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SCIENTIFIC OPINION

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Efficacy of a feed additive consisting of carvacrol (Nimicoat®) for weaned piglets (Techna France Nutrition)

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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 efficacy of a feed additive consisting of carvacrol (Nimicoat®) as a zootechnical feed additive for weaned piglets at the recommended use level of 250 mg/kg complete feed. In a previous assessment, three efficacy trials and one tolerance–efficacy trial were assessed. Only one of the efficacy trials was considered to support the efficacy at the recommended use level. The applicant provided amendments to two previously submitted studies and a new trial. The amendments to the previously submitted studies did not change the conclusions from the previous assessment. The new efficacy study showed a significant improvement of the zootechnical parameters. Two studies showed positive and significant effects on the performance of the weaned piglets when the additive was administered at 250 mg/kg feed. Due to the lack of sufficient data, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive for the target species.

KEYWORDS

efficacy, Nimicoat®, other zootechnical additives carvacrol, piglets, zootechnical additives

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] 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 Commission received an application form from Techna France Nutrition[2] for the authorisation of the product Carvacrol when used as a feed additive for piglets (weaned) (Table 1).

TABLE 1 Description of the substances.

Category of additive	Zootechnical additive
Functional group of additive	Other zootechnical additives
Description	Carvacrol
Target animal category	Piglets (weaned)
Applicant	Techna France Nutrition
Type of request	New opinion

On 17 March 2020, 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 27 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 issue a new opinion on Carvacrol as a feed additive for piglets (weaned) 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 Nimicoat® is composed of the active substance carvacrol encapsulated with high-melting lipid.

The FEEDAP Panel issued an opinion on the safety and efficacy of Nimicoat® (carvacrol) when used in feed for weaned piglets (EFSA FEEDAP Panel, 2020). The additive Nimicoat® (carvacrol) is not authorised in the European Union.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[3] to a previous application on the same product.[4]

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the supplementary information has been published on Open.EFSA.

[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]Techna France Nutrition: Route de Saint Etienne Montluc, 44220 Coueron, France.

[3]Dossier reference: EFSA-Q-2023-00165.

[4]Dossier reference: FAD-2016-0002.

[5]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of carvacrol (Nimicoat®) is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3 | ASSESSMENT

The additive Nimicoat® is composed of carvacrol (at least 40%) as the active substance, lipids from vegetable oils (30%–35%), amorphous silica (E 551a[8]) (20%–22%) and surfactant (mono and diglycerides of fatty acids; 4%–6%). It is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in premixtures or compound feed for weaned piglets to enhance the growth.

In the previous opinion (EFSA FEEDAP Panel, 2020), the FEEDAP Panel concluded that the additive is considered safe for the target species, consumers and the environment under the proposed conditions of use, but it is corrosive to skin and eyes, and the respiratory mucosae. The data provided were not sufficient to conclude on the efficacy of the additive in weaned piglets. In the current application, the applicant submitted additional data aimed at demonstrating the efficacy of the additive.

The applicant modified the previously proposed conditions of use from a minimum recommended level of 250 mg/kg and a maximum recommended level of 1000 mg/kg complete feed to a unique use level of 250 mg/kg complete feed.

3.1 | Efficacy

In the previous opinion, three long-term efficacy trials and one tolerance–efficacy trial were provided to support the efficacy of the additive when supplemented to feed for weaned piglets. Only one trial (Trial 1, in the previous opinion) was considered to support the efficacy of the additive in piglets at the minimum use level of 250 mg Nimicoat®/kg complete feed. The tolerance–efficacy trial (Trial 2, in the previous opinion) did not show a significant improvement of the performance at 1000 mg/kg complete feed (lower level tested) and two trials (Trials 3 and 4, in the previous opinion) could not be considered further in the assessment due to the high incidence of diarrhoea (up to 80% of animals in the control group of the first trial were treated with antibiotics) and mortality registered (3.3% in the first trial, 5.8%–10.9% in the second).

For the current assessment, the applicant submitted two of the previously assessed studies, but with some amendments regarding the statistical analysis, and a new efficacy study. The amendments to previously assessed studies regarded Trials 1 and 4.

The applicant resubmitted Trial 1[9] with a new statistical analysis in which the data from the group supplemented with 1000 mg Nimicoat®/kg complete feed were not included. The Panel already concluded in the previous opinion that the supplementation of the feed with the additive at 250 mg Nimicoat®/kg complete feed significantly improved the performance of weaned piglets. The re-analysed data would not change this conclusion.

Similarly, the applicant re-analysed the data of Trial 4[10] by removing the groups supplemented with Nimicoat® at 500, 750 and 1000 mg/kg complete feed. In addition, data from the animals reared in one of the rooms were removed from the analysis because the mortality was high. However, the Panel notes that the applicant did not provide a technical reason to remove these data, considering also that the mortality registered in this room was not significantly higher than that from other rooms. Therefore, the Panel considers that the removal of the data from one of the rooms was not duly justified, and consequently, the study should not be considered in the assessment due to the overall high incidence of diarrhoea and mortality.

In the new study submitted,[11] a total of 270 weaned hybrid piglets[12] of both sexes (27-day-old, average body weight 7.1 kg) were balanced by body weight and sex and distributed in 18 pens of 15 animals each, and randomly allocated into two dietary treatments (representing nine replicates per treatment). Two basal diets (pre-starter and starter phase) based on barley and wheat were either not supplemented (control) or supplemented with Nimicoat® at 250 mg/kg complete feed. The recovery of the additive in feed was analysed using carvacrol (active agent) as marker. The recovery values were 41.8% and 37% lower than intended, for the diets of the two growing phases, respectively.[13] The experimental diets were offered ad libitum in mash form for 42 days. The health status of the animals and mortality/culling were monitored daily. Piglets were weighed individually at the start of the trial. Thereafter, body weight and total feed intake were recorded per pen on days 21 and 42. The average daily feed intake, daily gain and feed-to-gain ratio were calculated. The zootechnical performance data were analysed with a mixed model, including the diet and time as fixed effects. The pen was the experimental unit. The significance was declared at 0.05. The results are shown in Table 2.

[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.

[8]The Panel notes that the additive is under re-evaluation.

[9]Annex_1.1.

[10]Annex_2.1.

[11]Annex_3.1.

[12]DanBred × Talent.

[13]Intended carvacrol level: 100 mg/kg. The analysed content in the pre-starter diets was 58.8 mg/kg and in the starter diets 63 mg/kg.

TABLE 2 Effects of Nimicoat® on the performance of weaned piglets.

Groups	Average daily feed intake	Final body weight	Average daily weight gain	Feed to gain ratio	Mortality
(mg/kg complete feed)	(g)	(g)	(g)		(%)
0	670	23.4	390[b]	1.72[a]	5.18
250	660	25.2	429[a]	1.54[b]	2.96

[a,b]Mean values within a column with a different superscript are significantly different $p < 0.05$.

The overall mortality was 4% and no differences were observed between the groups. The piglets that received Nimicoat® at 250 mg/kg complete feed showed a significantly higher average daily weight gain and a better feed-to-gain ratio compared with the control diet, thus supporting the efficacy potential of the additive.

3.1.1 | Conclusions on efficacy

Considering all the data provided by the applicant in the previous and current submissions, two trials showed positive effects in the zootechnical performance of the weaned piglets at the nominal level of 250 mg Nimicoat®/kg complete feed.

In the absence of a third study showing positive results in the performance of weaned piglets at the proposed use level, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive in weaned piglets.

3.2 | 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[14] and good manufacturing practice.

4 | CONCLUSIONS

Due to the lack of sufficient data, the FEEDAP Panel cannot conclude on the efficacy of Nimicoat® for weaned piglets.

ABBREVIATIONS

EC European Comission
EFSA European Food Safety Authority
EURL European Union Reference Laboratory
FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00165

PANEL MEMBERS

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[14]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.

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