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Safety and efficacy of the feed additive consisting of *Bacillus velezensis* CECT 5940 (Ecobiol®) for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (Evonik Operations GmbH)

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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 extension of use of the feed additive consisting of *Bacillus velezensis* CECT 5940 (tradename: Ecobiol®) to turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction). The product under assessment is based on viable spores of a strain originally identified as *Bacillus amyloliquefaciens*. During the course of the current assessment, the active agent has been reclassified as *B. velezensis* CECT 5940. The bacterial species *B. velezensis* is considered suitable for the qualified presumption of safety (QPS) approach. The identity of the active agent was established and the compliance with the other qualifications confirmed. Therefore, *B. velezensis* CECT 5940 is presumed safe for the target species, consumers and the environment. Since no concerns are expected from the other components of the additive, the additive Ecobiol® is also considered safe for the target species, consumers and the environment. The additive is not irritant to skin/eye or a skin sensitiser, but should be considered a respiratory sensitiser. The efficacy data previously evaluated allowed the Panel to conclude that the additive has the potential to be efficacious at the level of 1×10^9 CFU/kg feed in turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction).

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Requestor: European Commission

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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 Evonik Nutrition & Care GmbH² for a new use of the product consisting of *Bacillus velezensis* CECT 5940³ (Ecobiol®) when used as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction) (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 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 20 August 2020.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product consisting of *B. velezensis* CECT 5940 (Ecobiol®), when used under the proposed conditions of use (see 3.1.3).

1.2. Additional information

The additive under assessment is a preparation of spores of *B. velezensis* CECT 5940, formerly identified as *Bacillus amyloliquefaciens*, with the trade name Ecobiol®. EFSA issued an opinion on the safety and efficacy of Ecobiol® when used in chickens for fattening (EFSA, 2008), an opinion on the compatibility of Ecobiol® for chickens for fattening with coccidiostats (EFSA, 2010), and an opinion on the renewal of the authorisation of use in chickens for fattening and the extension of use in chickens reared for laying (EFSA FEEDAP Panel, 2020).

The additive is authorised as a zootechnical additive (functional group: gut flora stabilisers) for use in chickens for fattening and chickens 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* CECT 5940 (Ecobiol®) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁶

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the product consisting of *B. velezensis* CECT 5940 (Ecobiol®) is in line with the principles laid down in Regulation

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 On 14 July 2020, EFSA was informed by the European Commission that the applicant company changed to Evonik Operations GmbH, Rodenbacher-Chausee 4, 63457 Hanau-Wolfgang, Germany.

³ Originally designated as *Bacillus amyloliquefaciens* CECT 5940.

⁴ Commission Implementing Regulation (EU) 2020/1395 of 5 October 2020 concerning the renewal of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of authorisation Evonik Nutrition & Care GmbH). OJ L 324, 6.10.2020, p. 3–5.

⁵ FEED dossier reference: FAD-2020-0037.

⁶ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2009-0041?search&form-return>

(EC) No 429/2008⁷ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), 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), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

The additive consists of spores of *B. velezensis* CECT 5940 and is currently authorised for use as a zootechnical additive (gut flora stabiliser) in feed for chickens for fattening and chickens reared for laying. The additive will be referred to in this scientific opinion as Ecobiol® (its tradename).

This assessment regards a new use of Ecobiol® for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction).

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is a powder currently authorised and marketed in three forms:

- Ecobiol® with a minimum concentration of *B. velezensis* CECT 5940 of 1×10^9 colony forming units (CFU)/g additive
- Ecobiol® 500 with a minimum concentration of *B. velezensis* CECT 5940 of 2×10^9 CFU/g additive
- Ecobiol® Plus with a minimum concentration of *B. velezensis* CECT 5940 of 1×10^{10} CFU/g additive

In its three forms, the additive is composed by the spore concentrate (1–10%) and calcium carbonate (90–99% by weight).⁸ All forms of the additive have already been characterised in previous opinions (EFSA, 2008; EFSA FEEDAP Panel, 2020). The applicant stated that the manufacturing process⁹ and composition of the additive under assessment are the same as those described and evaluated in previous applications.¹⁰ Therefore, the data pertaining to impurities, physical properties, shelf life, stability and capacity to homogeneously disperse in feed provided in the previous opinions still apply. The applicant provided new data on the microbial contamination of the additive in three recent batches of Ecobiol® and Ecobiol® Plus, which showed values below the limit of detection (LOD): yeasts (< 100 CFU/g), moulds (< 100 CFU/g), *Escherichia coli* (< 1 CFU/g), Enterobacteriaceae (< 10 CFU/g), *Salmonella* spp. (not detected in 25 g), *Clostridium* spp. (most probable number (MPN) < 1.8/g in all batches except for one batch of Ecobiol® Plus where MPN was 2.0/g) and *Bacillus cereus* (< 100 CFU/g).¹¹

3.1.2. Characterisation of the active agent

The active agent, originally isolated [REDACTED], is deposited in the Spanish Type Culture Collection with the accession number CECT 5940.¹² It is not genetically modified and does not carry plasmids.

The active agent was formerly identified as *B. amyloliquefaciens* (EFSA, 2008; EFSA FEEDAP Panel, 2020). The data recently provided to support the taxonomic identification allocated the strain to the

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/Section II Identity/2.1.3 Qualitative and quantitative composition (active substance/agent, other components, impurities, batch to batch variation).

⁹ Technical dossier/Section II/Annex_II_15_Manufacturing_conf.

¹⁰ Technical dossier/Section II/Section II Identity/2.3.1. Active substance(s)/agent(s).

¹¹ Technical dossier/Supplementary Information December 2020/Annex_SIn_05_CoA_microbio.pdf.

¹² Technical dossier/Section II/Annex_II_02_Certificate_of_Deposit.

newly recognised species *B. velezensis*. [REDACTED]

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The strain was shown to be susceptible to relevant antibiotics and to lack acquired antimicrobial resistance genes and cytotoxicity potential in a recent opinion (EFSA FEEDAP Panel, 2020). During the current assessment, the applicant was asked to perform a new search to update the previous results.

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The production of aminoglycosides by *B. velezensis* CECT 5940 was tested [REDACTED]

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3.1.3. Conditions of use

Ecobiol® is intended to be used in complete feed for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction) at the minimum proposed level of 1×10^9 CFU/kg complete feed.

3.2. Safety

During the course of the current assessment, the active agent has been reclassified as *B. velezensis*, which 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 strain to be conclusively established and evidence that it does not harbour acquired antimicrobial resistance genes, that it lacks toxigenic potential and it does not have the capacity to produce aminoglycosides. The lack of toxigenic potential and acquired resistance determinants to antibiotics was demonstrated in a previous assessment (EFSA FEEDAP Panel, 2020). In the current submission, the identity of the active agent as *B. velezensis* was established and the compliance with the other qualifications of this species confirmed. Therefore, *B. velezensis* CECT 5940 is presumed safe for the target species, consumers and the environment. Since the other component of the additive (calcium carbonate) does not give rise to concerns, Ecobiol® is also considered safe for the target species, consumer and the environment. This conclusion applies also to the new species and categories (turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction)) for which a request for an extension of use is made.

In a previous opinion (EFSA FEEDAP Panel, 2020), the Panel concluded that Ecobiol® is not irritant to skin and eye or a dermal sensitiser, but should be considered a respiratory sensitiser. No new data have been provided that would lead the Panel to change these conclusions.

Moreover, a literature search covering the period 2007-2020 conducted in support of the latest application on Ecobiol® (EFSA FEEDAP Panel, 2020) was updated with publications that became available since the submission of the last application.¹⁶ There were no findings in the relevant papers that would lead the FEEDAP Panel to reconsider previous conclusions that the product Ecobiol is safe for the target species, consumers and the environment (EFSA, 2008; EFSA FEEDAP Panel, 2020). Regarding user safety, Ecobiol® is not irritant to skin and eye or a dermal sensitiser, but should be considered a respiratory sensitiser.

3.3. Efficacy

The efficacy of Ecobiol® for chickens for fattening has been established at 1×10^9 CFU/kg complete feed (EFSA, 2008). These conclusions can be extrapolated to the proposed avian species of

¹³ Technical dossier/Supplementary Information December 2020/Annex_SIn_01_Phylogenomic_analysis_update_CONF.pdf.

¹⁴ Technical dossier/Supplementary Information December 2020/Annex_SIn_02_Final_report_AMR_CONF.PDF.

¹⁵ Technical dossier/Supplementary Information December 2020/Annex_SIn_04_Final_report_aminoglycoside_prod_CONF.pdf and Annex_SIn_06_Final_report_MIA.pdf.

¹⁶ Technical dossier/Section III/Annexes Section III/Annex_III_01_literature search.

the current application when used under the same conditions of use. Therefore, the Panel considers that Ecobiol® has the potential to be efficacious in turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding, and ornamental birds (except for reproduction) at 1×10^9 CFU/kg complete feed.

3.4. Post-market monitoring

The FEEDAP Panel considered that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation (Regulation (EC) No 1831/2005) and Good Manufacturing Practice.

4. Conclusions

Ecobiol® is considered safe for the target species, consumer and the environment.

Ecobiol® is not irritant to skin/eye or a skin sensitiser but should be considered a respiratory sensitiser.

Ecobiol® has the potential to be efficacious in turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding, and ornamental birds (except for reproduction) at the level of 1×10^9 CFU/kg complete feed.

5. Documentation as provided to EFSA/Chronology

Date	Event
26/05/2020	Dossier received by EFSA. Ecobiol, Ecobiol 500, Ecobiol Plus (<i>Bacillus amyloliquefaciens</i> CECT 5940) for turkeys for fattening, turkey reared for breeding, minor poultry species for fattening and reared for laying and ornamental birds (except for reproduction). Submitted by Evonik Nutrition & Care GmbH.
11/06/2020	Reception mandate from the European Commission
20/08/2020	Application validated by EFSA – Start of the scientific assessment
09/10/2020	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 of the strain, purity</i>
23/11/2020	Comments received from Member States
10/12/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
05/05/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

BIOHAZ	EFSA Panel on Biological Hazards
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products of Substances used in Animal Feed
LOD	limit of detection
QPS	Qualified presumption of safety