Adopted: 17 April 2024

DOI: 10.2903/j.efsa.2024.8795

SCIENTIFIC OPINION

efsa JOURNAL

Efficacy of a feed additive consisting of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 (ROVABIO® ADVANCE) for weaned piglets (Adisseo France SAS)

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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 ROVABIO® ADVANCE (liquid and solid) which contains endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 as a zootechnical feed additive for weaned piglets at the recommended use level of 1800 U xylanase and 1250 U glucanase per kg feed. In a previous assessment, three long-term trials in weaned piglets were submitted. Two of them were considered to support the efficacy of the additive while a third trial was not further considered due to the large number of veterinary treatments applied. A new trial was provided to support the efficacy of the additive, but it did not show a significant improvement of the performance parameters at the minimum recommended use level. 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

digestibility enhancers, efficacy, endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase, rovabio, 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. In particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant ADISSEO FRANCE S.A.S., is seeking a community authorisation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 (ROVABIO® ADVANCE) as a feed additive for weaned piglets (Table 1).

TABLE 1 Description of the additive.

Category of additive	Zootechnical additivies
Functional group of additive	Digestibility enhancers
Description	endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 (ROVABIO® ADVANCE)
Target animal category	For weaned piglets
Applicant	ADISSEO France S.A.S.
Type of request	New Opinion

On 23.03.2022, 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 a feed additive consisting of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 (ROVABIO® ADVANCE) for weaned piglets and pigs for fattening, could not conclude on the efficacy of the product due to the lack of data.

The Commission gave the possibility to the applicant to submit supplementary information and data to complete the assessment and to allow a revision of the EFSA's opinion.

On 16.06.2023, the Commission received a letter from the applicant, formally requesting the partial withdrawal of the abovementioned application to limit the scope of the application to weaned piglets. The partial withdrawal, as regards pigs for fattening, was accepted by the Commission on 23.06.2023.

The new data, covering weaned piglets, have been received by the Commission on 24.07.2023 on the e-submission food chain platform (application number FEED-2023-17890).

In view of the above, the Commission asks EFSA to deliver a new opinion on ROVABIO® ADVANCE as a zootechnical feed additive for weaned piglets and pigs for fattening based on the supplementary information and data submitted by the applicant, in accordance with Article 29 (1) of Regulation (EC) No 178/2022.

1.2 | Additional information

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) issued one opinion on the safety and efficacy of this additive in weaned piglets (EFSA FEEDAP Panel, 2022).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[2] to a previous application on the same product.[3] The dossier was received on 25 July 2023 and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00520.

In accordance with Article 38 of the Regulation (EC) No 178/2002 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, a non-confidential version of the dossier 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]Dossier reference: EFSA-Q-2023-00520.
[3]Dossier reference: FAD-2020-0004 or EFSA-Q-2020-00147.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase (ROVABIO® ADVANCE) is in line with the principles laid down in Regulation (EC) No 429/2008[4] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3 | ASSESSMENT

The additive under assessment, herein referred to as ROVABIO® ADVANCE, contains endo-1,4-beta-xylanase (xylanase, Enzyme Commission Number 3.2.1.8) and endo-1,3(4)-beta-glucanase (glucanase: Enzyme Commission Number 3.2.1.6) produced by two strains of *Talaromyces versatilis* (IMI 378536 and DSM 26702) and is intended to be used as a zootechnical additive (functional group: digestibility enhancers) in feed for weaned piglets.

ROVABIO® ADVANCE is available in powder and liquid forms. The powder form ensures a minimum enzyme activity per gram of additive of 36,000 U[5] or 3740 DNS U[6] of xylanase activity and 25,000 U or 2600 DNS U of glucanase activity while the liquid form ensures a minimum enzyme activity per gram of additive of 9000 U or 940 DNS U of xylanase activity and 6250 U or 650 DNS U of glucanase activity.

The additive is intended for use in feed for weaned piglets at a minimum recommended level (in viscosity units) of 1800 U xylanase and 1250 U glucanase per kg feed.

In the previous assessment (EFSA FEEDAP Panel, 2022), the FEEDAP Panel concluded that the additive is safe for weaned piglets and the use of ROVABIO® ADVANCE as a feed additive raises no concerns for the consumers or the environment; the Panel also concluded that either form of the additive is not irritant to skin or eyes, but it is considered a dermal and respiratory sensitiser. In that opinion, the panel could not conclude on the efficacy of the additive in weaned piglets.

The applicant has provided new data to address the gaps identified in the previous opinion, which are assessed below.

3.1 | Efficacy

In the previous opinion (EFSA FEEDAP Panel, 2022), three long-term trials in weaned piglets were submitted. Two of the trials supported the efficacy of the additive as a zootechnical additive at the minimum recommended level. A third trial was not further considered due to the large number of animals treated with antibiotics (about 30%), mainly for respiratory and enteric disorders.

The applicant has submitted a long-term trial in weaned piglets to complement the previous assessment.[7]

A total of 608 (two weaning batches of 304) 28-day-old hybrid[8] weaned piglets (50% ♀: ♂) were distributed by sex in 32 pens of 19 animals, which were randomly allocated to two experimental groups (16 replicates per group, 8 replicates per sex). Two basal diets (starter, from day 1 to 24; and grower, from day 25 to 42) based on wheat, wheat bran, soybean meal and rapeseed meal were either not supplemented (control) or sprayed with liquid Rovabio® Advance to provide 1800 U of xylanase and 1250 U of glucanase per kg complete feed (confirmed by analysis[9]). The experimental diets were offered ad libitum in pelleted form for 42 days.

Mortality and health status were checked daily, and the most likely cause of death or reason for culling provided. Animals were weighed individually on days 1, 14 and 42 and feed intake was registered per pen on days 14 and 42. The average daily feed intake, average daily gain and feed-to-gain ratio were calculated and corrected for mortality for the overall period.

The experimental data for body weight and average daily weight gain were analysed with a mixed model, considering the diet, sex and weaning batch as fixed effects and the initial body weight as a random factor. The feed intake and feed-to-gain ratio data were analysed with a generalised linear model considering diet, sex and weaning batch as fixed effects. Significance level was set at 0.05.

The overall mortality was 4.6% and not significantly different between groups. The inclusion of the additive at 1800 U of xylanase and 1250 U of glucanase per kg complete feed did not result in any statistical difference in the performance parameters of the weaned piglets when compared to the control (Table 2).

[4]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.

[5]One xylanase (or beta-glucanase) viscosity unit (U) is defined as the amount of xylanase (or beta-glucanase) that hydrolyses wheat arabinoxylan (or barley beta-glucan), reducing the solution viscosity, in order to change the relative fluidity by one dimensionless unit per minute, at pH 5.5 and 30°C.

[6]One xylanase (or beta-glucanase) DNS unit corresponds to the amount of xylanase (or beta-glucanase) which liberates from the birchwood xylan (or barley beta-glucan) one µmol of xylose (or glucose) per minute at 50°C and pH 4.0 (or pH 5.0).

[7]Annex IV_1_A and Annex IV_1_A_Statistics.

[8]M Excelium × F (Topigs TN70 Landrace × Large White).

[9]Xylanase intended level: 1800 U, analysed (starter/grower): 1564/1923 U; Glucanase intended level: 1250 U, analysed (starter/ grower): 1026/1190 U.

TABLE 2 Effects of ROVABIO® ADVANCE on the performance of weaned piglets.

Groups (xylanase/glucanase U per-kg complete feed)	Daily feed intake (g)	Initial body weight (kg)	Final body weight (kg)	Average daily weight gain (g)	Feed to gain ratio	Mortality (culling) (%)
0	520	6.9	18.3	271	1.98	6.3 (1.6)
1800/1250	530	6.9	18.4	274	1.96	3.0 (1.0)

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

3.1.1 | Conclusions on efficacy

Considering all the data provided in the previous and current applications, two trials showed positive effects in the zootechnical performance of the weaned piglets at the proposed conditions of use. In the absence of a third study showing positive results, 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[10] and good manufacturing practice.

4 | CONCLUSIONS

The FEEDAP Panel cannot conclude on the potential of ROVABIO® ADVANCE to be efficacious when supplementing the diet of weaned piglets under the proposed conditions of use.

ABBREVIATION

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

ACKNOWLEDGEMENTS

The Panel wishes to thank Jaume Galobart and Marianna Kujawa for the support provided to this scientific output.

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-2023-00520

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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, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Martino, L. (2018). Guidance on the assessment of the efficacy of feed additives. *EFSA Journal*, *16*(5), 5274. 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). Scientific opinion on the safety and efficacy of a feed additive consisting of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with Talaromyces versatilis IMI 378536 and DSM 26702 (ROVABIO®ADVANCE) for weaned piglets and pigs for fattening (ADISSEO France S.A.S). *EFSA Journal*, *20*(5), 7251. https://doi.org/10.2903/j.efsa.2022.7251

[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.

How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Dierick, N., Martelli, G., Casanova, J. O., … Pagés Plaza, D. (2024). Efficacy of a feed additive consisting of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 (ROVABIO® ADVANCE) for weaned piglets (Adisseo France SAS). *EFSA Journal*, *22*(5), e8795. https://doi.org/10.2903/j.efsa.2024.8795