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Safety and efficacy of AviPlus[®] as a feed additive for turkeys for fattening, turkeys reared for breeding and suckling piglets

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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 an application for the authorisation of AviPlus[®], an additive containing a mixture of sorbic acid, citric acid, thymol and vanillin, for use in turkeys for fattening and for breeding at a recommended dose range of 200–500 mg/kg complete feed and in suckling piglets at 1,000–3,000 mg/kg complete feed. AviPlus[®] is considered safe for turkeys for fattening and turkeys reared for breeding up to the maximum recommended dose of 500 mg/kg complete feed. For suckling piglets, the additive is safe up to the maximum recommended dose of 3,000 mg/kg complete feed. The additive is considered safe for the consumer and the environment. The additive is considered a potential skin/eye irritant and a skin sensitiser. The additive has the potential to be efficacious as a zootechnical additive in turkeys for fattening, turkeys reared for breeding at a minimum dose of 200 mg/kg complete feed. For suckling piglets, AviPlus[®] has the potential to be efficacious at a minimum dose of 1,000 mg/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 Vetagro SPA² for authorisation of the product AviPlus®, a preparation of citric acid, sorbic acid, thymol and vanillin, when used as a feed additive for turkeys for fattening, turkeys for breeding and suckling piglets (category: zootechnical additives; functional group: other zootechnical additives).

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 25 April 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 product AviPlus®, a preparation of citric acid, sorbic acid, thymol and vanillin, when used under the proposed conditions of use (see Section 3.1.1).

1.2. Additional information

AviPlus®, a preparation of protected microbeads containing citric acid, sorbic acid, thymol and vanillin, is currently authorised as a zootechnical feed additive for weaned piglets³ and for chickens for fattening, chicken reared for laying, all minor species for fattening and reared for laying and weaned Suidae other than *Sus scrofa domesticus*.⁴

The EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued two opinions on the safety and efficacy of AviPlus® for weaned piglets (EFSA FEEDAP Panel, 2010) and for chickens and minor avian species for fattening and reared for laying and minor porcine species (weaned) (EFSA FEEDAP Panel, 2012).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of two technical dossiers⁵ in support of the authorisation request for the use of AviPlus®, a preparation of citric acid, sorbic acid, thymol and vanillin, as a feed additive.

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.

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 citric acid, sorbic acid and thymol 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 Vetagro SPA, Via Porro 2 - 42124 Reggio Emilia – Italy.

³ Commission Regulation (EU) No 1117/2010 of 2 December 2010 concerning the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for weaned piglets (holder of the authorisation Vetagro SpA). OJ L 317, 3.12.2010, p. 3.

⁴ Commission Implementing Regulation (EU) No 849/2012 of 19 September 2012 concerning the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for chickens for fattening, chickens reared for laying, all minor avian species for fattening and reared for laying and weaned Suidae other than *Sus scrofa domesticus* (holder of the authorisation Vetagro SpA). OJ L 253, 20.9.2012, p. 8.

⁵ FEED dossier references: FAD-2019-0012 and FAD-2019-0013.

⁶ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0049.pdf>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of AviPlus®, a preparation of citric acid, sorbic acid, thymol and vanillin, is in line with the principles laid down in Regulation (EC) No 429/2008⁷ and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The present opinion deals with the assessment of the safety and efficacy of a preparation of protected microbeads containing citric acid, sorbic acid, thymol and vanillin. It is marketed with the trade name AviPlus®. It is intended to be used as a zootechnical additive (functional group other zootechnical additives) in feed for turkeys for fattening and reared for breeding at a dose range of 200–500 mg/kg complete feedingstuffs and suckling piglets at a dose range of 1,000–3,000 mg/kg complete feedingstuffs.

3.1. Characterisation

The additive, manufactured in the form of fat-coated spherical microbeads, is a preparation containing a minimum of 250 g/kg citric acid, 167 g/kg sorbic acid, 17 g/kg thymol and 10 g/kg vanillin. This formulation is authorised for use in weaned piglets and other weaned Suidae, in chickens for fattening, chickens reared for laying, all minor avian species for fattening and reared for laying. No changes are foreseen when AviPlus® is used in feed for the additional species under consideration.

The active substances and the additive were fully characterised in a previous opinion, therefore, all data pertaining to composition, purity, physico-chemical properties and stability described thereof are considered valid also for this application (EFSA FEEDAP Panel, 2010).

3.1.1. Conditions of use

AviPlus® is intended for use in feeds for turkeys for fattening and reared for breeding, at a dose range of 200–500 mg/kg complete feed and at 1,000–3,000 mg/kg complete feed for suckling piglets. No withdrawal period is proposed.

3.2. Safety

The safety of AviPlus® for the target species, consumers, users and the environment has been evaluated in previous opinions (EFSA FEEDAP Panel, 2010, 2012). The Panel concluded that the additive is safe for weaned piglets and minor porcine species (weaned) up to 3,000 mg/kg complete feed and for chickens for fattening, chicken reared for laying, all minor species for fattening and reared for laying up to 500 mg/kg complete feed. The Panel also concluded that the use of the product as a feed additive raises no concern for consumer safety or for the environment. Concerns for the user were limited to its potential for dermal irritation/sensitisation and eye irritation.

Since the application includes new species/categories, the safety for these new target species should be assessed.

3.2.1. Safety for the target species

Safety for chickens for fattening, chickens reared for laying and for all minor avian species for fattening or reared for laying was established in a previous assessment (EFSA FEEDAP Panel, 2012). In two tolerance studies performed in chickens for fattening, the results showed no negative effects on the performance, blood parameters and gross pathology examination of the birds when fed up to 15× the maximum recommended dose of 500 mg/kg complete feed. This conclusion was extended to chicken reared for laying and to all minor avian species for fattening or reared for laying.

Considering that the margin of safety observed in the tolerance study in chickens for fattening is > 10, and that the maximum recommended doses in chickens and the target species under application

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.

is the same, the Panel extrapolates the conclusions reached in chickens to turkeys for fattening and turkeys reared for breeding.

Safety for weaned piglets was established in a previous assessment (EFSA FEEDAP Panel, 2010). In a tolerance study performed in weaned piglets, the results showed no negative effects on the performance and gross pathology examination, and no treatment-related effects on blood parameters of the animals when fed up to 10 × the maximum recommended dose of 3,000 mg/kg complete feed. This conclusion was extended to all minor porcine species over a developmental period corresponding to the weaned piglets (EFSA FEEDAP Panel, 2012).

Considering that the margin of safety observed in the tolerance study in weaned piglets is > 10, and that the maximum recommended dose in suckling piglets is the same, the Panel extends the conclusions reached in weaned piglets to suckling piglets.

3.2.1.1. Conclusions on safety for the target species

The FEEDAP Panel concludes that the additive is safe for turkeys for fattening, turkeys reared for breeding up to the maximum recommended dose of 500 mg/kg complete feed and for suckling piglets up to the maximum recommended dose of 3,000 mg/kg complete feed.

3.3. Efficacy

The efficacy of AviPlus® was previously established in chickens for fattening, chickens reared for laying and for all minor avian species for fattening or reared for laying (EFSA FEEDAP Panel, 2012) based on efficacy studies in chickens for fattening that showed improvements of the feed to gain ratio at the minimum level of 200 mg/kg complete feed.

The conclusions from the efficacy studies in chickens for fattening can be extrapolated to turkeys for fattening and turkeys reared for breeding at the same use level.

The efficacy of AviPlus® was previously established in weaned piglets (EFSA FEEDAP Panel, 2010), based on efficacy studies that showed improvements of daily weight gain and feed to gain ratio at the minimum level of 1,000 mg/kg complete feed. This conclusion was extended to all minor weaned porcine species piglets (EFSA FEEDAP Panel, 2012).

The conclusions from the efficacy studies in weaned piglets can be extended to suckling piglets at the same use level.

3.3.1. Conclusions on efficacy

AviPlus® has the potential to be efficacious in turkeys for fattening and breeding at a minimum dose of 200 mg/kg complete feed, and in suckling piglets at a minimum dose of 1,000 mg/kg complete feed.

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 Regulation⁸ and Good Manufacturing Practice.

4. Conclusions

AviPlus® (citric acid, sorbic acid, thymol and vanillin) is considered safe for turkeys for fattening and turkeys reared for breeding up to the maximum recommended level of 500 mg/kg complete feed. For suckling piglets, the additive is safe up to the maximum recommended level of 3,000 mg/kg complete feed.

The additive is considered safe for the consumer and the environment. The additive is considered a potential skin/eye irritant and a skin sensitiser.

The additive has the potential to be efficacious as a zootechnical additive in turkeys for fattening and turkeys reared for breeding at a minimum level of 200 mg/kg complete feed. For suckling piglets, AviPlus® has the potential to be efficacious at a minimum level of 1,000 mg/kg complete 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 268, 24.9.2003, p. 1.

5. Documentation as provided to EFSA/Chronology

Date	Event
21/02/2019	Dossiers received by EFSA: <ul style="list-style-type: none"> – AviPlus® (preparation of sorbic acid, citric acid, thymol and vanillin) for turkeys for fattening and turkeys reared for breeding. – AviPlus® (preparation of sorbic acid, citric acid, thymol and vanillin) for suckling piglets. Submitted by Vetagro S.p.A.
11/03/2019	Reception of the mandates from the European Commission
24/04/2019	Applications validated by EFSA – Start of the scientific assessment
26/06/2019	Comments received from Member States
04/07/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2010. Scientific Opinion on the safety and efficacy of AviPlus® as feed additive for weaned piglets. EFSA Journal 2010;8(6):1633, 15 pp. <https://doi.org/10.2903/j.efsa.2010.1633>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2012. Scientific Opinion on the safety and efficacy of AviPlus® as feed additive for chickens and minor avian species for fattening and reared for laying and minor porcine species (weaned). EFSA Journal 2012;10(5):2670, 11 pp. <https://doi.org/10.2903/j.efsa.2012.2670>
- 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, 2017. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. <https://doi.org/10.2903/j.efsa.2017.5021>
- 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>

Abbreviations

- EURL European Union Reference Laboratory
FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed