Adopted: 2 February 2024

DOI: 10.2903/j.efsa.2024.8650

efsa JOURNAL

SCIENTIFIC OPINION

Assessment of the feed additive consisting of *Bacillus velezensis* ATCC PTA-6737 (PB6) for turkeys for fattening and turkeys reared for breeding for the renewal of its authorisation and the modification of the conditions of the authorisation for other growing poultry species (Kemin Europe N.V)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | **Vasileios Bampidis** | **Giovanna Azimonti** | **Maria de Lourdes Bastos** | **Henrik Christensen** | **Mojca Durjava** | **Birgit Dusemund** | **Maryline Kouba** | **Marta López-Alonso** | **Secundino López Puente** | **Francesca Marcon** | **Baltasar Mayo** | **Alena Pechová** | **Mariana Petkova** | **Fernando Ramos** | **Roberto Edoardo Villa** | **Ruud Woutersen** | **Jaume Galobarts I Cots** | **Elisa Pettenati** | **Daniel Pagés Plaza**

Correspondence: feedap@efsa.europa.eu

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 stabiliser) in the context of the renewal of the authorisation for turkeys for fattening and turkeys reared for breeding. The applicant is also requesting to modify the target species in the current authorisations to 'all growing poultry', the increase of the recommended use level in chickens for fattening, chickens reared for laying and minor poultry species except minor poultry for laying from 1×10^7 to 1×10^8 CFU/kg complete feed and the compatibility of the additive with halofuginone. The applicant provided evidence that the additive currently in the market complies with the conditions of the authorisation. There was no new evidence that would lead to reconsider previous conclusions. Therefore, the FEEDAP Panel concluded that the additive remains safe for all poultry species for fattening and reared for laying/breeding, the consumers and the environment under the current authorised conditions of use. The additive is not irritant to the skin and eyes, but it should be considered a respiratory sensitiser. The Panel could not conclude on the skin sensitisation potential of the additive. The Panel concluded that the additive has a potential to be efficacious as a zootechnical additive for poultry for fattening and reared for laying/breeding under the proposed conditions of use.

KEYWORDS

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

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7. In addition, 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 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 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 as a feed additive in turkeys for fattening and turkeys reared for breeding and the modification of the authorisation in poultry for fattening and reared for laying/breeding (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), Article 13(3) (modification of the authorisation of a feed additive), Article 14(1) (renewal of the authorisation). The dossier was received on 21 October 2022 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00746. The particulars and documents in support of the application were considered valid by EFSA as of 18 April 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of *Bacillus velezensis* 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 a strain of *Bacillus velezensis* ATCC PTA-6737.

EFSA has issued several opinions on the safety and efficacy of *Bacillus velezensis*[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 velezensis* ATCC PTA-6737 with coccidiostats was also published in 2010 (EFSA FEEDAP Panel, 2010) and an opinion with the modification of the species 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 minor poultry for laying and ornamental birds[4] weaned piglets and weaned Suidae other than Sus scrofa

[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.).

domesticus,[5] turkeys for fattening and turkeys reared for breeding,[6] for laying hens and minor poultry species for laying[7] and for sows[8] (4b1823). The taxonomic identification of the active agent was amended in all the authorisations as per Commission implementing regulation (EU) No 2023/366.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on the 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.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 05 January 2023 to 05 April 2023 for which the received comments were considered for the assessment.

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 39–39e 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.

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, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 11 January to 1 February 2024 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' (elicitation) 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.[12]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Bacillus velezensis* ATCC PTA-6737 is in line with the principles laid down in Regulation (EC) No 429/2008[13] 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 FEEEDAP Panel, 2017b); Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018); and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021). EFSA statement on the requirements for whole-genome sequence (WGS) analysis of microorganisms intentionally used in the food chain (EFSA, 2021).

3 | ASSESSMENT

The product under assessment is a preparation consisting of viable cells of *Bacillus velezensis* ATCC PTA-6737 authorised to be used as a zootechnical additive (functional group: gut flora stabilisers) in the feed of several avian species (see Section 1.2).

The applicant is requesting the renewal of the authorisation for turkeys for fattening and turkeys reared for breeding. The applicant is also requesting the increase of the recommended use level in chickens for fattening, chickens reared for

[5]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.

[6]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.

[7]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.

[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.

[9]Dossier reference: FEED-2022-7310.

[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 at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[12]Evaluation report received on 14 April 2009 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/publications/fad-2008-0039_en

[13]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.

laying and minor poultry species (except minor poultry for laying) from 1×10^7 to 1×10^8 CFU/kg feed, to modify the target species in the current authorisations to 'all growing poultry', and the compatibility of the additive with halofuginone.

3.1 | Characterisation

3.1.1 | Characterisation of the active agent

The active agent is a non-genetically modified microorganism originally isolated from intestinal tract of a chicken[14] and was deposited in the American Type Culture Collection with the accession number ATCC PTA-6737.[15]

The taxonomic identification of the active agent as *B. velezensis* was established by bioinformatic analysis of the WGS data.[16] The analysis was based on [redacted] which showed an [redacted] value of [redacted]. Identity as *B. velezensis* was further confirmed by a phylogenomic analysis carried out using orthologous genes extracted from the [redacted]. The phylogenomic analysis included strains of the *Bacillus subtilis* group. [redacted][17]

The WGS data of the active agent were also interrogated for the presence of plasmids using the [redacted]. No plasmid sequences were detected.[18]

The antimicrobial susceptibility profile of *B. velezensis* ATCC PTA-6737, its toxigenic potential and 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 shown to be non-toxigenic in a test using Vero cells and did not have antimicrobial activity.[19]

The applicant submitted an updated interrogation of the WGS data of the active agent *B. velezensis* ATCC PTA-6737 for the presence of genes encoding for antimicrobial resistance (AMR), toxins and virulence factors.[20]

The interrogation of the WGS data for the presence of AMR genes was done against [redacted] Therefore, it can be concluded that no genes of concern were identified. Nevertheless, the applicant submitted an updated antimicrobial susceptibility test against [redacted].[22] [redacted]

The interrogation of the WGS data for the presence of genes encoding for toxins and virulence factors was done against the [redacted] 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 and 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 (CFUs) 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 (~5%–25%) and sodium bicarbonate (75%–95%)) and the manufacturing process as that considered in the opinion adopted by the FEEDAP Panel in 2020 (EFSA FEEDAP Panel, 2020). Therefore, the data pertaining to characterisation of the additive, composition, physico-chemical properties, shelf-life, stability and homogeneity described in that opinion apply to the current assessment.

[14]Annex_II_20.
[15]Annex Deposition1 and Annex Deposition2.
[16]Annex_II_22.
[17]Annex_II_RFI_1, Annex_II_RF and Annex_II_RFI_4 and Annex_II_RFI_4.
[18]Annex_II_RFI_5.
[19]Annex_II_32.
[20]Annex_II_RFI_1 and Annex_II_RFI_2.
[21]This database is no longer maintained; last version available is May 2018.
[22]Annex_II_RFI_6.

Analytical data to confirm the specifications were provided for six recent batches of the additive, showing an average value of 3.73×10^{11} (range $1.1–9.1 \times 10^{11}$) CFU/g.[23]

Three batches of the additive were analysed for impurities. Cadmium (Cd), lead (Pb), mercury (Hg) and arsenic (As) concentrations showed the following average values: 0.39 mg Cd/kg (0.35–0.43), 1.37 mg Pb/kg (1.2–1.5), 0.01 mg Hg/kg and 0.47 mg As/kg (0.45–0.48).[24]

The analysis of mycotoxins, including aflatoxins (B1, G1, B2, G2), acetyldeoxynivalenol, fumonisins B1 + B2, zearalenone, nivalenol, cytochalasin E, ochratoxin A, deoxynivalenol, T2-toxin and HT2-toxin showed values below the limit of quantification (LOQ) of the analytical methods.[25]

Microbiological contamination was analysed in the same three batches by the determination of yeasts and moulds < 10 CFU/g, *Enterobacteriaceae* < 10 CFU/g, presumptive *Bacillus cereus* < 100 CFU/g and *Salmonella* spp. not detected in 25 g[26] and in six additional batches by determination of yeasts and moulds (< 10 cfu/g) *E.coli*, *Staphylococcus aureus* and coliforms (not detected in 10 g), *salmonella* spp. (not detected in 25 g).[27]

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns.

3.1.3 | Conditions of use

The applicant is requesting the renewal of the authorisation for turkeys for fattening and turkeys reared for breeding. The additive *Bacillus velezensis* ATCC PTA-6737 is currently authorised for the mentioned species at a minimum content of 1×10^8 CFU/kg complete feed. Under other provisions, the regulation states:

1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.
2. The use is permitted in feed containing the authorised coccidiostats: diclazuril, robenidine hydrochloride, lasalocid A sodium, maduramicin ammonium and monensin sodium, on conditions that this coccidiostat is authorised for the relevant species.

The applicant has not requested the modification of the above conditions.

In addition, the applicant has requested the modification of the current authorisation in feed for chickens for fattening, chickens reared for laying and minor poultry species other than laying, by increasing the minimum use level from 1×10^7 to 1×10^8 CFU/kg complete feed.

Under other provisions of the authorisation, it is stated the additive is compatible with the following coccidiostats, provided they are authorised for the relevant species: diclazuril, robenidine hydrochloride, lasalocid A sodium, maduramicin ammonium, monensin sodium, decoquinate, salinomycin sodium, narasin and narasin/nicarbazin.

The applicant also requests the authorisation for the use of the additive in combination with the coccidiostat halofuginone and to combine all species/categories already covered in the current authorisations under the category 'all growing poultry'.

3.2 | Safety

For the present dossier, the applicant states that no adverse events have been reported since the market authorisation of the additive (2013).[28]

In the previous assessments (EFSA FEEDAP Panel, 2012a, 2013, 2017a, 2020, 2022), the active agent *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, the 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 is 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

[23] Annex_II_8.

[24] Annex_II_12.

[25] LOQ mycotoxins (mg/kg): Aflatoxine B1, B2, G1, G2: 1; 3 + 15 Acetyldeoxynivalenol: 20; Fumonisin B1 + B2: 20; Zearalenone:15; Nivalenol: 50; Cytochalasine E: 2; Ochratoxine-A: 1; Deoxynivalenol (DON): 20 and T2 & HT2-toxin: 10.

[26] Annex_II_13.

[27] Annex_II_8.

[28] Annex_III_RFI_08 Annex_III_RFI_09 Annex_III_RFI_10 and Annex_III_RFI_11.

assays for assessing the sensitisation potential of microorganisms are available. Therefore, the Panel cannot conclude on the dermal sensitisation potential of the additive.

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 all poultry species, the consumers and the environment under the current authorised conditions of use.

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 present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of use for turkeys for fattening and turkeys reared for breeding. Therefore, there is no need to assess the efficacy of the additive in the context of the renewal of the authorisation.

The current application includes the request to combine the species/categories already covered in the authorisations under the category of 'all growing poultry' and to harmonise the minimum recommended inclusion level to 1×10^8 CFU/kg feed.

The Panel notes that the additive is currently authorised for use in feed for chickens for fattening, chickens reared for laying and all minor poultry species except minor poultry for laying and turkeys for fattening and reared for breeding, which, in practice, covers all growing poultry species. The efficacy of the additive in chickens for fattening and other poultry for fattening at the level of 1×10^7 CFU/kg feed was demonstrated in a previous opinion (EFSA FEEDAP Panel, 2009, 2011). Therefore, the proposed increase of the minimum inclusion level to 1×10^8 CFU/kg feed does not need a further demonstration of efficacy.

The applicant provided an in vitro study to support the compatibility of *B. velezensis* ATCC PTA-6737 with halofuginone. The MIC value against the active agent was assessed using a broth microdilution method in aerobic conditions and resulted in > 12 mg/kg. Since the MIC value was greater than four times the maximum authorised level of the coccidiostat in feed for chickens for fattening and turkeys (3 mg/kg), *B. velezensis* ATCC PTA-6737 is considered to be compatible with halofuginone.[29]

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[30] 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 FEEDAP Panel confirms that *Bacillus velezensis* ATCC PTA-6737 remains safe for all poultry species, consumers and the environment under the authorised conditions of use.

The additive should be considered to be non-irritant to skin and eyes but should be considered a respiratory sensitiser. No conclusions can be drawn on the skin sensitisation potential of the additive.

The additive *Bacillus velezensis* ATCC PTA-6737 has the potential to be efficacious in poultry for fattening and reared for laying/breeding ('all growing poultry') at the minimum use level of 1×10^8 CFU/kg complete feed.

The additive is compatible with halofuginone.

ABBREVIATIONS

AMR	Antimicrobial resistance
ATCC	American Type Culture Collection
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOQ	limit of quantification
MIC	minimum inhibitory concentration

[29] Annex_II_59.

[30] 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.

WGS Whole-genome sequence
QPS qualified presumption of safety

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.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2022-00746

COPYRIGHT FOR NON-EFSA CONTENT

PANEL MEMBERS

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

LEGAL NOTICE

REFERENCES

EFSA (European Food Safety Authority). (2007). Opinion of the scientific committee on a request from EFSA on the introduction of a qualified presumption of safety (QPS) approach for assessment of selected microorganisms referred to EFSA. *EFSA Journal*, *587*, 1–16. https://doi.org/10.2903/j.efsa.2007.587

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Álvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Prieto Maradona, M., … Herman, L. (2023). Scientific opinion on the update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA. *EFSA Journal*, *21*(1), 7747. https://doi.org/10.2903/j.efsa.2023.7747

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2009). Scientific opinion on the safety and efficacy of Bacillus subtilis PB6 (*Bacillus subtilis)* as a feed additive for chickens for fattening. *EFSA Journal*, *7*(9), 1314. https://doi.org/10.2903/j.efsa.2009.1314

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2010). Scientific Opinionon the compatibility of Bacillus subtilis PB6 (*Bacillus subtilis*) with coccidiostats in chickens for fattening. *EFSA Journal*, *8*(10), 1836. https://doi.org/10.2903/j.efsa.2010.1836

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2011). Scientific Opinionon the safety and efficacy of *Bacillus subtilis* PB6 for chickens reared for laying, ducks for fattening, quails,pheasants, partridges, Guinea fowl, pigeons, geese for fattening and ostriches. *EFSA Journal*, *9*(3), 2114. https://doi.org/10.2903/j.efsa.2011.2114

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2012a). Scientific Opinionon the safety and efficacy of *Bacillus subtilis* PB6 as a feed additive for weaned piglets and weaned minorporcine species. *EFSA Journal*, *10*(5), 2671. https://doi.org/10.2903/j.efsa.2012.2671

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

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2013). Scientific Opinionon the safety and efficacy of Bacillus subtilis PB6 (Bacillus subtilis) as a feed additive for turkeys for fatteningand turkeys reared for breeding. *EFSA Journal*, *11*(4), 3176. https://doi.org/10.2903/j.efsa.2013.3176

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2015). Scientific Opinionon the safety and efficacy of Bacillus subtilis PB6 as a feed additive for laying hens and minor poultry species for laying. *EFSA Journal*, *13*(1), 3970. https://doi.org/10.2903/j.efsa.2015.3970

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2017a). ScientificOpinion on the safety and efficacy of Bacillus subtilis PB6 (Bacillus subtilis ATCC PTA-6737) as a feed additive for sows. *EFSA Journal*, *15*(5), 4855. https://doi.org/10.2903/j.efsa.2017.4855

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Innocenti, M. L. (2017b). Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal*, *15*(10), 5023. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Galobart, J. (2018). Guidance on the characterisation of microorganisms used as feed additives or as production organisms. *EFSA Journal*, *16*(3), 5206. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2020). Scientific Opinion on the safety and efficacy of Bacillus subtilis PB6 (Bacillus velezensis ATCC PTA-6737) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species (except for laying purposes), ornamental, sporting and game birds. *EFSA Journal*, *18*(11), 6280. https://doi.org/10.2903/j.efsa.2020.6280

EFSA (European Food Safety Authority). (2021). EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain. *EFSA Journal*, *19*(7), 6506. https://doi.org/10.2903/j.efsa.2021.6506

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Fašmon Durjava, M., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Anguita, M., … Innocenti, M. L. (2021). Guidance on the renewal of the authorisation of feed additives. *EFSA Journal*, *19*(1), 6340. https://doi.org/10.2903/j.efsa.2021.6340

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Fašmon Durjava, M., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Anguita, M., … Brozzi, R. (2022). Scientific opinion on the safetyand efficacy of a feed additive consisting ofBacillus velezensisATCC PTA-6737 (Bacillus velezensis PB6) for turkeys for fattening, turkeys reared for breeding, laying hens, minor poultry species for laying,piglets (weaned), weaned minor porcine species and sows (Kemin Europe N.V.). *EFSA Journal*, *20*(4), 7244. https://doi.org/10.2903/j.efsa.2022.7244

Fan, B., Blom, J., Klenk, H. P., & Borriss, R. (2017). Bacillus amyloliquefaciens, Bacillus velezensis, and Bacillus siamensis form an "Operational Group *B. Amyloliquefaciens*" within the *B. Subtilis* species complex. *Frontiers in Microbiology*, (8), 22.

Nøhr-Meldgaard, K., Struve, C., Ingmer, H., & Agersø, Y. (2022). Intrinsic tet(L) sub-class in *Bacillus velezensis* and *Bacillus amyloliquefaciens* is associated with a reduced susceptibility toward tetracycline. *Frontiers in Microbiology*, *13*, 966016. https://doi.org/10.3389/fmicb.2022.966016

How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., Puente, S. L., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Galobarts I Cots, J., Pettenati, E., & Pagés Plaza, D. (2024). Assessment of the feed additive consisting of *Bacillus velezensis* ATCC PTA-6737 (PB6) for turkeys for fattening and turkeys reared for breeding for the renewal of its authorisation and the modification of the conditions of the authorisation for other growing poultry species (Kemin Europe N.V). *EFSA Journal*, *22*(3), e8650. https://doi.org/10.2903/j.efsa.2024.8650