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## Assessment of the application for renewal of authorisation of Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940) as a feed additive for chickens for fattening and its extension of use for chickens reared for laying

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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 Ecobiol® when used as a zootechnical additive in feed for chickens for fattening and chickens reared for laying at  $1.0 \times 10^9$  colony forming units (CFU)/kg feed. Ecobiol® is the trade name for a feed additive based on *Bacillus amyloliquefaciens* CECT 5940, currently authorised for use in chickens for fattening. This opinion concerns the renewal of the authorisation of Ecobiol® for chickens for fattening and the evaluation of the new use with chickens reared for laying. The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation. The FEEDAP Panel concludes that Ecobiol® is safe under the current conditions of authorisation for the target species (chickens for fattening and chickens reared for laying), consumers of products from animals fed the additive and the environment. Ecobiol® is not irritant to skin/eye or a skin sensitiser but should be considered a potential respiratory sensitiser. Due to a high dusting potential, exposure of users by inhalation is likely. There is no need for assessing the efficacy of Ecobiol® in the context of the renewal of the authorisation. The additive, at the level of  $1 \times 10^9$  CFU/kg feed, has the potential to be efficacious in chickens reared for laying.

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## 1. Introduction

### 1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> 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. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Evonik Nutrition and Care GmbH<sup>2</sup> and for a new use of a feed additive in chickens reared for laying (zootechnical additive; functional group: gut flora stabiliser) and for renewal of the authorisation of the Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940), when used as a feed additive for chickens 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) and under Article 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 19 January 2018.

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 Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940), when used under the proposed conditions of use (see Section 3.1.2).

### 1.2. Additional information

Ecobiol® is a preparation of spores of *Bacillus amyloliquefaciens* CECT 5940. EFSA issued one opinion on the safety and efficacy of Ecobiol® when used in chickens for fattening (EFSA, 2008) and an opinion on the compatibility of Ecobiol® with coccidiostats (EFSA, 2010).

The additive is currently authorised as a zootechnical additive (functional group: gut flora stabiliser) for use in chickens for fattening.<sup>3</sup>

## 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<sup>4</sup> in support of the authorisation request for the use of Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940) 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.<sup>5</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940) is in line with the principles laid down in Regulation (EC) No 429/2008<sup>6</sup> and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives

<sup>1</sup> 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.

<sup>2</sup> Evonik Nutrition and Care GmbH, Rodenbacher Chaussee 4, D-63457 Hanau-Wolfgang, Germany.

<sup>3</sup> Commission Regulation (EC) No 1292/2008 of 18 December 2008 concerning the authorisation of *Bacillus amyloliquefaciens* CECT 5940 (Ecobiol and Ecobiol plus) as a feed additive. OJ L 340, 19.12.2008, p. 36.

<sup>4</sup> FEED dossier reference: FAD-2017-0068.

<sup>5</sup> 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>

<sup>6</sup> 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.

(EFSA FEEDAP Panel, 2013) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

### 3. Assessment

The additive Ecobiol® is a preparation of spores of *Bacillus amyloliquefaciens* CECT 5940 currently authorised for use as a zootechnical additive (gut flora stabiliser) in feed for chickens for fattening.

This assessment regards the renewal of the authorisation of Ecobiol® when used in feed for chickens for fattening, and a new authorisation for use in feed for chickens reared for laying.

#### 3.1. Characterisation

##### 3.1.1. Characterisation of the additive

The additive is a powder currently authorised and marketed as:

- Ecobiol® with a minimum concentration of *B. amyloliquefaciens* CECT 5940 of  $1 \times 10^9$  CFU/g additive, and
- Ecobiol® Plus with a minimum concentration of *B. amyloliquefaciens* CECT 5940 of  $1 \times 10^{10}$  CFU/g additive.

The applicant is requesting the authorisation of a third form, Ecobiol® 500, with a minimum concentration of *B. amyloliquefaciens* CECT 5940 of  $2 \times 10^9$  CFU/g additive. In its three forms, the additive is composed by the spore concentrate and calcium carbonate, the last corresponding to approximately 90-99% by weight.<sup>7</sup>

The applicant states that minor changes in the manufacturing process<sup>8</sup>

Compliance with specifications was confirmed by analysis of five batches for Ecobiol® and Ecobiol® Plus and three of Ecobiol® 500, all produced in 2017 (Ecobiol® mean:  $1.6 \times 10^9$  CFU/g additive, range:  $1.2\text{--}2.3 \times 10^9$  CFU/g; Ecobiol® 500 mean:  $3.7 \times 10^9$  CFU/g additive, range:  $3.6\text{--}4.0 \times 10^9$  CFU/g and Ecobiol® Plus mean:  $1.7 \times 10^{10}$  CFU/g additive, range:  $1.5\text{--}1.9 \times 10^{10}$  CFU/g).<sup>10</sup>

Two batches of Ecobiol® and three of Ecobiol® Plus produced in 2016 were analysed for microbial<sup>11</sup> and chemical contaminants.<sup>12</sup> Results confirm compliance with limit levels (coliforms < 10 CFU/g, *Escherichia coli* < 10 CFU/g, *Staphylococcus aureus* < 50 CFU/g, *Clostridium perfringens* < 10 CFU/g, yeasts and filamentous fungi < 10 CFU/g, *Salmonella* (absence in 25 g), total aflatoxins (B1, B2, G1 and G2) < 1.75 µg/kg, aflatoxin B1 < 1 µg/kg, fluorine < 0.05 mg/kg, arsenic < 0.05 mg/kg, cadmium < 0.00025 mg/kg, mercury < 0.008 mg/kg, lead < 0.005 mg/kg and dioxins (PCDD and PCDF) < 0.11 pg/kg. Analysis of additional three batches of the additive (form not specified) showed values of aflatoxins B1, B2, G1 and G2 and of their sum < 0.08 µg/kg. Since the composition of the three forms of the additive differs by the proportion between spores and carrier, and the analysis involved the least and most concentrated forms of the additive (Ecobiol® and Ecobiol® Plus), the Panel does not see the need for additional analysis for the third form, Ecobiol® 500.

The dusting potential of three recent batches of Ecobiol® (from 2017), measured using the Stauber–Heubach dustometer, showed a mean value of 8.5 g/m<sup>3</sup>.<sup>13</sup> This result indicates that Ecobiol® shows a high dusting potential.

Recent analysis of particle size distribution by laser diffraction showed 44% of particles with a diameter < 10 µm and 73% of particles with a diameter < 50 µm for Ecobiol® (mean of six batches)<sup>14</sup>

<sup>7</sup> Technical dossier/Section/Annex\_II\_13.

<sup>8</sup> Technical dossier/Section/Annex\_II\_12 and Supplementary information February 2019.

<sup>9</sup> Commission Regulation (EC) No 1292/2008 of 18 December 2008 concerning the authorisation of *Bacillus amyloliquefaciens* CECT 5940 (Ecobiol and Ecobiol plus) as a feed additive. OJ L 340, 19.12.2008, p. 36, plus amendments.

<sup>10</sup> Technical dossier/Section/Annex\_II\_03.

<sup>11</sup> Technical dossier/Section/Annex\_II\_04.

<sup>12</sup> Technical dossier/Section/Annex\_II\_05.

<sup>13</sup> Technical dossier/Section/Annex\_II\_10.

<sup>14</sup> Technical dossier/Section/Annexes\_II\_06 and II\_07.

and 34.5% of particles with a diameter < 10 µm and 62.3% of particles with a diameter < 50 µm for Ecobiol® Plus (mean of three batches).<sup>15</sup>

### 3.1.2. Characterisation of the active agent

The active agent is a *B. amyloliquefaciens* strain originally isolated [REDACTED]. It is deposited in the Spanish Type Culture Collection with accession number CECT 5940.<sup>16</sup> It has not been genetically modified and does not harbour plasmids.

With the intention to confirm the genetic stability of *B. amyloliquefaciens* CECT 5940, the applicant produced an analysis comparing the whole genome sequence of a product sample extracted from two recent batches (2017 and 2018) with those extracted from older isolates, one from a batch produced in 2013 (described by the applicant as the reference sample) and the other two from isolates deposited in the culture collection in 2001 and 2014.<sup>17</sup> Only one point mutation was detected and therefore it can be concluded that the genome of the production strain is very stable.

Identification of the strain was performed by phylogenomics by the alignment of 422 core genes in 75 *Bacillus* strains including *B. amyloliquefaciens*, *B. velezensis*, *B. licheniformis*, *B. paralicheniformis*, *B. tequilensis*, *B. atrophaeus*, *B. vallismortis* and *B. subtilis* strains.<sup>18</sup> Based on the analysis, the production strain proved to belong to the 'Operational Group *B. amyloliquefaciens*' (clade D). This group contains the very closely related species *B. amyloliquefaciens*, *B. velezensis* and *B. siamensis*, which cluster together in the phylogenetic tree.

The susceptibility of *B. amyloliquefaciens* CECT 5940 to the antibiotics recommended by the FEEDAP Panel was tested (EFSA FEEDAP Panel, 2018). All the minimum inhibitory concentration (MIC) values found fell below the FEEDAP cut-off values.<sup>19</sup> Moreover, the whole genome was interrogated for the presence of known antimicrobial resistance genes. The search in the database CARD did not identify any relevant hit.

No cytotoxic effects were detected in a cytotoxicity test performed using Vero cells and supernatants from the active agent, in accordance with the FEEDAP guidance (EFSA FEEDAP Panel, 2018).<sup>20</sup> In addition, the whole genome sequence (WGS) was interrogated for the presence of the genes codifying for *Bacillus cereus* toxins: *nheA*, *nheB*, *nheC* (non-haemolytic enterotoxin, three protein components); *hblA*, *hblB*, *hblC*, *hblD* (haemolysin BL, four protein components); *cytK* (single protein cytotoxin K) and *cesA* (cereulide synthetase gene cluster) using the VFDB and NCBI databases. No hits were found.<sup>21</sup>

The compatibility of Ecobiol® with the authorised coccidiostats monensin sodium, diclazuril and nicarbazin was established in a previous opinion (EFSA, 2010).

### 3.1.3. Conditions of use

Ecobiol® is currently authorised for use in feed for chickens for fattening at the minimum level of  $1 \times 10^9$  CFU/kg complete feedingstuffs.

The authorisation, under other provisions, foresees:

- In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
- May be used in feed containing the permitted coccidiostats: diclazuril, monensin sodium, or nicarbazin.
- For safety reasons: breathing protection; glasses and gloves shall be used during handling

The applicant proposes to keep the same conditions for chickens for fattening and requests the authorisation for chickens reared for laying with the same conditions of use.

<sup>15</sup> Technical dossier/Section/Annex\_II\_07.

<sup>16</sup> Technical dossier/Section/Annex\_II\_21.

<sup>17</sup> Technical dossier/Section/Annex\_II\_9 and Supplementary information February 2019/Annex\_SIn\_1\_Genetic\_stability\_amended.

<sup>18</sup> Technical dossier/Supplementary information September 2019/Annex\_SIn2\_1\_Phylogenomic\_analysis.

<sup>19</sup> Technical dossier/Supplementary information February 2019/Annex\_SIn\_2\_Assessment\_antimic\_suscept.

<sup>20</sup> Supplementary information February 2019/Annex\_SIn2\_2\_Cytotox\_study.

<sup>21</sup> Technical dossier/Supplementary information February 2019/Annex\_SIn\_3\_Toxigenic\_potential.



### 3.2. Safety

The species *B. amyloliquefaciens* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2017). This approach requires the identity of the strain to be conclusively established and evidence that it lacks toxigenic potential and does not show acquired antimicrobial resistance determinants for antibiotics of human and veterinary importance. In the view of the FEEDAP Panel, the identity of the active agent is established and the lack of toxigenic potential confirmed. *B. amyloliquefaciens* CECT 5940 does not show acquired resistance to antibiotics, and therefore, is presumed safe for the target species, consumers of products derived from animals fed the additive and the environment. Since the other components of the additive do 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 category (chickens reared for laying) for which a request for an extension of use is made.

The safety for the user has been assessed by the FEEDAP Panel in a former opinion of the same product (EFSA, 2008). The Panel concluded that Ecobiol® is not irritant to skin and eye and is not a skin sensitiser, but owing to its proteinaceous nature of the product, should be treated as a potential respiratory sensitiser. The data submitted indicate a high dusting potential, therefore, exposure of users by inhalation is likely. This was translated in the authorising legislation in provisions to protect of users during the handling of the additive.

The applicant maintains records of quality control parameters, non-conformities and recalls and declares that no adverse effects have been reported or new interaction or incompatibilities identified since the preparation of the first dossier in 2007. ■

The applicant conducted a literature search to support the safety of the additive using eight databases: ■

■ The search covered the period 2007–2017 and included the terms *Bacillus amyloliquefaciens*, CECT 5940 and Ecobiol. Thirteen relevant papers and one EFSA opinion (EFSA, 2008) were identified. None was designed to assess the safety per se of the additive, but the effects of the supplementation on the performance of animals/preservation of food. However, some studies investigated or included some health endpoints (i.e. faecal consistency, faecal microbiota). None of these studies reported safety issues with the additive under assessment.

Based on the above and the fact that the manufacturing process of additive has not been significantly modified and that the conditions of use are the same, the Panel considers that there is no evidence to reconsider the conclusions reached in previous assessments. The Panel concludes that Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940) is considered safe for the target species, for the consumer, and the environment under the conditions of use currently authorised. The additive is not irritant to skin and eyes and is not a skin sensitiser but should be considered a potential respiratory sensitiser.

### 3.3. Efficacy

The efficacy of Ecobiol® for chickens for fattening has been established at  $1 \times 10^9$  CFU/kg feed (EFSA, 2008). The application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive and therefore no further assessment is needed for the renewal of the authorisation.

The applicant has requested to extend the use of the additive at the level of  $1 \times 10^9$  CFU/kg feed to chickens reared for laying. The efficacy data from chickens for fattening can be extended to chickens reared for laying. Therefore, the Panel considers that the additive has the potential to be efficacious in this species at the proposed conditions of use.

### 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<sup>24</sup> and Good Manufacturing Practice.

## 4. Conclusions

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

The FEEDAP Panel concludes that Ecobiol® is safe under the current conditions of authorisation for the target species (chickens for fattening and chickens reared for laying), consumers of products from animals fed the additive and the environment. Ecobiol® is not irritant to skin/eye or a skin sensitizer but should be considered a potential respiratory sensitizer. Exposure of users by inhalation is likely.

There is no need for assessing the efficacy of Ecobiol® in the context of the renewal of the authorisation. The additive, at the level of  $1 \times 10^9$  CFU/kg feed, has the potential to be efficacious in chickens reared for laying.

### Documentation as provided to EFSA/Chronology

Date	Event
20/12/2017	Dossier received by EFSA
19/01/2018	Reception mandate from the European Commission
25/05/2018	Application validated by EFSA – Start of the scientific assessment
06/09/2018	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, safety and efficacy</i>
27/02/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
28/01/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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<sup>24</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.



## Abbreviations

AGRIIS	International Information System for the Agricultural Sciences and Technology
CCOHS	Canadian Centre for Occupational Health and Safety
CFU	colony forming unit
ECHA	European Chemicals Agency
EURL	European Union Reference Laboratory
IPCS	International Programme on Chemical Safety
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
PCDD	polychlorinated dibenzo- <i>p</i> -dioxin
PCDF	polychlorinated dibenzofuran
TOXNET	Toxicology Data Network of the United States National Library of Medicine
WGS	whole genome sequence