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Efficacy of Liderfeed[®] (eugenol) for chickens for fattening

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Abstract

Liderfeed[®] is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in feed of chickens for fattening to increase the performance. The additive contains eugenol as an active ingredient with some excipients and has not been authorised in the EU for use in food or feed. In 2015, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted an opinion on the safety and efficacy of Liderfeed[®] as a zootechnical additive for chickens for fattening. In that opinion, the Panel could not conclude on the efficacy of the additive because only two out of the three efficacy studies considered showed a significant effect on the performance of chickens for fattening as a result of the supplementation with the additive. The Commission gave the applicant the possibility of submitting additional information to allow the FEEDAP Panel to complete its assessment. For this reason, additional data have been provided related to the efficacy of the additive for the target species and this new information is the subject of this opinion. The new efficacy study on chickens for fattening is the subject of this assessment; the results of this study indicate an improvement in performance parameters with the use of the additive at 100 mg/kg complete feed. Considering the results of the current study, along with the two efficacy studies already assessed in the previous FEEDAP Panel opinion of 2015, the Panel concludes that Liderfeed[®] at 100 mg/kg complete feed has the potential to improve the growth of chickens for fattening.

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Summary

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 efficacy of Liderfeed® (eugenol) for chickens for fattening.

Liderfeed® is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in feed of chickens for fattening to increase the performance. The additive contains eugenol as an active ingredient with some excipients and has not been authorised in the European Union (EU) for use in food or feed.

In 2015, the FEEDAP Panel adopted an opinion on the safety and efficacy of Liderfeed® as a zootechnical additive for chickens for fattening. In that opinion, the Panel could not conclude on the efficacy of the additive because only two out of the three efficacy studies considered showed a significant effect on the performance of chickens for fattening as a result of the supplementation with the additive. The Commission gave the applicant the possibility of submitting additional information to allow the FEEDAP Panel to complete its assessment. For this reason, additional data have been provided related to the efficacy of the additive for the target species and this new information is the subject of this opinion.

The new efficacy study on chickens for fattening is the subject of this assessment; the results of this study indicate an improvement in performance parameters with the use of the additive at 100 mg/kg complete feed. Considering the results of the current study, along with the two efficacy studies already assessed in the previous FEEDAP Panel opinion of 2015, the Panel concludes that Liderfeed® at 100 mg/kg complete feed has the potential to improve the growth of chickens for fattening.

Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background and Terms of Reference as provided by the European Commission	5
2. Data and methodologies.....	5
2.1. Data.....	5
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. Efficacy for chickens for fattening	6
4. Conclusions.....	6
Documentation provided to EFSA	7
References.....	7
Abbreviation	7

1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

Regulation (EC) No 1831/2003¹ establishes rules governing the Community authorisation of additives for animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Lidervet S.L., is seeking a Community authorisation of Liderfeed® (*Clove oil, eugenol*) as a zootechnical additive for chickens for fattening (Table 1).

Table 1: Description of the substances²

Category of additive	Zootechnical additive
Functional group of additive	Other zootechnical additives
Description	<i>Clove oil (eugenol)</i>
Target animal category	Chickens for fattening
Applicant	Lidervet S.L.
Type of request	New Opinion

In its opinion on the safety and efficacy of the product, adopted on 21 October 2015, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ('Authority') concluded that only two out of the three efficacy studies considered showed a significant effect on the performance of chickens for fattening as a result of the supplementation with the additive. Therefore, the European Food Safety Authority (EFSA) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was unable to conclude on the efficacy of Liderfeed® in chickens for fattening.

On 23 May 2016, the Commission has received new data on efficacy for Liderfeed® in chickens for fattening. The supplementary data are sent to the Authority by applicant.

In view of the above, the Commission asks the Authority to deliver a new opinion on the efficacy of Liderfeed® as a feed additive for chickens for fattening based on the additional data submitted by the applicant.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of additional information³ to a previous application of the same product.⁴

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Liderfeed® 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), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

3. Assessment

Liderfeed® is intended as a zootechnical additive (functional group: other zootechnical additives) for use in feed for chickens for fattening to increase performance. The additive contains eugenol (5%) as the active ingredient with some excipients (56% glyceryl polyethyleneglycol ricinoleate (E 484), 33% silica amorphous and 6% acrylic polymers (Eudragit L 30 D-55) as a coating agent).

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 The FEEDAP Panel notes that the Description of the additive 'Clove oil (eugenol)' does not correspond to the latest indicated by the applicant and it should be 'Eugenol'.

³ FEED dossier reference: FAD-2016-0034.

⁴ EED dossier reference: FAD-2010-0396.

Liderfeed® was initially formulated with clove oil as a source of eugenol. Subsequently, the applicant replaced the clove oil with purified eugenol at the same concentration as in the original formulation. The FEEDAP Panel considers that the efficacy studies made with the original and subsequently modified formulation are equivalent (EFSA FEEDAP Panel, 2015). Liderfeed® is intended to be used in feed for chickens for fattening during the whole life of the animals at the dose of 100 mg/kg complete feed equivalent to 5 mg eugenol/kg complete feed.

The FEEDAP Panel adopted, in 2015, an opinion on the safety and efficacy of the product as a zootechnical additive for chickens for fattening (EFSA FEEDAP Panel, 2015). In that opinion, the FEEDAP Panel could not conclude on the efficacy of the additive because only two out of the three efficacy studies considered showed a significant effect on the performance of chickens for fattening as a result of the supplementation with the additive.

The applicant has submitted additional information related to the efficacy of the additive for the target species and this new information is the subject of this opinion.

3.1. Efficacy for chickens for fattening

The applicant provided an additional efficacy study with chickens for fattening.⁵ A total of 144 one-day-old male Ross 308 chickens were allotted to two treatments, each with 12 pens of 6 birds. The animals were fed a basal maize-soybean meal diet supplemented with Liderfeed® at either 0 or 100 mg/kg. Broilers were fed a starter diet (analysed: 5.5 mg eugenol/kg feed) from day 1 until day 21 and a grower diet (analysed: 5.5 mg eugenol/kg feed) from day 22 until day 35. Feed was provided *ad libitum*. Body weight and feed intake were weekly recorded and average daily gain, cumulative feed intake per bird, average daily feed intake and feed-to-gain ratio were calculated. Mortality and health incidences were daily checked. Data were subjected to analysis of variance considering the pen as the experimental unit. Statistical significance was declared at $p < 0.05$.

No deaths or health incidences occurred during the study period. Supplementation with Liderfeed® resulted in a significant improvement in final body weight, average daily gain and feed-to-gain ratio over the whole study period compared to the control group (Table 2). There were no differences between control and treated groups in cumulative or average daily feed intake.

Results of the two positive studies (studies 1 and 2) assessed in the previous opinion of the FEEDAP Panel (EFSA FEEDAP Panel, 2015) together with the newly submitted study (study 3) are shown in Table 2.

Table 2: Effect of Liderfeed® on mortality and performance of chickens in three efficacy studies

Trial Duration (days)	Total number of birds (birds/pen × pens/treatment)	Liderfee® (mg/kg feed)	Feed intake (g)	Average weight gain (g/day)	Final body weight (g)	Feed to gain	Mortality (%)
1 (35)	247 (13/14 × 9)	0	2,932	55.3	1,981	1.51	3.2
		100	2,880	57.3*	2,048*	1.44*	0.8
2 (35)	216 (9 × 12)	0	3,510	60.0	2,146	1.64	4.8
		100	3,569	62.4*	2,230*	1.60*	4.8
3 (35)	144 (6 × 12)	0	3,527	65.3	2,324	1.54	0.0
		100	3,490	68.7*	2,442*	1.46*	0.0

*: Means of treated and controls within the same trial are significantly different ($p < 0.05$).

Considering the results of the current study, along with the two efficacy studies already assessed in the previous opinion of the FEEDAP Panel, in which the performance of chickens for fattening was positively affected as a result of the supplementation with the additive at 100 mg/kg complete feed, the FEEDAP Panel concludes that Liderfeed® has the potential to improve the growth of chickens for fattening at the supplementation level of 100 mg/kg complete feed.

4. Conclusions

Liderfeed® has the potential to improve the growth of chickens for fattening when used at 100 mg/kg complete feed.

⁵ Technical Dossier/Supplementary Information.

Documentation provided to EFSA

- 1) Clove oil eugenol (Liderfeed®). May 2016. Submitted by Lidervet S.L.
- 2) Clove oil eugenol (Liderfeed®). Supplementary information. March 2017. Submitted by Lidervet S.L.
- 3) Clove oil eugenol (Liderfeed®). March 2011. Submitted by Lidervet S.L.

References

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. <https://doi.org/10.2903/j.efsa.2011.2175>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 14 pp. <https://doi.org/10.2903/j.efsa.2012.2536>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of Liderfeed® (eugenol) for chickens for fattening. EFSA Journal 2015;13(11):4273, 16 pp. <https://doi.org/10.2903/j.efsa.2015.4273>

Abbreviation

FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed