Suidae*.

3.1 | Characterisation

3.1.1 | Characterisation of the active agent

The active agent is a non-genetically modified microorganism originally isolated from the intestinal tract of a chicken and deposited in the American Type Culture Collection with the accession number ATCC PTA-6737.[17]

[9]Dossier reference: FEED-2022-4933.

[10]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p.1–48.

[11]Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[12]Available online: https://open.efsa.europa.eu/dossier/FEED-2022-4933.

[13]Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[14]The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-FAD-2008-0039.pdf.

[15]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.

[16]Formerly identified as *Bacillus subtilis*.

[17]Annex Deposition1.

The taxonomic identification of the active agent as *B. velezensis* was established by bioinformatic analysis of the whole-genome sequence (WGS) data.[18] The analysis was based on average nucleotide identity (ANI) which showed an ANI value of [redacted] Identity as *B. velezensis* was further confirmed by a phylogenomic analysis carried out using orthologous genes extracted from the bacillales ODB9 database [redacted] The phylogenomic analysis included strains of the *Bacillus subtilis* group. [redacted][19]

The WGS data of the active agent were also interrogated for the presence of plasmids using the [redacted] No plasmid sequences were detected.[20]

The antimicrobial susceptibility profile of *B. velezensis* ATCC PTA-6737, its toxigenic potential and its capacity to produce antimicrobials were assessed in a previous opinion (EFSA FEEDAP Panel, 2020). The Panel concluded that the active agent was susceptible to all relevant antimicrobials, was non-toxigenic and did not show antimicrobial activity.[21]

The applicant submitted an updated interrogation of the WGS data of *B. velezensis* ATCC PTA-6737 for the presence of genes encoding for antimicrobial resistance (AMR), toxins and virulence factors.[22]

The interrogation of the WGS data for the presence of AMR genes was done against [redacted][23] [redacted]. Therefore, it can be concluded that no genes of concern were identified. Nevertheless, the applicant submitted an updated antimicrobial susceptibility test against [redacted][24] [redacted]

The interrogation of the WGS data for the presence of genes encoding for toxins and virulence factors was done against the [redacted] (thresholds applied: > 80% identity and > 70% coverage). No hits of concern were identified.

The data newly submitted confirm that the active agent *B. velezensis* ATCC PTA-6737 does not harbour acquired AMR genes, nor genes encoding for toxins or virulence factors.

3.1.2 | Characterisation of the additive

The additive currently authorised is a preparation of *B. velezensis* ATCC PTA-6737 containing a minimum of 1×10^{10} colony forming units (CFU) per gram of additive.

In the current dossier, the applicant proposes a modification of the specifications of the additive, in particular an increase of the minimum concentration from 1×10^{10} CFU/g to 8×10^{10} CFU/g additive.

In addition, some minor changes have been introduced in the manufacturing process, namely changes in the composition of the growth medium. This change does not raise any safety concerns. The additive under assessment has the same formulation (spores concentrate (ca. 5%–25%) and sodium bicarbonate (75%–95%)), concentration and the manufacturing process as that considered in the opinion adopted by EFSA FEEDAP Panel (2020). Therefore, the data pertaining to characterisation of the additive, composition, impurities, physico-chemical properties, shelf-life, stability and homogeneity described in that opinion apply to the current assessment.

3.1.3 | Conditions of use

The additive is currently authorised for use in weaned piglets and weaned *Suidae* other than *Sus scrofa domesticus* at a minimum inclusion level of 1×10^7 CFU/kg of complete feed, and in sows at a minimum inclusion level of 1×10^8 CFU/kg of complete feed.

Under other provisions of the authorisation in weaned piglets and weaned *Suidae* other than *Sus scrofa domesticus*, it is stated:

1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
2. For use in (weaned) piglets up to ~ 35 kg.

[18] Annex_II.35.
[19] Annex_II.36_1.2, Annex_II.36_1.3 and Annex_II.36_1.
[20] Annex_II.36_1.4 and Annex_II.36_1.
[21] Annex_II_44, Annex_II_49 and Annex_II_54.
[22] Annex_II.36_1.1 and Annex_II.36_1.
[23] This database is no longer maintained; last version available is May 2018.
[24] Annex_II.36_2.

Under other provisions of the authorisation in sows, it is stated:

1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.
2. For the use in sows from 3 weeks before farrowing to whole lactation period.
3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.

The applicant wishes to maintain the same conditions of use for the authorised species.

The applicant is also requesting the extension of use to all *Suidae* at a minimum inclusion level of 1×10^7 CFU/kg of complete feed in all growing *Suidae* (including suckling and fattening categories) and at 1×10^8 CFU/kg of complete feed in minor reproductive *Suidae* species.

3.2 | Safety

For the present dossier, the applicant states that no adverse events have been reported since the market authorisation of the additive (2011).[25]

In the previous assessments (EFSA FEEDAP Panel, 2012b, 2013, 2017a), *B. velezensis* ATCC PTA-6737 was presumed safe for the target species, consumers and the environment based on the qualified presumption of safety (QPS) approach (EFSA, 2007; EFSA BIOHAZ Panel, 2023).

In the context of the current assessment, the applicant submitted data which confirm the identification of the active agent as *Bacillus velezensis*. Following the QPS approach to safety assessment, the strain is presumed safe for the target species, consumers and the environment. As the other component of the additive is a feed material and does not raise safety concerns, the FEEDAP Panel concludes that the additive is safe for the target species, consumers and the environment.

In 2022, the FEEDAP Panel concluded that the additive was non-irritant to skin and eyes or a dermal sensitiser, but it should be considered a respiratory sensitiser (EFSA FEEDAP Panel, 2022). The Panel notes that the OECD test guidelines available at present are designed to assess the skin sensitisation potential of chemical substances only and that currently no validated assays for assessing the sensitisation potential of microorganisms are available. Therefore, the FEEDAP Panel cannot conclude on the dermal sensitisation potential of the additive.

The FEEDAP Panel considers that the use of the additive in the new species and categories proposed would not add concerns not already identified in the previous opinions.

3.2.1 | Conclusions on safety

Considering the above and the fact that the composition and manufacturing process of the additive has not been substantially modified, the FEEDAP Panel concludes that the additive remains safe for weaned piglets, weaned *Suidae* other than *Sus scrofa domesticus* and sows; the consumers; and the environment. The FEEDAP Panel concludes that the additive is safe for all *Suidae* and that the use of the additive in the new species/categories is safe for the consumer and the environment.

The additive is not irritant to the skin and eyes, but it should be considered a respiratory sensitiser. The Panel cannot conclude on the skin sensitisation potential of the additive.

3.3 | Efficacy

The applicant submitted a new trial in weaned piglets,[26] which was not further considered because the copper content of the diets was above the maximum authorised levels in the EU.

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of use for those species/categories for which there is an authorisation. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

The applicant requested the extension of use of the additive to all *Suidae*; it is proposed to use the additive at a minimum inclusion level of 1×10^7 CFU/kg of complete feed in all growing *Suidae* (including suckling, weaned and fattening categories) and at 1×10^8 CFU/kg of complete feed in sows and minor reproductive *Suidae* species.

Considering that the efficacy of the additive was demonstrated in weaned piglets and sows, the FEEDAP Panel concludes, in line with the provisions of the guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a),

[25]Safety Annex Addendum.

[26]Annex_IV.12.

that the additive has the potential to be efficacious in all growing *Suidae* at the minimum inclusion level of 1×10^7 CFU/kg complete feed and in sows and minor reproductive *Suidae* species at 1×10^8 CFU/kg of complete feed.

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[27] and good manufacturing practice.

4 | CONCLUSIONS

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

The additive remains safe for weaned piglets, weaned *Suidae* other than *Sus scrofa domesticus* and sows; the consumers; and the environment; the FEEDAP Panel concludes that the additive is safe for the new target species and that the use of the additive in the new species/categories is safe for the consumer and the environment.

The additive is not irritant to skin and eyes, but it should be considered a respiratory sensitiser. The Panel cannot conclude on the skin sensitisation potential of the additive.

The FEEDAP Panel concludes that the additive has the potential to be efficacious in all growing *Suidae* (suckling, weaned and fattening categories) at the minimum inclusion level of 1×10^7 CFU/kg of complete feed and in sows and minor reproductive *Suidae* species at the minimum inclusion level of 1×10^8 CFU/kg of complete feed.

ABBREVIATIONS

AMR	Antimicrobial resistance genes
ANI	Average Nucleotide Identity
ATCC	American Type Culture Collection
CFU	colony forming unit
EC	European Commission
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
OECD	Organisation for Economic Co-operation and Development
WGS	Whole-genome sequence

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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QUESTION NUMBER

EFSA-Q-2022-00320

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