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Efficacy of a feed additive consisting of *Bacillus velezensis* NITE BP-01844 (BA-KING®) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening, or rearing to slaughter or point of lay including non-food producing species (Toa Biopharma Co., Ltd.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the efficacy of BA-KING® *Bacillus velezensis* as a zootechnical feed additive to be used as a gut flora stabiliser for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening or rearing to slaughter or point of lay including non-food producing species. The product under assessment is based on viable spores of a strain identified as *B. velezensis*, which is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment. In a previous opinion, the FEEDAP Panel concluded that BA-KING® was safe for the target species, consumers of products derived from animals fed the additive and the environment. Additionally, the additive was not irritant to skin but potentially irritant to eyes and respiratory sensitiser. The Panel could not conclude on the efficacy of the additive for the target species at the proposed conditions of use. In the current application, two additional efficacy trials in chickens for fattening were provided. The results showed an improvement in the performance parameters of chickens when supplemented with BA-KING® at 2.0×10^8 CFU/kg complete feed relative to a control group. Considering the previously submitted studies and the newly submitted studies in chickens for fattening, the Panel concluded that BA-KING®, supplemented at 2.0×10^8 CFU/kg complete feed, has the potential to be efficacious in all avian species for fattening or reared for laying/breeding and non-food-producing avian species at the same physiological stage.

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Question number: EFSA-Q-2023-00077

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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 and, in particular Article 9 defines the terms of the authorisation by the Commission.

The applicant TOA BIOPHARMA Co., Ltd, Japan, represented in EU by TOA BIOPHARMA Co., Ltd, Europe Representative Office, is seeking a Community authorisation of *Bacillus amyloliquefaciens* TOA5001 (NITE BP-01844)² as a feed additive to be used gut flora stabilisers for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening, or rearing to slaughter or point of lay including non-food producing species (Table 1).

Table 1: Description of the substances

Category of additive	Zootechnical additives
Functional group of additive	Gut flora stabilisers
Description	<i>Bacillus amyloliquefaciens</i> TOA5001 (NITE BP-01844)
Target animal category	Chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening, or rearing to slaughter or point of lay including non-food producing species
Applicant	TOA BIOPHARMA Co., Ltd, Japan, represented in EU by TOA BIOPHARMA Co., Ltd, Europe Representative Office
Type of request	New Opinion

On 26 January 2022, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of the additive.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 31 January 2023 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks EFSA to deliver a new opinion on *Bacillus amyloliquefaciens* TOA5001 (NITE BP-01844) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, or rearing to slaughter or point of lay including non-food producing species based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2. Additional information

The additive BA-KING® contains viable spores of *Bacillus velezensis* (NITE BP-01844; originally designated as *Bacillus amyloliquefaciens* ssp. *plantarum*), which has not been previously authorised in the European Union.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted in 2022 an opinion on the safety and efficacy of *B. velezensis* NITE BP-01844 when used as feed additive in for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening or rearing to slaughter or point of lay including non-food producing species (EFSA FEEDAP Panel, 2022). The Panel was not in the position to conclude on the efficacy of the feed additive in chickens for fattening, and consequently for any avian species due to insufficient evidence.

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 Although originally designated as *Bacillus amyloliquefaciens* ssp. *plantarum* by the applicant in the previous opinion EFSA FEEDAP Panel (2022) it was already referred as *Bacillus velezensis* (NITE BP-01844) as this is considered the correct classification.

2. Data and Methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information³ to a previous application on the same product.⁴ The dossier was received on 31/1/2023 and the general information and supporting documentation available on Open.EFSA online <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00077>.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA to deliver the present output.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of *B. velezensis* NITE BP-01844 (BA-KING®) is in line with the principles laid down in Regulation (EC) No 429/2008⁵ and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

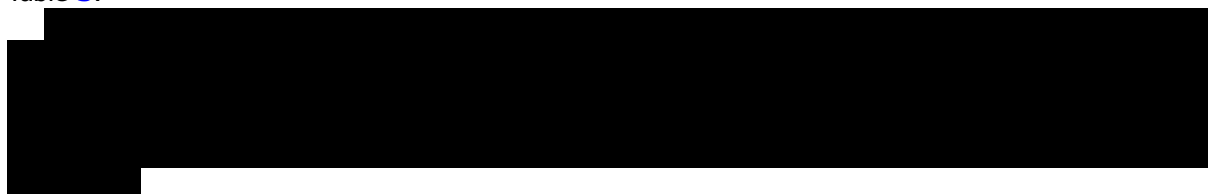
The additive is a preparation of viable spores of *B. velezensis* NITE BP-01844 (herein and after referred as to BA-KING®) intended for use as a zootechnical feed additive (functional group: gut flora stabilisers) in feed for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening or rearing to slaughter or point of lay including non-food producing species at the minimum concentration of 5.0×10^7 CFU/kg complete feed and 2.5×10^7 CFU/L water. The additive was fully characterised in the previous opinion (EFSA FEEDAP Panel, 2022). The FEEDAP Panel concluded that *B. velezensis* NITE BP-01844 is presumed to be safe for the target species, consumers of products derived from animals fed the additive and the environment. Also, the additive was considered an eye irritant and a respiratory sensitiser. However, the Panel was not in the position to conclude on the efficacy of BA-KING® for the target species.

The applicant has provided supplementary information to support the efficacy of the feed additive in chickens for fattening that is assessed below.

3.1. Efficacy

In the previous opinion (EFSA FEEDAP Panel, 2022), five studies in chickens for fattening were assessed, two of which were not further considered as husbandry conditions where birds were kept did not reflect standard farming practices within the EU and were not in line with Directive 2007/43/EC. The data from the other three studies were pooled and showed significant positive effects on the zootechnical performance of the birds when fed BA-KING® at 5.0×10^7 or 2.0×10^8 CFU/kg complete feed. In the same opinion, the FEEDAP Panel concluded that the *B. velezensis* NITE BP-01844 is compatible with diclazuril, decoquinate, halofuginone, monensin sodium, salinomycin, narasin, robenidine and maduramicin.

The applicant provided two new studies with chickens for fattening which shared a similar experimental design. These trials aimed to study the effect of BA-KING® on zootechnical performance of chickens for fattening. The study design specifications are provided in Table 2 and the results in Table 3.



³ Dossier reference: EFSA-Q-2023-00077.

⁴ Dossier reference: FAD-2020-0049.

⁵ 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.

Table 2: Experimental design of the efficacy trials performed in chickens for fattening

Study	Treatment	Control	BA-KING®	Outcome		
				Parameter	Significance	Value
6	Control	Control	BA-KING®	Weight gain	p < 0.05	10%
	Control	Control	BA-KING®	Feed efficiency	p < 0.05	5%
7	Control	Control	BA-KING®	Weight gain	p < 0.05	15%
	Control	Control	BA-KING®	Feed efficiency	p < 0.05	10%

[Redacted text]

Mortality was low in both studies and not treatment related.

[Redacted text]

Table 3: Effects of BA-KING® [Redacted]

Study	Treatment	Control	BA-KING®	Outcome		
				Parameter	Significance	Value
6	Control	Control	BA-KING®	Weight gain	p < 0.05	10%
	Control	Control	BA-KING®	Feed efficiency	p < 0.05	5%
7	Control	Control	BA-KING®	Weight gain	p < 0.05	15%
	Control	Control	BA-KING®	Feed efficiency	p < 0.05	10%

3.2. Conclusions on efficacy

Based on the efficacy assessment in the previous opinion and the two new efficacy studies, the Panel concludes that the feed additive BA-KING® (*B. velezensis* NITE BP-01844) is efficacious in improving zootechnical performance of chickens for fattening when supplemented at the minimum inclusion level of 2.0×10^8 CFU/kg complete feed.

The conclusions reached for chickens for fattening are extended to chickens reared for laying/breeding and extrapolated to all other avian species for fattening or reared for laying/breeding and non-food-producing avian species at the same physiological stage.

⁶ Annex_IV_3_7_efficiency_broilers_Conf.

⁷ Annex_IV_3_8_efficiency_broilers_Conf.

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 Regulation⁸ and Good Manufacturing Practice.

4. Conclusions

The Panel concludes that BA-KING® supplemented at 2.0×10^8 CFU/kg complete feed has the potential to be efficacious improving zootechnical performance in all avian species for fattening or reared for laying/breeding and non-food-producing avian species at the same physiological stage.

References

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. <https://doi.org/10.2903/j.efsa.2018.5274>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed, 2022. Safety and efficacy of a feed additive consisting of *Bacillus velezensis* NITE BP-01844 (BA-KING®) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening, or rearing to slaughter or point of lay including non-food producing species (Toa Biopharma Co., Ltd.). EFSA Journal 2022;20(2):7152, 12 pp. <https://doi.org/10.2903/j.efsa.2022.7152>

Abbreviations

BW	body weight
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

⁸ 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.