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Safety and efficacy of a feed additive consisting of *Bacillus velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104 (Enviva[®] PRO 202 GT) for turkeys for fattening (Danisco Animal Nutrition)

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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 the safety and efficacy of the additive consisting of *Bacillus amyloliquefaciens* PTA-6507, *B. amyloliquefaciens* NRRL B-50013 and *B. amyloliquefaciens* NRRL B-50104 (trade name: Enviva[®] PRO 202 GT) for turkeys for fattening. The product under assessment is based on viable spores of three strains originally identified as *B. amyloliquefaciens* which, in the course of the current assessment, were reclassified as *Bacillus velezensis*. The bacterial species *B. velezensis* is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment. The identity of the active agents was established. The active agents do not harbour acquired antimicrobial resistance genes and lack toxigenic potential and the capacity to produce aminoglycosides. Following the QPS approach, the three bacterial strains are presumed safe for the target species, consumers and the environment. Since no concerns are expected from the other components of the additive, Enviva[®] PRO 202 GT is also considered safe for the target species, consumers and the environment. Enviva[®] PRO 202 GT is non-irritant to skin and eyes and is not a dermal sensitiser. Due to the proteinaceous nature of the active agents, the additive should be considered a respiratory sensitiser. In a previous opinion, it was concluded that Enviva[®] PRO 202 GT has a potential to be efficacious as a zootechnical additive in chickens for fattening at the recommended level of 7.5×10^7 CFU/kg complete feed. It is considered that conclusions on efficacy of Enviva[®] PRO 202 GT in chickens for fattening can be extrapolated to turkeys for fattening. Therefore, the FEEDAP Panel concludes that Enviva[®] PRO 202 GT has the potential to be efficacious in turkeys for fattening at 7.5×10^7 CFU/kg complete feed.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003¹ 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.

The European Commission received a request from Danisco Animal Nutrition represented in the EU by Genencor International B.V.² for authorisation of the feed additive consisting of *Bacillus velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104³ (Enviva® PRO 202 GT), when used as a feed additive for turkeys for fattening (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). The particulars and documents in support of the application were considered valid by EFSA as of 15 October 2019.

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 *B. velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104 (Enviva® PRO 202 GT), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The subject of the assessment is the product consisting on viable spores of *B. velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted an opinion on the safety and efficacy of Enviva® PRO 202 GT for chickens for fattening, chickens reared for laying and minor poultry species for fattening and to point of lay (EFSA FEEDAP Panel, 2016).

The additive is currently authorised for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying.⁴

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of the product consisting of *B. velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104 (Enviva® PRO 202 GT) as a feed additive.

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 Enviva® PRO 202 GT in animal feed are valid and applicable for the current application.⁶

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 Danisco Animal Nutrition, PO Box 777, Marlborough, Wiltshire, UK, SN8 1XN; Represented by Genencor International B.V., Archimedesweg 30, 2333 CN, Leiden, The Netherlands.

³ The three strains were originally designated as *Bacillus amyloliquefaciens*.

⁴ Commission Implementing Regulation (EU) 2017/440 of 13 March 2017 concerning the authorisation of the preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition). OJ L 67, 14.3.2017, p. 74.

⁵ FEED dossier reference: FAD-2019-0049.

⁶ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2015-0008?search&form-return>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Enviva® PRO 202 GT is in line with the principles laid down in Regulation (EC) No 429/2008⁷ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

3. Assessment

The subject of the assessment is a product consisting on viable spores of *B. velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104 with trade name Enviva® PRO 202 GT, intended to be used as a zootechnical additive (functional group: gut flora stabiliser) for turkeys for fattening.

3.1. Characterisation

3.1.1. Characterisation of the active agents

The additive Enviva® PRO 202 GT is a preparation of three non-genetically modified *B. velezensis* strains deposited in the American Type Culture Collection (ATCC) (accession number PTA-6507) and in the United States Department of Agriculture (USDA) Agricultural Research Culture Collection (NRRL) (accession numbers NRRLB-50104 and NRRLB-50013).⁸ In a previous assessment, the FEEDAP Panel (EFSA FEEDAP Panel, 2016) fully characterised the additive. The applicant has provided new information on the identification and characterisation of the active agents as described below.

The strains PTA-6507, NRRL B-50013 and NRRL B-50104 were identified at species level as *B. velezensis*

The toxigenic potential of each strain was assessed according to the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a,b). No lysis of Vero cells was detected with any of the strains. Therefore, the strains are considered to be non-toxicogenic.¹⁰

The susceptibility of each of the three strains to the antimicrobials recommended by FEEDAP guidance (EFSA FEEDAP Panel, 2018a) was tested by broth microdilution. All the minimum inhibitory concentration (MIC) values determined were equal or fell below the corresponding cut-off values defined by the FEEDAP Panel except for streptomycin. The MIC values for streptomycin were 16 mg/L for the strain NRRL B-50013 and 32 mg/L for the strain NRRL B-50104. These exceeded the EFSA cut-off values by one and two dilutions, respectively.¹¹ Exceeding the cut-off value by one dilution is considered to be within the normal range of variation and thus, not a matter of concern.

The whole genome sequence (WGS) of each strain was interrogated for the presence of antimicrobial resistance genes (AMR) by searching

No hits of concern were identified. Although the strain NRRL B-50104 was resistant to streptomycin, since no acquired AMR genes were found in the WGS, it can be assumed that this resistance does not raise safety concerns.

⁷ 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.

⁸ Technical dossier/Section II/Annex II.14.

⁹ Technical dossier/Section II/Annex II.13c and Supplementary Information November 2020/Annex II.2.SI2.

¹⁰ Technical dossier/ Supplementary Information November 2020/Annex II.9.SI2, Annex II.10.SI2 and Annex II.11.SI2.

¹¹ Technical dossier/ Supplementary Information November 2020/Annex II.3.SI2, Annex II.4.SI2 and Annex II.5.SI2.

¹² Technical dossier/ Supplementary Information November 2020/Annex II.6.SI2, Annex II.7.SI2 and Annex II.8.SI2.

To exclude the capacity of the active agents to produce aminoglycosides, the supernatants of cultures from the three strains tested individually¹³ and in combination¹⁴ (three batches each) were tested using the disk-diffusion method against reference strains (*Staphylococcus aureus* ATCC 6538, *Streptococcus pyogenes* ATCC 12344, *Bacillus cereus* ATCC 2, *Bacillus circulans* ATCC 4516, *Escherichia coli* ATCC 11229, and *Serratia marcescens* ATCC 14041). No inhibition was observed, denoting the lack of antimicrobial production of the strains, including aminoglycosides.

3.1.2. Characterisation of the additive

The additive under assessment has the same composition: spores concentrate (██████████), carrier (calcium carbonate, ██████████), anticaking agent (sodium aluminosilicate, ██████████) and mineral oil (██████████) and method of manufacture as those considered in the previous application and current authorisation (EFSA FEEDAP Panel, 2016). It ensures a minimum bacterial concentration of 2.5×10^9 total CFU/g additive (8.3×10^8 CFUs of each strain/g additive). The data pertaining to composition, physical properties and stability submitted in the previous application dossier still apply. However, this application contains new data that are described below.

The batch-to-batch variation of five recent batches of the additive showed compliance with the minimum specifications based on total counts (mean 3.5×10^9 CFU/g, with a range of $2.8\text{--}4.2 \times 10^9$ CFU/g).¹⁵ No data were provided to confirm the compliance with the declared ratio between the three active agents (1:1:1). The only data available regarded the counts of the individual spores' concentrates used in the manufacture of five batches of Enviva® Pro 202 GT prior to mixing.¹⁶

Specifications are set for chemicals (< 15 mg arsenic/kg, < 2 mg cadmium/kg, < 20 mg lead/kg, < 0.3 mg mercury/kg) and microbiological impurities (*Staphylococcus aureus* < 10 CFU/g, *Bacillus cereus* < 10 CFU/g, absence of *Salmonella* spp. and *Listeria* spp. in 25 g, *Escherichia coli* < 10 CFU/g, coliforms < 10 CFU/g, Enterobacteriaceae < 10 CFU/g, yeasts < 10 CFU/g and filamentous fungi < 10 CFU/g). Analyses of three recent batches showed compliance with these specifications.^{17,18}

3.1.3. Conditions of use

The additive is intended to be used in feed for turkeys for fattening at the recommended use level of 7.5×10^7 CFU/kg complete feeds.

3.2. Safety

The bacterial species *B. velezensis* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach (EFSA, 2007; EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strains to be conclusively established and evidence that they do not harbour acquired antimicrobial resistance genes, that the strains lack toxigenic potential and they do not have the capacity to produce aminoglycosides. In the view of the FEEDAP Panel, the identities of the active agents as *B. velezensis* were established and the compliance with the other qualifications confirmed. Therefore, the Panel concludes that *B. velezensis* PTA-6507, *B. velezensis* NRRL B-50013 and *B. velezensis* NRRL B-50104 can be presumed safe for target animals, consumers and the environment. Since the excipients included in the additive do not raise concerns, Enviva® PRO 202 GT is also presumed safe for target animals, consumers of products derived from animals fed the additive and the environment.

No new information has been made available that would lead the FEEDAP Panel to reconsider the conclusion drawn in the previous opinion on this additive (EFSA FEEDAP Panel, 2016). Moreover, the use of the additive in the new target species/categories would not introduce hazards/risks not already considered.

In the context of the previous opinion, Enviva® PRO 202 GT was considered to be non-irritant to skin and eyes and not a dermal sensitiser. However, owing to the proteinaceous nature of the active

¹³ Technical dossier/Supplementary Information February 2021/Annex_1_ Reply_EFSA_Q_2019_00457_Enviva PRO 202 GT_Conf, Annex_II_1S_COA_AM_50104_Conf, Annex_II_2S_COA_AM_6507_Conf, Annex_II_3S_COA_AM_50013_Conf, Annex_II_5.0S_MoA_Conf and Annex_II_5.1S_MoA_supplementary_Conf.

¹⁴ Technical dossier/Section II/Annex_II_12_SI2_Antimicrobial Activity CoAs_Conf.pdf.

¹⁵ Technical dossier/Section II/ Annex II.2_conf.

¹⁶ Technical dossier/Supplementary Information February 2021/Annex_1_ Reply_EFSA_Q_2019_00457_Enviva PRO 202 GT_Conf and Annex_II_4S_COA_Batch_strain_Conf.

¹⁷ Limits of detection (LOD): 0.02 mg arsenic /kg, 0.01 mg cadmium /kg, 0.02 mg lead /kg, 0.010 mg mercury/kg.

¹⁸ Technical dossier/Section II/Annex II.6, Annex II.7 and Annex II.8.

agents, it should be considered a respiratory sensitiser. No new information supporting safety of the additive for the user has been submitted in the current application.

3.3. Efficacy

3.3.1. Efficacy for turkeys

In the previous opinion, the Panel concluded that Enviva® PRO 202 GT has a potential to be efficacious as a zootechnical additive in chickens for fattening at the recommended dose of 7.5×10^7 CFU/kg (EFSA, 2016). Since the effects to the additive can be reasonably assumed to be the same in both poultry species, the Panel considers that the results from the efficacy studies in chickens for fattening can be used to conclude on turkeys for fattening 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 Regulation¹⁹ and Good Manufacturing Practice.

4. Conclusions

The active agents fulfil the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Enviva® PRO 202 GT can be presumed to be safe for turkeys for fattening, consumers and for the environment.

Enviva® PRO 202 GT is non-irritant to skin and eyes and is not a dermal sensitiser. Given the proteinaceous nature of the active agents, the additive should be considered a respiratory sensitiser.

The FEEDAP Panel concludes that Enviva® PRO 202 GT has the potential to be efficacious in turkeys for fattening at 7.5×10^7 CFU/kg complete feed.

5. Documentation as provided to EFSA/Chronology

Date	Event
08/07/2019	Dossier received by EFSA. Enviva® PRO 202 GT (<i>Bacillus amyloliquefaciens</i> PTA-6507, <i>Bacillus amyloliquefaciens</i> NRRL B-50013 and <i>Bacillus amyloliquefaciens</i> NRRL B-50104) for turkeys for fattening. Submitted by Danisco (UK) Ltd. represented in the EU by Genencor International B.V.
16/07/2019	Reception mandate from the European Commission
15/10/2019	Application validated by EFSA – Start of the scientific assessment
13/11/2019	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</i>
06/12/2019	Clarification teleconference hold with the applicant during the risk assessment
20/01/2020	Comments received from Member States
10/02/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
18/05/2020	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</i>
23/06/2020	Clarification teleconference hold with the applicant during the risk assessment
17/07/2020	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
20/11/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
14/12/2020	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</i>
22/12/2020	Clarification teleconference hold with the applicant during the risk assessment
19/02/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
17/03/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

¹⁹ Regulation (EC) No 1831/2005 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.

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Abbreviations

CFU	colony forming unit
EURL	European Union Reference Laboratory
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
QPS	qualified presumption of safety
WGS	whole genome sequence