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Scientific Opinion on the efficacy of Suilectin™ (*Phaseolus vulgaris* lectins) as a zootechnical additive for suckling piglets (performance enhancer)

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

Abstract

Suilectin™ is a preparation of *Phaseolus vulgaris* (kidney bean) lectins which contains a mixture of five phytohaemagglutinin (PHA) isoforms: PHA-E_4, PHA-E_3L, PHA-E_2L_2, PHA-EL_3 and PHA-L_4. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of Suilectin™ as a zootechnical additive for suckling piglets. The Panel could not conclude on the efficacy of the additive because the efficacy studies available were not acceptable for the assessment. As a result of additional information provided by the applicant, showing that piglet mortality during the suckling period was within the mortality range commonly observed on commercial pig farms, the FEEDAP Panel has now considered five long-term studies which are acceptable for the assessment of efficacy. The administration of Suilectin™ at the recommended dose of 660 haemagglutinating units (HAU)/piglet, whether administered in a single dose at 14 days of age or in three consecutive doses of 220 HAU/piglet/day between days 12 and 14 of age, does not have any effect during the suckling period (0–28 days of age). Although there is uncertainty arising from the study design, which does not allow a separate assessment of the potential effects of the additive and the litter, the FEEDAP Panel concludes that the proposed use of the additive might have some potential to improve the performance of the piglets during the post-weaning period (28–70 days of age).

Keywords: zootechnical additive, suckling piglets, lectins, kidney bean, efficacy

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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 Suilectin™ (*Phaseolus vulgaris* lectins) when used as a zootechnical additive to enhance the performance of suckling piglets, particularly during the lactating period, and to enhance piglets' welfare. The additive is a preparation of *Phaseolus vulgari*s (kidney bean) lectins which contains a mixture of five phytohaemagglutinin (PHA) isoforms: PHA-E_4, PHA-E_3L, PHA-E_2L_2, PHA-EL_3 and PHA-L_4.

In 2014, the FEEDAP Panel adopted an opinion on the safety and efficacy of Suilectin™ as a zootechnical additive for suckling piglets. The FEEDAP Panel could not conclude on the efficacy of the additive because the efficacy studies provided were not acceptable for the assessment.

The applicant provided additional information in relation to the mortality of piglets during the pre-weaning period. The information provided shows that, in the efficacy studies submitted, piglet mortality during the suckling period was within the mortality range commonly observed on commercial pig farms. Because of this additional information, the FEEDAP Panel has now considered five long-term studies which are acceptable for the assessment of efficacy.

The administration of Suilectin™ at the recommended dose of 660 haemagglutinating units (HAU)/piglet, whether administered in a single dose at 14 days of age or in three consecutive doses of 220 HAU/piglet/day between days 12 and 14 of age, does not have any effect during the suckling period (0–28 days of age).

Although there is uncertainty arising from the study design, which does not allow a separate assessment of the potential effects of the additive and the litter, the FEEDAP Panel concludes that the proposed use of the additive might have some potential to improve the performance of the piglets during the post-weaning period (28–70 days of age).

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1. Introduction

1.1. Background and Terms of Reference as provided by the 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, Biolek, Sp. z o.o., is seeking a Community authorisation of Suilectin (*Phaseolus vulgaris* lectins) to be used as a zootechnical additive for suckling piglets (Table 1).

Table 1: Description of the substance

Category of additive	Zootechnical feed additive
Functional group of additive	Other (performance enhancer)
Description	Preparation of red kidney bean (*Phaseolus vulgaris*) lectins
Target animal category	Suckling piglets
Applicant	Biolek, Sp. Z o.o.
Type of request	New opinion

On 29 October 2014, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of Suilectin (*Phaseolus vulgaris* lectins) as a zootechnical additive for suckling piglets considering that provided efficacy studies were not acceptable for assessing the efficacy of the additive.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the efficacy and to allow a revision of Authority's opinion.

On 12 March 2015, the Commission received new data on the efficacy of Suilectin (*Phaseolus vulgaris* lectins).

In view of the above, the Commission asks the Authority to deliver a new opinion on the efficacy of Suilectin (*Phaseolus vulgaris* lectins) as a zootechnical additive for suckling piglets 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 information[1] to a previous application on the same product.[2]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of Suilectin™ is in line with the principles laid down in Regulation (EC) No 429/2008[3] and the Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012).

[1] FEED dossier reference: FAD-2015-0009.
[2] FEED dossier reference: FAD-2010-0079.
[3] 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.

3. Assessment

The additive Suilectin™ is a preparation of *Phaseolus vulgari*s (kidney bean) lectins which contains a mixture of five phytohaemagglutinin (PHA) isoforms: PHA-E_4, PHA-E_3L, PHA-E_2L_2, PHA-EL_3 and PHA-L_4 (the E type is the erythrocyte-agglutinating subunit and the L type is the lymphocyte-agglutinating subunit). It is intended to be used as a zootechnical feed additive (functional group: other zootechnical additives) to enhance the performance of suckling piglets, particularly during the lactating period and to enhance piglets' welfare.

The European Food Safety Authority (EFSA) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted, in 2014, an opinion on the safety and efficacy of the product as a zootechnical additive for suckling piglets (EFSA FEEDAP Panel, 2015). In that opinion, the Panel did not consider the efficacy trials provided since the mortality rates and the percentage of sick animals at weaning were considered too high.

The applicant has submitted additional information related to the mortality of piglets in the pre-weaning period. Because of this additional information, the FEEDAP Panel has decided to reconsider the acceptability of all long-term studies provided.

According to the applicant, the additive is intended for only aqueous suspension in water for drinking or in liquid complementary feed for suckling piglets.[4] The recommended dose is 660 haemagglutinating units (HAU)/piglet (corresponding to 516 mg), administered between days 12 and 14 of age. The dose can be administered in a single feed (660 HAU/piglet on a single day), or as three daily feeds supplying 220 HAU/piglet/day (corresponding to 172 mg/piglet/day).

The additive may be administered to suckling piglets from 12 days of age until weaning (usually at 21–28 days of age) by direct oral administration, for example via a suitable pipette or feeder bottle with a nipple attachment.[5]

3.1. Efficacy

The applicant provided additional information in relation to the mortality of piglets during the pre-weaning period. The information provided shows that in the efficacy studies submitted, piglet mortality during the suckling period was within the mortality range commonly observed on commercial pig farms.[6,7] Therefore, the FEEDAP Panel reconsidered all nine efficacy studies provided by the applicant.[8] After consideration, four of the studies were excluded because of flaws in the experimental design or insufficient data. The five remaining studies are presented below.

Trial 1

A total of 212 piglets, originating from 18 multiparous sows, were distributed at birth in three treatment groups of 70 or 71 piglets (six sows/treatment).[9] There were 18 replicates (pens) with 9–14 piglets/replicate. The three treatment groups were the following: control, Suilectin™ (640 HAU) included in water at 14 days of age and Suilectin™ (220 HAU) included in water at 12, 13 and 14 days of age. To ensure that the piglets received the recommended volume, the test substances were administered by bottle-feeding. Sows were fed *ad libitum* with a regular diet and piglets had *ad libitum* access to creep feed from day seven. The health status of sows and piglets was monitored and recorded throughout the study. The individual body weight of piglets, weight gain, feed intake and feed conversion ratios were recorded at days 7, 14, 28, 42 and 84. Statistical analysis included a one-way analysis of variance (ANOVA) followed by Tukey's test. The litter or pen was considered the experimental unit.

No significant differences were observed with regard to the pre-weaning performances (0–28 days) of the suckling piglets (Table 2). The mortality during the pre-weaning period was not reported; however, the total mortality rate of the piglets used in this study was 10.4 %, with no differences

[4] Technical Dossier FAD-2010-0079/Technical dossier/Section II.2.4.1.
[5] Technical Dossier FAD-2010-0079/Technical dossier/Section II.2.
[6] Technical Dossier FAD-2015-0009/11_RCVS Literature Review.
[7] www.ifip.asso.fr
[8] Technical Dossier FAD-2010-0079/Supplementary information December 2013.
[9] Technical Dossier FAD-2010-0079/Section IV/Annexes_Sect.IV/Annex IV.3.1.

among the three treatment groups (Table 3). The body weights at 84 days of age were significantly higher (P = 0.002) in piglets given 640 HAU of Suilectin™ than in piglets in the control group. The average daily weight gain at 84 days of age was significantly higher in piglets given a single dose of 640 HAU Suilectin™ and piglets given three doses of 220 HAU Suilectin™ (P < 0.0001) than in piglets in the control group. The other parameters were not affected by the treatments (Table 3).

Trial 2

In a combined tolerance/efficacy study,[10] a total of 314 piglets, originating from 30 multiparous sows (line 990, sows matched for parity, 107 days of gestation), were distributed into five treatment groups (randomised complete block design). The treatment groups were the following: a placebo group receiving 2 mL of water and four Suilectin groups receiving 220, 440, 1 100 or 2 200 HAU/piglet/day in a 2 mL suspension (except for the 1 100 and 2 200 HAU/piglet doses, which were suspended in 4 and 8 mL, respectively). The test substances were administered by bottle-feeding on days 11, 12 and 13 after birth. A full description of this study was published in the previous opinion (EFSA FEEDAP Panel, 2015).

The health statuses of sows and piglets were monitored throughout the study. The performance parameters included mortality, the number of piglets born and weaned, and the body weight and feed consumption of piglets and sows. All data were analysed by ANOVA using the generalised linear modelling (GLM) procedure. The litter or pen was considered to be the basic experimental unit.

No significant differences were observed with regard to the performance of the suckling piglets during the pre-weaning (0–28 days) or the post-weaning period (28–70 days) (Tables 2 and 3).

Trials 3, 4 and 5

The remaining three long-term studies were all carried out at the same location, in a European Union Member State, with the same diets, with sows of the same genetic origin (ACMC sow × Piétrain boar) and with the same experimental design.

In the third trial, 264 piglets, originating from 24 multiparous sows (sows matched for parity, 107 days of gestation), were distributed into two treatment groups of 132 piglets. There were 12 replicates (pens)/treatment and 11 piglets/replicate.[11] In the fourth and fifth trials, a total of 132 piglets, originating from 12 multiparous sows (sows matched for parity, 107 days of gestation), were distributed into two treatment groups of 66 piglets. There were six replicates (pens)/treatment and 11 piglets/replicate.[12]

In all three trials, on day 1, cross-fostering was applied to give 11 piglets/litter. Piglets had *ad libitum* access to creep feed (based on maize, extruded maize/wheat/barley (50/25/25) and delactosed whey) from days 10 to 28 of age. On days 11, 12 and 13 of age, Suilectin™ was administered orally by bottle-feeding in 2 mL suspensions (220 HAU/piglet/day); a placebo group received water (2 mL/piglet).

At day 28, piglets were moved from the lactation room to the post-weaning room. The number of piglets per pen was reduced from 11 to 6 because of the smaller size and capacity of the pens in the post-weaning room.[13] Piglets that showed any sign of disease, poor body condition, arthritis, hernia, diarrhoea, dehydration, etc. were removed from the trial to leave a pool of healthy piglets. From the remaining piglets in each pen, six were randomly selected and moved to pens in the post-weaning room.

After weaning, the six piglets/litter selected were housed in the same pen to avoid post-weaning mixing stress and fighting. A total of 144 piglets distributed among 24 pens (third trial) or 72 piglets distributed among 12 pens (fourth and fifth trials) with partially slatted floors were included in the post-weaning (28–70 days) experimental period.

From day 28 to day 42, piglets were fed, *ad libitum*, a post-weaning pre-starter diet (based on maize, extruded maize/wheat/barley (50/25/25) and delactosed whey. From day 42 to day 70, pigs were fed

[10] Technical Dossier FAD-2010-0079/Supplementary information December 2013/Annex III.1.1.2, Parts I and II.
[11] Technical Dossier FAD-2010-0079/Supplementary information December 2013/Annex IV.3.3.
[12] Technical Dossier FAD-2010-0079/Supplementary information December 2013/Annexes IV.3.4 and IV.3.5.
[13] Technical Dossier FAD-2010-0079/Supplementary information June 2014/Annex IV.3.7.

a starter feed (based on maize, barley and soybean meal). The three trials ended when pigs were 70 days old (59 days duration).

The health statuses of sows and piglets were monitored throughout the three trials. The performance parameters included mortality, the number of piglets born and weaned, and the body weight and feed consumption of piglets and sows. The pen allocation of treatments was performed at random (computer-generated random allocation), to give a random complete block design, taking into account the number of parity of sows. The studies were reported to be blind: colour codes concealed the treatment. All data were analysed by GLM. The litter/pen was considered to be the basic experimental unit in the three trials.

No significant differences were observed in the three long-term trials with regard to the pre-weaning performance of the suckling piglets (day 0–day 28) (Table 2). The body weight loss (indirect indication of milk production) of the sows between farrowing and weaning was not different among treatments.

In the third study,[14] the overall weight gain of the piglets from the Suilectin™ group was significantly higher than in the control group (P = 0.0227). During the post-weaning period (28–70 days on trial), the weight gain was significantly higher (P = 0.0260) in piglets receiving Suilectin™ (220 HAU/piglet/day) than in piglets in the control group. The feed-to-gain ratio was also significantly improved in piglets receiving Suilectin™ (P = 0.0267) (Table 3).

In the fourth study,[15] the overall weight gain of the piglets from the Suilectin™ group was significantly higher (P = 0.0026) than in the control group. During the post-weaning period (28–70 days of age), the feed intake of piglets receiving Suilectin™ was significantly higher (P = 0.0268) than piglets in the control group (Table 3).

In the fifth study,[16] no significant differences in piglet mortality or performances were observed between treatments during both pre-weaning and post-weaning periods (Tables 2 and 3). During the overall post-weaning period (28–70 days of age), the feed intake of the piglets in the Suilectin™ group was non-significantly higher than the piglets in the control group (P = 0.0955) (Table 3).

Table 2: Pre-weaning (0–28 days of age) zootechnical performance of suckling piglets

Trial	Treatment (HAU/piglet/day during 3 days)	Replicates/ treatment (piglets/ replicate)	Body weight, 1 day of age (kg)	Body weight, 28 days of age (kg) [(a)]	Average gain (g/day)	Average creep feed intake (g/day)	Mortality pre-weaning 0–28 days of age (%)
1	0	6 × (10–14)	1.63	7.22	5.61 [(c)]	20.8 [(d)]	NA
	640 [(b)]	6 × (8–14)	1.56	7.00	5.49 [(c)]	16.6 [(d)]	NA
	220	6 × (9–13)	1.55	7.00	5.55 [(c)]	20.0 [(d)]	NA
2	0	6 × 10	1.54	7.62	217.0	5.2	3.2
	220	6 × 10	1.45	7.45	213.9	5.0	4.7
3	0	12 × 11	1.40	7.25	217.9	20.2	20.5
	220	12 × 11	1.40	7.45	226.3	19.1	9.8
4	0	6 × 11	1.46	7.49	229.8	12.3	13.6
	220	6 × 11	1.43	7.88	244.8	25.1	10.6
5	0	6 × 11	1.45	7.83	240.5	32.0	10.6
	220	6 × 11	1.45	7.79	237.2	24.8	12.1

(a): Body weight at weaning before reduction of the number of piglets/pen (trials 3, 4 and 5).
(b): Trial 1: 640 HAU/piglet at 14 days of age.
(c): Weight in kg at day 28.
(d): Average feed intake 7–14 days.

[14] Technical Dossier FAD-2010-0079/Supplementary information December 2013/Annex IV.3.3.
[15] Technical Dossier FAD-2010-0079/Supplementary information December 2013/Annex IV.3.4.
[16] Technical Dossier FAD-2010-0079/Supplementary information December 2013/Annex IV.3.5.

Table 3: Post-weaning (28–70 days of age) zootechnical performance of piglets

Trial	Treatment (HAU/piglet/day for 3 days)	Replicates/ treatment (piglets/ replicate)	Body weight, 28 days of age (kg) [a]	Body weight, 70 days of age (kg)	Average gain (g/day)	Average feed intake (g/day)	Feed-to-gain ratio	Mortality 28–70 days (%)
1 [b]	0	6 × (10–14)	7.22	35.70	405.1	659.0	1.50	9.8 [c]
	640	6 × (8–14)	7.00	40.90*	467.7*	718.0	1.49	15.5[c]
	220	6 × (9–13)	7.00	37.80	431.7	698.9	1.47	5.7[c]
2	0	6 × 10	7.62	24.40	401.3	639.3	1.60	4.7
	220	6 × 10	7.45	25.80	435.4	629.5	1.50	1.7
3	0	12 × 6	7.60	23.02	366.9	493.9	1.35	0
	220	12 × 6	7.83	24.64*	400.3*	505.0	1.27*	0
4	0	6 × 6	7.76	23.78	380.0	489.0	1.29	8.3
	220	6 × 6	8.36	26.14*	423.9	555.7*	1.31	2.7
5	0	6 × 6	8.26	24.10	376.7	463.3	1.25	2.7
	220	6 × 6	8.01	24.94	402.9	516.3	1.30	2.7

*Statistically significant difference ($P < 0.05$).
(a): Body weight at weaning after reduction of the number of piglets/pen (trials 3, 4 and 5).
(b): Trial 1: 640 HAU/piglet at 14 days of age; duration 84 days.
(c): Mortality reported at 0–84 days.

No effects of giving Suilectin™ to suckling piglets were seen on the growth and survival of piglets during the pre-weaning period (0–28 days of age) in all trials.

Three of the five long-term efficacy studies considered showed a significant positive effect on the performance (body weight, average daily weight gain, average daily feed intake or feed-to-gain ratio) of weaned piglets as a result of supplementing feed with Suilectin™. This was seen at the recommended dose of 660 HAU/piglet, whether administered as a single dose at 14 days of age or as three consecutive doses of 220 HAU/piglet/day between days 12 and 14 of age.

However, for trials 3, 4 and 5, the FEEDAP Panel noted the study design, namely the reduction in the number of piglets at weaning, from 11 to 6 in each litter, to leave a pool of healthy piglets which were housed in the same pen during the post-weaning period. Because of this study design (piglets grouped by litter throughout the entire study period), a separate assessment of the potential effects of the additive and the litter is not possible in any of the three trials and, therefore, this gives rise to uncertainty.

Although there is uncertainty arising from the study design, the FEEDAP Panel concludes that Suilectin™ might have some potential to improve the performance of the piglets during the post-weaning period (28–70 days of age).

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[17] and Good Manufacturing Practice.

4. Conclusions

The administration of Suilectin™ at the recommended dose of 660 HAU/piglet, whether administered in a single dose at 14 days of age or in three consecutive doses of 220 HAU/piglet/day between days 12 and 14 of age, does not have an effect during the suckling period (0–28 days of age).

Although there is uncertainty arising from the study design, which does not allow a separate assessment of the potential effects of the additive and the litter, the FEEDAP Panel concludes that the

[17] 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.

proposed use of the additive might have some potential to improve the performance of the piglets during the post-weaning period (28–70 days of age).

Documentation provided to EFSA

1. Suilectin™ (*Phaseolus vulgaris* lectins) for suckling piglets. Supplementary Information. March 2015. Submitted by Biolek, Sp. z o.o.

2. Suilectin™ (*Phaseolus vulgaris* lectins) for suckling piglets. October 2012. Submitted by Biolek Sp. z o.o.

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of Suilectin™ (*Phaseolus vulgaris* lectins) as a zootechnical additive for suckling piglets (performance enhancer). EFSA Journal 2015;13(1):3903, 25 pp. doi:10.2903/j.efsa.2015.3903