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Efficacy of Bergazym[®] P100 (endo-1,4- β -xylanase) as a feed additive for chickens for fattening and weaned piglets

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

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Abstract

The product Bergazym[®] P100 contains a xylanase which is produced by a non-genetically modified strain of *Trichoderma reesei*. The additive is available in a coated granular form and it is intended to be used as a zootechnical additive (functional group: digestibility enhancers) for chickens for fattening, and weaned piglets at the dose of 1,500 EPU/kg feed. The production strain and the additive were fully characterised in a previous assessment of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel). In that assessment, the FEEDAP Panel concluded that the additive is safe for chickens for fattening, weaned piglets and pigs for fattening and that the use of this product as a feed additive raises no concerns for consumers of food products obtained from animals receiving it or for the environment. The FEEDAP Panel also concluded that the additive is not irritant to skin or eyes but should be considered as a potential skin and respiratory sensitiser. The Panel evaluated the efficacy of the additive and concluded that it has a potential to be efficacious in pigs for fattening at 1,500 EPU/kg feed. However, the Panel could not conclude regarding the efficacy of the additive for chickens for fattening and weaned piglets due to insufficient data/information. The applicant has now provided supplementary information in order to complement the information available supporting the efficacy of the additive. With the newly submitted efficacy studies and clarifications, the Panel concluded that the additive has a potential to be efficacious in chickens for fattening and weaned piglets at 1,500 EPU/kg feed.

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1. Introduction

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

Regulation (EC) No 1831/2003 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, Berg + Schmidt GmbH Co. KG, is seeking a Community authorisation of endo-1,4- β -xylanase as a feed additive for chickens for fattening, weaned piglets and pigs for fattening (Table 1).

Table 1: Description of the substances

Category of additive	Zootechnical additive
Functional group of additive	Digestibility enhancers
Description	Endo-1,4- β -xylanase
Target animal category	Chickens for fattening, weaned piglets
Applicant	Berg + Schmidt GmbH Co. KG
Type of request	New opinion

On 25 January 2017, the Panel on Additives and Products or Substance used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, was not in a position to conclude on the efficacy in chickens for fattening and weaned piglets.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of Authority's opinion. The new data have been sent to European Commission and EFSA by applicant on 20 September 2017.

In view of the above, the Commission asks the Authority to deliver a new opinion on endo-1,4- β -xylanase as a zootechnical additive for chickens for fattening and weaned piglets based on the additional data submitted by the applicant.

1.2. Additional information

The FEEDAP Panel issued an opinion on the safety and efficacy of this additive (Bergazym® P100) as a feed additive for chickens for fattening, weaned piglets and pigs for fattening (EFSA FEEDAP Panel, 2017). In that assessment, the Panel could not conclude regarding the efficacy of the additive in chickens for fattening and weaned piglets due to insufficient data/information.

The product is authorised in the European Union as a zootechnical additive for pigs for fattening.¹

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information² to a previous application on the same product.³

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of Bergazym® P100 is in line with the principles laid down in Regulation (EC) No 429/2008⁴ and the Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and the technical guidance on tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

¹ Commission Implementing Regulation (EU) 2018/130 of 25 January 2018 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as feed additive for pigs for fattening (holder of authorisation Berg and Schmidt GmbH Co. KG). OJ L 22, 26.1.2018, p.25.

² FEED dossier reference: FAD-2017-0051.

³ FEED dossier reference: FAD-2014-0029.

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. 1–65.

3. Assessment

The product under assessment is Bergazym® P100 which contains a xylanase (Enzyme Commission number 3.2.1.8; 15,000 EPU⁵ per gram) produced by a non-genetically modified strain of *Trichoderma reesei*. The additive and its production strain were fully characterised in a previous assessment (EFSA FEEDAP Panel, 2017). In that assessment, the FEEDAP Panel concluded that the additive is safe for chickens for fattening, weaned piglets and pigs for fattening and that the use of this product as a feed additive raises no concerns for consumers of food products obtained from animals receiving it or for the environment. The FEEDAP Panel also concluded that the additive is not irritant to skin or eyes but should be considered as a potential skin and respiratory sensitiser. The Panel evaluated the efficacy of the additive and concluded that it has a potential to be efficacious in pigs for fattening at 1,500 EPU/kg feed. However, the Panel could not conclude regarding the efficacy of the additive in chickens for fattening and weaned piglets due to insufficient data/information.

The applicant has now provided supplementary information in order to complement the information available supporting the efficacy of the additive in chickens for fattening and weaned piglets. The additive is intended to be used as a zootechnical additive (functional group: digestibility enhancers) in feed for chickens for fattening, and weaned piglets at the dose of 1,500 EPU/kg feed.

3.1. Efficacy

3.1.1. Efficacy for chickens for fattening

In the previous assessment (EFSA FEEDAP Panel, 2017), three long-term trials were considered in the assessment. The birds receiving the additive at the recommended dose showed a better performance in two trials. In Tables 2 and 3, the trial design and the results, respectively, are shown (trials 1 and 2). However, the Panel noted limitations in these studies. In one of the studies (trial 1), the enzyme activity in feed was not confirmed and, in the other (trial 2), the statistical analysis did not take into account the fact that multiple comparisons had been done. Therefore, there were only two trials in which significant effects were reported and with limitations. Consequently, the Panel concluded that there was insufficient data to conclude on the efficacy of the additive.

In order to address the limitations identified in the previous assessment the applicant submitted two new trials (trials 3 and 4 in Tables 2 and 3) and modified the statistical analysis for trial 2. The confirmation of the enzyme activity in the feeds that was missing from trial 1 was not submitted by the applicant (see Table 2).

For trial 2, an analysis of variance was done and group means were compared with Tukey test, which accounts for the multiple comparisons being done between groups.⁶ The outcome of this new statistical analysis confirmed the statistical difference in the feed to gain ratio found previously between the control and the recommended dose. The effect of the diet on the feed intake and final body weight was not significant according to the newly submitted analysis.

In the newly submitted studies (trials 3 and 4), 1-day-old chickens were used, in trial 3 only males and in trial 4 males and females (sex separated). In the two studies, the birds were fed either with a non-supplemented diet (control) or a diet containing the xylanase under assessment at the recommended level (analysis confirmation in Table 2). The diets were offered *ad libitum* for 35 days. Animal health and mortality were monitored throughout the study period, feed intake and body weight were measured at different time points and feed to gain ratio was calculated for the corresponding periods. The data were statistically analysed with an analysis of variance, pen basis. Significance level was set at $p < 0.05$.

⁵ EPU, endopentoanase unit, is defined as the amount of enzyme required to release 0.0083 μmol of reducing sugar equivalents (xylose equivalents) from oat spelt xylan per minute at pH 4.7 and 50°C.

⁶ Technical dossier FAD-2017-0051/Supplementary information September 2018/Annexes 1a and 1b.

Table 2: Trial design and dosages of the efficacy trials done in chickens for fattening

Trial	Total No Animals (animals/replicate) Replicates/treatment	Breed Duration Sex	Diet composition of the diets	Enzyme activity (EPU/kg feed)	
				Intended	Analysed
1 ^(a)	600 (50) 4	Cobb 500 49 ♂/♀	Maize, soya bean meal	0 1,500 3,000	Not provided
2 ^(b)	144 (6) 8	Ross 308 35 ♀	Wheat, rye, soya bean meal	0 1,500 300,000	388 1,365 446,000
3 ^(c)	400 (20) 10	Ross 308 35 ♂	Wheat, barley, triticale and soybean meal	0 1,500	480 1,563
4 ^(d)	1,000 (25) 20	Ross 308 35 ♂/♀	Wheat, barley, rye and soybean meal	0 1,500	426 1,410

(a): Technical dossier FAD-2014-0029/Section IV/Annex 4.3.1.2.a-b. and Supplementary information November 2016/Annex 19.

(b): Technical dossier FAD-2014-0029/Supplementary information November 2016/Annex 18.1.a-d.

(c): Technical dossier FAD-2017-0051/Study broilers/17-12 Annex 1a-e, Annex 3b-e, Annex C and final report.

(d): Technical dossier FAD-2017-0051/Supplementary information September 2018/Annexes 2a to 2j.

Table 3: Effects of Bergazym® P100 on the performance of chickens for fattening

Trial	Treatments (EPU/kg feed)	Feed intake (g) ¹	Final body weight (g)	Feed to Gain ratio	Mortality and culling (%)
1	0	5,825	2,857 ^b	2.04 ^a	4.5
	1,500	6,045	3,172 ^a	1.91 ^b	4.0
	3,000	6,020	3,125 ^a	1.93 ^{ab}	4.0
2	0	97.8	2,053	1.70 ^a	4.2
	1,500	96.6	2,106	1.64 ^b	4.2
	300,000	93.6	2,147	1.56 ^c	2.1
3	0	110	2,621	1.49 ^a	3
	1,500	109	2,644	1.47 ^b	2
4	0	96	2,275 ^b	1.50 ^a	5 ^a
	1,500	94	2,315 ^a	1.44 ^b	2 ^b

¹In trial 1 values are total feed intake and in trial 2,3 and 4 the data shows daily feed intake.

^{a,b,c}Within a column and within a trial, values with a different superscript are significantly different ($p < 0.05$).

In the newly submitted studies, the birds receiving the additive at the recommended dose showed a significantly better feed to gain ratio (trials 3 and 4) and a higher body weight (trial 4) compared to the control group.

Considering the data previously assessed and those newly submitted, birds receiving the additive at 1,500 EPU/kg feed showed a better feed to gain ratio in four trials and a higher body weight in two trials (trials 1 and 4, however, for trial 1 the confirmation of the enzyme activity was not given). Consequently, the FEEDAP Panel concludes that Bergazym® P100 has a potential to be efficacious as a zootechnical additive in chickens for fattening at 1,500 EPU/kg feed.

3.1.2. Efficacy for weaned piglets

In the previous assessment (EFSA FEEDAP Panel, 2017), the Panel considered a total of four trials in weaned piglets, two short-term trials and two long-term trials. In one of the short-term trials, a higher metabolisable energy content of the diet was found in the piglets receiving the additive at the recommended dose (14.1 vs 14.4 MJ/kg feed). No other significant effects were found in the other three trials considered in the evaluation. Therefore, the FEEDAP Panel could not conclude on the efficacy of Bergazym® P100 in weaned piglets.

The applicant has provided two new trials conducted in the same location with the same trial design.⁷ In each of these trials, a total of 144 weaned male and female piglets (Hybrid, approx. 25 days old) were distributed to pens in groups of six piglets each (mixed gender) and allocated to two dietary treatments (representing twelve replicate pens per treatment, in three rounds). The distribution to the pens was done according to sex, litter and weight. Basal diets (pre-starter and starter) based on wheat, barley, rye and soybean were either not supplemented (control) or supplemented with the xylanase to provide 1,500 EPU/kg feed. The enzyme activity was confirmed by analysis. Feed in pelleted form and water were available *ad libitum* over an experimental period of 42 days. General health status and mortality were monitored daily. Body weight and feed intake were recorded at days 14 and 42 (body weight also at the beginning). Average daily gain, average daily feed intake and feed to gain ratio were calculated. An analysis of variance was performed with the data considering the pen as the experimental unit and using the initial weight as a covariate. Significance level was set at $p < 0.05$.

The results of the studies are presented in Table 4. Only one animal died in trial 2 and another one had to be culled in trial 1. Compared to the control group, the piglets receiving Bergazym® P100 at 1,500 EPU/kg feed showed a significantly higher daily feed intake, a higher final weight and a better feed to gain ratio in trial 1, and a better feed to gain ratio in trial 2.

Table 4: Effects of Bergazym® P100 on the performance of weaned piglets

Trial	Treatments (EPU/kg feed)	Daily feed intake (kg)	Body weight (kg)		Feed to gain ratio	Mortality and culling (n)
			Initial	Final		
1	0	0.61 ^b	7.2	24.2 ^b	1.51 ^a	0
	1,500	0.64 ^a	7.3	25.5 ^a	1.49 ^b	1 culled
2	0	0.71	7.5	27.3	1.50 ^a	1 dead
	1,500	0.70	7.6	27.4	1.47 ^b	0

^{a,b}Within a column and within the same trial, values with a different superscript are significantly different ($p < 0.05$).

Considering the results of these two long-term trials and the results obtained in a previously assessed short-term trial, the FEEDAP Panel concludes that Bergazym® P100 has a potential to be efficacious as a zootechnical additive in weaned piglets at 1,500 EPU/kg feed.

4. Conclusion

Bergazym® P100 has a potential to be efficacious in chickens for fattening and in weaned piglets at 1,500 EPU/kg feed.

Documentation provided to EFSA

- 1) Bergazym® P100 for chickens for fattening and weaned piglets. September 2017. Submitted by Berg + Schmidt GmbH Co. KG.
- 2) Bergazym® P100 for chickens for fattening and weaned piglets. Supplementary information. September 2018. Submitted by Berg + Schmidt GmbH Co. KG.

Chronology

Date	Event
26/09/2017	Dossier received by EFSA
28/09/2017	Reception mandate from the European Commission
11/12/2017	Request of supplementary information to the applicant in line with Article 7(3) of Commission Regulation (EC) No 1304/2003 – Scientific assessment suspended. <i>Issues: efficacy for the target species</i>
04/09/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
02/10/2018	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

⁷ Technical dossier FAD-2017-0051/Study Piglets and supplementary information September 2018 (Annex 3) and Supplementary information July 2018 Annexes 4a and 4b.

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, 19 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), 2017. Scientific Opinion on the safety and efficacy of Bergazym® P100 (endo-1,4- β -xylanase) as a feed additive for chickens for fattening, weaned piglets and pigs for fattening. EFSA Journal 2017;15(2):4707, 15pp. <https://doi.org/10.2903/j.efsa.2017.4707>

Abbreviation

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