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Safety and efficacy of B-Act® (*Bacillus licheniformis* DSM 28710) as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening or raised for laying

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed was asked to deliver a scientific opinion on the safety and efficacy of B-Act® when used in feed for turkeys for fattening, reared for breeding and minor poultry species for fattening or raised for laying. B-Act® is a preparation containing viable spores of a *Bacillus licheniformis* strain. This species is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment, which requires the identity of the strain to be established and evidence that it is not toxigenic and does not show acquired resistance to relevant antibiotics. In a previous opinion, the strain was found to meet the criteria for the QPS approach. Since no concerns are expected from other components of the additive, B-Act® is presumed safe for the target species, consumers and the environment. In the same opinion, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but B-Act® was considered a potential respiratory sensitiser. Since the use of B-Act® with the target species is considered unlikely to introduce hazards for users of the product not already considered, the conclusions previously reached apply to the current application. B-Act® at the recommended dose of 1.6×10^9 colony forming units (CFU)/kg feed has the potential to be efficacious in turkeys for fattening. Since the same dose is proposed for the minor poultry species for fattening or raised for laying, the conclusions can be extended/extrapolated to these species. The conclusions on the compatibility of B-Act® with coccidiostats previously drawn apply to the current application provided that the maximum authorised concentrations of the coccidiostats for the target species are equal/lower than those for chickens.

Keywords: zootechnical additive, gut flora stabilisers, B-Act®, *Bacillus licheniformis*, safety, efficacy, turkeys and minor poultry species

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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 a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from HuvePharma NV[2] for authorisation of the product B-Act® (*Bacillus licheniformis* DSM 28710) when used as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species (category: zootechnical additives; functional group: gut flora stabilisers). In the course of the assessment the applicant clarified that the minor poultry species were for fattening and rearing.[3]

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). 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 2 August 2017.

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 B-Act® (*Bacillus licheniformis* DSM 28710), when used under the proposed conditions of use (see Section 3.1.2).

1.2. Additional information

The additive B-Act® is a preparation containing viable spores of *B. licheniformis* DSM 28710. EFSA has issued an opinion on the safety and efficacy of this product when used with chickens for fattening and reared for laying (EFSA FEEDAP Panel, 2016).

The additive is currently authorised for use as a zootechnical feed additive (gut flora stabiliser) in feed for 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 dossier[5] in support of the authorisation request for the use of B-Act® (*Bacillus licheniformis* DSM 28710) 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 B-Act® (*Bacillus licheniformis* DSM 28710) is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and Technical guidance on tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

[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] HuvePharma NV, Uitbreidingstraat 80, 2600, Antwerp, Belgium.
[3] Technical dossier/Supplementary information July 2018/EFSA letter ListDoc.
[4] Commission Implementing Regulation (EU) 2017/1904 of 18 October 2017 concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for chickens for fattening and chickens reared for laying. OJ L 269, 19.10.2017, p. 27.
[5] FEED dossier reference: FAD-2017-0034.
[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2015-0016?search&form-return

3. Assessment

B-Act® is a preparation of viable spores of a single strain of *B. licheniformis* intended for use as a zootechnical additive (gut flora stabiliser) in feeds for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening or raised for laying to improve their performance.

3.1. Characterisation

3.1.1. Characterisation of the additive

B-Act® is a powder with a minimum declared content of 3.2×10^9 colony forming units (CFU) of *B. licheniformis* DSM 28710[7] per gram of additive. It has the same formulation (spores concentrate, ~ 3% and calcium carbonate, ~ 97%) and method of manufacture as that considered in a previous application (EFSA FEEDAP Panel, 2016). Thus, the data pertaining to composition, impurities, physical properties and shelf life still apply.

The stability and capacity of the additive to homogeneously mix with poultry feed and premixtures were established in the previous opinion (EFSA FEEDAP Panel, 2016). The FEEDAP Panel is of the opinion that these existing data are sufficient to establish the stability and capacity to homogeneously mix of the additive in premixtures and feeds for the target species.

3.1.2. Conditions of use

The additive B-Act® is intended for use in feed for turkeys for fattening, turkeys reared for breeding and minor growing species for fattening or raised for laying at the proposed dose of 1.6×10^9 CFU/kg complete feedingstuffs.

It is intended for use in the presence of the permitted coccidiostats: salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone.

3.2. Safety

3.2.1. Safety for the target species, consumers and environment

The species *B. licheniformis* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) 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 of toxigenic potential and does not show resistance to antibiotics of human and veterinary importance. In a previous opinion on the use of the additive with chickens for fattening (EFSA FEEDAP Panel, 2016), the identification of the strain and compliance with the QPS qualifications were confirmed. Therefore, *B. licheniformis* DSM 28710 was presumed safe for the target animals, consumers of products derived from the animals fed the additive and the environment. Since no concerns arise from other components of the additive, B-Act® is also presumed safe for the target animals, consumers and the environment.

3.2.2. Safety for the user

In the previous opinion, owing to the absence of data, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but the Panel considered B-Act® to be a potential respiratory sensitiser (EFSA FEEDAP Panel, 2016). No additional studies were provided in the current application. The use of the additive with turkeys for fattening, turkeys reared for breeding and minor growing poultry species is considered unlikely to introduce hazards for users of the product not already considered as part of the first assessment. Therefore, the conclusions reached in the previous assessment apply to the current application.

[7] The applicant uses BL11 as in-house identifier.

3.3. Efficacy

3.3.1. Efficacy for turkeys for fattening

Five floor pen studies conducted in three Member States with fattening turkeys were performed to demonstrate the efficacy of the product. However, one study[8] was not considered adequate to support the efficacy of the additive due to the low and extremely variable performance of the animals[9]; therefore, it was disregarded.

The detailed design of the remaining four studies is presented in Table 1 and the results in Table 2. They were floor pen studies with one-day-old turkeys (females in studies 1, 2 and 4, and males in study 3) randomly allocated to two treatment groups (control and B-Act® at the recommended dose), and fed their respective diets *ad libitum* during the whole experimental period. Three or four phase-diets were used. Concentration of the additive in feed was confirmed by analysis. In all studies, the health status of birds was monitored throughout the experimental periods. In the first study, birds that died within the first week were replaced. Feed intake and body weight of the animals were measured at diet change and the feed to gain ratio was calculated. Data were analysed using one-way analysis of variance (ANOVA), then mean groups were compared with the Duncan or Tukey's test. The pen was the experimental unit for all parameters.

Table 1: Details on the study design for the studies performed in turkeys

Study	Duration of the study (days)	Breed (sex)	Total animals Replicates/ treatment × animals/ replicate	B-Act® (CFU/kg feed)	Basal diets (main ingredients) Diet form
1(1)	98	Hybrid converter ♀	612 18 × 17	0 1.6×10^9	Wheat/soybean meal mash
2(2)	84	Hybrid converter ♀	1,300 13 × 50	0 1.6×10^9	Wheat/barley/rye/triticale/ soybean meal pelleted
3(3)	84	Hybrid converter ♂	600 30 × 10	0 1.6×10^9	Wheat/soybean meal pelleted
4(4)	84	BUT premium ♀	240 12 × 10	0 1.6×10^9	Wheat/soybean meal/rye mash and pelleted

CFU: colony forming unit.
(1): Technical dossier/Section IV/Annex IV.02.
(2): Technical dossier/Supplementary information July 2018/Annex IV_03.
(3): Technical dossier/Supplementary information July 2018/Annex IV_04.
(4): Technical dossier/Supplementary information July 2018/Annex IV_05.

Table 2: Summary of the overall performance results of the trials made with turkeys for fattening

Trial no	B-Act® (CFU/kg feed)	Feed intake (g)(1)	Weight (kg)(2)	Average daily weight gain (g/day)	Feed:gain	Dead and culled (%)
1	0	218.0	8.66	87.8	2.36^a	9.4
	1.6×10^9	213.7	8.73	88.4	2.31^b	7.6
2	0	228.2	7.96^b	94.0^b	2.38^a	4.9
	1.6×10^9	227.8	8.12^a	95.9^a	2.34^b	4.1
3	0	$21,503^b$	10.47^b	n.r.	2.07	2.0
	1.6×10^9	$22,697^a$	10.93^a	n.r.	2.08	1.3

[8] Technical dossier/Section IV/Annex IV.01.
[9] Birds (BUT big 6, males) showed a daily weight gain at 84 days of life of 71.6 and 76.5 g/day in the control and treated groups respectively, and an individual bodyweight ranging from 4 to 8.7 kg.

Trial no	B-Act® (CFU/kg feed)	Feed intake (g)(1)	Weight (kg)(2)	Average daily weight gain (g/day)	Feed:gain	Dead and culled (%)
4	0	161.0	6.28	74.1	2.17[a]	0
	1.6×10^9	149.6	6.30	74.4	2.00[b]	1.7

CFU: colony forming unit; n.r.: not reported.
a,b: Means within a column with different superscript letters are significantly different at $p < 0.05$.
(1): Average daily feed intake per bird in studies 1, 2 and 4 and total feed intake per bird in study 3.
(2): Final weight in studies 1, 2 and 4 and total weight gain in study 3.

Mortality was not treatment related. The supplementation of B-Act® at the minimum recommended dose significantly increased the weight of turkeys in two of the studies (2 and 3) and significantly improved the feed to gain ratio in three of the four studies.

Conclusions on efficacy for turkeys for fattening

The FEEDAP Panel concludes that B-Act® at the minimum recommended dose of 1.6×10^9 CFU/kg complete feedingstuffs has the potential to improve the performance of turkeys for fattening.

3.3.2. Efficacy for turkeys reared for breeding and minor poultry species for fattening or raised for laying

The efficacy for turkeys for fattening was established in the studies described above and that for chickens for fattening was established in a previous opinion (EFSA FEEDAP Panel, 2016). Since the applicant proposes the use of the same dose (1.6×10^9 CFU/kg complete feedingstuffs) with turkeys reared for breeding and minor poultry species for fattening or raised for laying, the conclusions reached in turkeys and chickens for fattening can be extended/extrapolated to these poultry species/categories.

3.3.3. Compatibility with coccidiostats

In the previous opinion on the use of B-Act® in feed for chickens for fattening and reared for laying, the compatibility of *B. licheniformis* DSM 28710 with the coccidiostats salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone at the highest authorised levels for chickens for fattening was established (EFSA FEEDAP Panel, 2016). Conclusions previously drawn apply to the current application provided that the maximum authorised concentration of the coccidiostats for turkeys for fattening, turkeys reared for breeding and minor growing poultry species (when maximum authorised concentrations exist), are equal or lower than those for chickens for fattening.

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[10] and Good Manufacturing Practice.

4. Conclusions

The active agent fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, B-Act® can be presumed to be safe for the target animals, consumers of products from treated animals and the environment.

In the absence of data, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but B-Act® is considered a potential respiratory sensitiser.

B-Act® at the recommended dose of 1.6×10^9 CFU/kg feed has the potential to be efficacious in turkeys for fattening. Since the applicant proposes the use of the same dose (1.6×10^9 CFU/kg complete feedingstuffs) with turkeys reared for breeding and minor poultry species for fattening or raised for laying, the conclusions reached in turkeys for fattening and previously in chickens for fattening can be extended/extrapolated to these poultry species/categories.

[10] 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.

In the previous opinion on the use of B-Act® in feed for chickens for fattening and reared for laying, the compatibility of *B. licheniformis* DSM 28710 with the coccidiostats salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone at the highest authorised levels for chickens for fattening was established. Conclusions previously drawn apply to the current application provided that the maximum authorised concentration of the coccidiostats for turkeys for fattening, turkeys reared for breeding and minor growing poultry species (when they exist), are equal or lower than those for chickens for fattening.

Documentation provided to EFSA

1) B-Act® (*Bacillus licheniformis*). August 2017. Submitted by HuvePharma NV.
2) B-Act® (*Bacillus licheniformis*). Supplementary information. July 2018. Submitted by HuvePharma NV.
3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for B-Act®.
4) Comments from Member States.

Chronology

16/6/2017	Dossier received by EFSA
21/6/2017	Reception mandate from the European Commission
2/2/2017	Application validated by EFSA – Start of the scientific assessment
16/10/2017	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: efficacy*
3/7/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
24/10/2018	Comments received from Member States
28/11/2018	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ANOVA	analysis of variance
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
QPS	qualified presumption of safety