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Safety and efficacy of a feed additive consisting of *Bacillus velezensis* ATCC 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.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of *Bacillus subtilis* ATCC PTA-6737 (*Bacillus subtilis* PB6) when used as a feed additive for turkeys for fattening, turkeys reared for breeding, laying hens, minor poultry species for laying, piglets (weaned), weaned minor porcine species and sows. With this application, the company requested the modification of the current authorisations as regards the strain taxonomy from *B. subtilis* ATCC PTA-6737 to *Bacillus velezensis* ATCC PTA-6737. The FEEDAP Panel concluded that the active agent of *B. subtilis* PB6 should be taxonomically designated as *B. velezensis* ATCC PTA-6737. The Panel also concluded that *Bacillus velezensis* PB6 is presumed safe for the target species, consumers and the environment and is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. The Panel reiterated the previous conclusions reached on the efficacy of the additive when used with the target species.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from Kemin Europe N.V.² for the modification of the terms of the authorisation of the additive consisting of *Bacillus subtilis* ATCC PTA-6737 (*Bacillus subtilis* PB6) when used as a feed additive for turkeys for fattening, turkeys reared for breeding, laying hens, minor poultry species for laying, piglets (weaned), weaned minor porcine species and sows (category: zootechnical additives; functional group: gut flora stabilisers).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 13(3) (modification of the authorisation of a feed additive). 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 15 June 2021.

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 (*Bacillus velezensis* PB6), when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

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, 2012), 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). 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,⁴ chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches,⁵ weaned piglets and weaned *Suidae* other than *Sus scrofa domesticus*,⁶ turkeys for fattening

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 Formerly identified as *Bacillus subtilis*.

⁴ Regulations Commission Regulation (EU) No 107/2010 of 8 February 2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (holder of authorisation Kemin Europa NV). OJ L 36, 9.2.2010, p.1. Amended by Reg. (EU) No 168/2011 of 23 February 2011.

⁵ Commission Implementing Regulation (EU) No 885/2011 of 5 September 2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (holder of authorisation Kemin Europa N.V.). OJ L 229, 6.9.2011, p. 3.

⁶ 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.

and turkeys reared for breeding,⁷ for laying hens and minor poultry species for laying⁸ and for sows⁹ (4b1823).

The applicant is requesting to change the name of the active agent *B. subtilis* in the existing authorisations to *B. velezensis*.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier¹⁰ in support of the modification of the terms of the authorisation of the feed additive 4b1823.

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 active agent in animal feed are valid and applicable for the current application.¹¹

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Bacillus velezensis* ATCC PTA-6737 (*Bacillus velezensis* PB6) is in line with the principles laid down in Regulation (EC) No 429/2008¹² and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

The subject of the assessment is currently authorised as *B. subtilis* ATCC PTA-6737 (zootechnical additive, functional group: gut flora stabilisers) for use in several avian and pig species (see Section 1.2). In a recent opinion on the renewal of the authorisation for chickens for fattening, chickens reared for laying, minor poultry species (except for laying purposes), ornamental, sporting and game birds (EFSA FEEDAP Panel, 2020), the active agent, originally designated as *Bacillus subtilis*, was taxonomically identified as *Bacillus velezensis*. With the current application the applicant is seeking the modification of the strain designation from *Bacillus subtilis* ATCC PTA-6737 to *Bacillus velezensis* ATCC PTA-6737¹³ in the existing authorisations for turkeys for fattening, turkeys reared for breeding, laying hens, minor poultry species for laying and sows, weaned piglets, weaned *Suidae* other than *Sus scrofa domestica*. The additive will be hereafter referred to as PB6.

3.1. Characterisation

3.1.1. Characterisation of the active agent

In the 2020 opinion (EFSA FEEDAP Panel, 2020), the active agent originally identified as *Bacillus subtilis* was reclassified as *Bacillus velezensis* and was fully characterised as per the requirements of

⁷ 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.

⁸ 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.

⁹ 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.

¹⁰ FEED dossier reference: FAD-2020-0109.

¹¹ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039?search&form-return>

¹² 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.

¹³ Technical dossier/Supplementary information January 2022/Annex SIn1.

the FEEDAP guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018). Nevertheless, new data have been submitted and are described below.

The full genome of the strain was sequenced and used for assignment, [REDACTED]

[REDACTED] Altogether, the analyses confirm the identity of the active agent as *B. velezensis*.

The whole genome sequence (WGS) of the strain was interrogated for the presence of known genes coding for antimicrobial resistance (AMR) [REDACTED]

[REDACTED] None of the searches retrieved any relevant hits.¹⁵

The WGS was also interrogated for the presence of genes coding for virulence factors [REDACTED]

[REDACTED]¹⁶ and for the presence of genes encoding secondary metabolites including aminoglycoside biosynthetic genes and clusters, [REDACTED]¹⁷ No known genes encoding for virulence factors or aminoglycoside production were found in the genome of the strain.

The data newly submitted confirm previous conclusions on the characterisation of the active agent.

3.1.2. Characterisation of the additive

PB6 is a flowing powder with a minimum declared content of 8×10^{10} colony forming units (CFU) of *Bacillus velezensis* ATCC PTA-6737 per gram of additive.

It has the same formulation ((spores concentrate ~ 5–25%) and sodium bicarbonate (75–95%)) and method of manufacture as that considered in the most recent opinion adopted by the FEEDAP Panel in 2020. Thus, the data pertaining to composition, impurities, physico-chemical properties and shelf-life described in that opinion (EFSA FEEDAP Panel, 2020) apply to the current assessment.

3.1.3. Conditions of use

PB6 is authorised for use in feed for weaned piglets and weaned minor porcine species at 1×10^7 CFU/kg complete feed and for sows, laying hens, minor poultry species for laying, turkeys for fattening and turkeys reared for breeding at 1×10^8 CFU/kg complete feed.¹⁸ The present application does not intend to modify the conditions of use as already authorised.

3.2. Safety and efficacy

In the previous assessments (EFSA FEEDAP Panel, 2012, 2013, 2017a), PB6 (*B. velezensis* PTA-6737) was presumed safe for the target species, consumers and the environment based on the qualified presumption of safety (QPS) approach. In a recent opinion (EFSA FEEDAP Panel, 2020) and in the current assessment, the active agent has been reclassified as *B. velezensis* and its taxonomical identity and its compliance with the QPS qualifications confirmed. Consequently, the safety of PB6 for the target species, consumers and the environment, is presumed.

The additive has not been modified and no new information has been provided to reconsider the previous conclusions on the safety for the user. Therefore, PB6 is not a dermal/eye irritant or a dermal sensitiser, but it should be considered a respiratory sensitiser.

The Panel considers that the efficacy of the additive for the target species and its compatibility with coccidiostats would not be affected by the taxonomic reclassification of the active agent. The Panel confirms that PB6 is efficacious when used in feed for the target species concerned by this application at the authorised conditions of use, including its compatibility with coccidiostats.

¹⁴ Technical dossier/Section II/Annex_II_40d.

¹⁵ Technical dossier/Section II/Annex_II_40d and Annex_II_40e.

¹⁶ Technical dossier/Section II/Annex_II_40d and Annex_II_40f.

¹⁷ Technical dossier/Section II/Annex_II_41c, Annex_II_41d and Annex_II_41e.

¹⁸ Technical dossier/Supplementary information January 2022/FAD-2020-0109_SIn_021221.pdf.

3.3. 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 Regulation¹⁹ and Good Manufacturing Practice.

4. Conclusions

The active agent of PB6 should be designated as *Bacillus velezensis* ATCC PTA-6737.

The Panel confirms its previous conclusions that PB6 is safe for the target species, consumers and the environment. PB6 is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser.

The Panel confirms that PB6 is efficacious when used in feed for the target species concerned by this application at the authorised conditions of use including the compatibility with coccidiostats.

5. Documentation provided to EFSA/Chronology

Date	Event
18/02/2021	Dossier received by EFSA. Application for the modification of the conditions of the authorisation of <i>Bacillus velezensis</i> PB6 as a zootechnical feed additive according to Article 13(3) of Regulation (EC) No 1831/2003. Submitted by Kemin Europa N.V.
07/05/2021	Reception mandate from the European Commission
15/06/2021	Application validated by EFSA – Start of the scientific assessment
16/09/2021	Comments received from Member States
02/12/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation and conditions of use</i>
11/01/2022	Reception of supplementary information from the applicant - Scientific assessment re-started
22/03/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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- EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2010. Scientific Opinion on the compatibility of *Bacillus subtilis* PB6 (*Bacillus subtilis*) with coccidiostats in chickens for fattening. EFSA Journal 2010;8(10):1836, 6 pp. <https://doi.org/10.2903/j.efsa.2010.1836>
- EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2011. Scientific Opinion on 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 2011;9(3):2114, 8 pp. <https://doi.org/10.2903/j.efsa.2011.2114>
- EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2012. Scientific Opinion on the safety and efficacy of *Bacillus subtilis* PB6 as a feed additive for weaned piglets and weaned minor porcine species. EFSA Journal 2012;10(5):2671, 8 pp. <https://doi.org/10.2903/j.efsa.2012.2671>
- EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2013. Scientific Opinion on the safety and efficacy of *Bacillus subtilis* PB6 (*Bacillus subtilis*) as a feed additive for turkeys for fattening and turkeys reared for breeding. EFSA Journal 2013;11(4):3176, 10 pp. <https://doi.org/10.2903/j.efsa.2013.3176>
- EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of *Bacillus subtilis* PB6 as a feed additive for laying hens and minor poultry species for laying. EFSA Journal 2015;13(1):3970, 10 pp. <https://doi.org/10.2903/j.efsa.2015.3970>
- EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2017a. Scientific Opinion on the safety and efficacy of *Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) as a feed additive for sows. EFSA Journal 2017;15(5):4855, 9 pp. <https://doi.org/10.2903/j.efsa.2017.4855>

¹⁹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 October 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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Abbreviations

AMR	Antimicrobial Resistance
CFU	colony-forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
QPS	qualified presumption of safety
WGS	whole genome sequence