Safety and efficacy of APSA PHYTAFeed® 20,000 GR/L (6-phytase) as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Jaume Galobart, Orsolya Holczknecht, Paola Manini, Fabiola Pizzo, Jordí Tarrés Call and Montserrat Anguita

Abstract

Following a request from the European Commission, the EFSA Panel on Additives and products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of APSA PHYTAfeed® 20,000 GR/L (6-phytase) as a feed additive turkeys for fattening, turkeys reared for breeding and minor poultry species. The additive is a preparation of 6-phytase produced by a genetically modified strain of Komagataella phaffii and has been previously assessed by the FEEDAP Panel in the context of an application for its use in feed for chickens for fattening. The Panel concluded in that opinion that the production strain is safe, and that the use of the additive as a feed additive would raise no safety concerns for the consumers and the environment. The additive was also considered not to be irritant to skin or eyes or a dermal sensitiser but that should be considered as a respiratory sensitiser. The Panel considered that the new use in turkeys would not modify the previously drawn conclusions with respect to the consumers, users and the environment. A tolerance trial and a subchronic oral toxicity study were made available to support the safety for the new target species. From the results obtained, the FEEDAP Panel concluded that APSA PHYTAfeed® GR/L is safe for turkeys for fattening at the recommended level of 250 U/kg feed with a wide margin of safety. This conclusion was extended to turkeys reared for breeding. The applicant submitted three efficacy trials to support the efficacy of the additive. In these trials, the utilisation of phosphorus and bone ash/phosphorus content were measured. From the results obtained, the FEEDAP Panel concluded that APSA PHYTAfeed® GR/L is efficacious for turkeys for fattening, turkeys reared for breeding and minor poultry at the level of 250 U/kg feed.

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Keywords: safety, efficacy, zootecchnical additives, digestibility enhancers, phytase, turkeys

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003\(^1\) establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Andrés Pintaluba S.A.\(^2\) for authorisation of the product APSA PHYTAFEED\(^\circledR\) 20,000 GR/L (6-phytase), when used as a feed additive for turkeys for fattening or reared for breeding and minor growing poultry species (category: zootechnical additives; functional group: digestibility enhancers).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 3 May 2019.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product APSA PHYTAFEED\(^\circledR\) 20,000 GR/L (6-phytase), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

The FEEDAP Panel adopted an opinion on the safety and efficacy of APSA PHYTAFEED\(^\circledR\) 20,000 GR/L (6-phytase) as a feed additive for chickens for fattening or reared for laying and minor poultry species for fattening or reared for laying (EFSA FEEDAP Panel, 2019).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier\(^3\) in support of the authorisation request for the use of APSA PHYTAFEED\(^\circledR\) 20,000 GR/L (6-phytase) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the APSA PHYTAFEED\(^\circledR\) 20,000 GR/L (6-phytase) in animal feed are valid and applicable for the current application.\(^4\)

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of APSA PHYTAFEED\(^\circledR\) 20,000 GR/L (6-phytase) is in line with the principles laid down in Regulation (EC) No 429/2008\(^5\) and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

\(^{1}\) 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.

\(^{2}\) Andrés Pintaluba S.A. Pol. Ind. Agro Reus, c/. Prudenci Bertrana, 5, Reus 43206, Spain.

\(^{3}\) FEED dossier reference: FAD-2019-0019.

\(^{4}\) The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/fn_report_fad-2018-0031_phytafeed.pdf

\(^{5}\) 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 APSA PHYTAFEEED® 20,000 GR/L contains 6-phytase activity (EC 3.1.3.26; phytase) and is intended to be used in feed for turkeys for fattening or reared for breeding and minor poultry species as a zootechnical additive (functional group: digestibility enhancers).

3.1. Characterisation

The phytase present in the additive is produced by a genetically modified strain of the yeast Komagataeae phaffii that has been deposited in the China General Microbiological Culture Collection Centre (CGMCC) with the deposit number 12056. The additive is available in two formulations, a solid one APSA PHYTAFEEED® 20,000 GR and a liquid one APSA PHYTAFEEED® 20,000 L. The two formulations of the additive ensure a guaranteed minimum phytase activity of 20,000 U/g or mL of product. In a previous opinion, the Panel characterised the additive and its manufacturing process including the production strain (EFSA FEEDAP Panel, 2019). The applicant has provided new data on the taxonomic classification of the production strain and on the stability and the capacity of the additive to homogeneously distribute when added to feed for turkeys.

K. phaffii is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2017), when used for enzyme production.

The stability of the phytase in feed was evaluated when added to a complete feed for turkeys. The two formulations of the additive (one batch each) were added to a mash feed to provide 1,000 U/kg feed. The mash feed supplemented with the solid formulation was also pelleted (60–65°C) to study the effect of the temperature. Recovery values after pelleting showed no modifications of the initial enzyme activity. Samples of the mash and pelleted feed were stored for 3 months at 20–25°C and 50–60% relative humidity (containers not specified). After 3 months of storage, recovery values showed reductions of the initial enzyme activity below 5%.

The capacity of the phytase to homogeneously distribute was studied in 10 subsamples of the feed used in the stability studies. Samples of the mash feeds showed a coefficient of variation (CV) of 6% for both the solid and liquid formulations and the samples of the pelleted feed showed a CV of 9%.

The additive is to be used in feed for turkeys for fattening or reared for breeding and minor poultry species at a minimum recommended enzyme activity of 250 U/kg feed.

3.2. Safety

The safety aspects regarding the use of this additive in feed including the safety of the genetic modification of the production strain, the safety for the target species, the safety for the consumers, for the user and for the environment have been previously assessed (EFSA FEEDAP Panel, 2019). The Panel concluded that the genetic modification raises no concerns, and that the use of the product as a feed additive raises no concerns for chickens for fattening, chickens reared for laying and minor poultry species for fattening or reared for laying, for consumer safety and for the environment. Regarding the safety for the user the Panel concluded that additive is not irritant for skin or eyes and it is not a dermal sensitiser, but it is considered a potential respiratory sensitisier.

The FEEDAP Panel is not aware of any new information that would lead it to reconsider the conclusions drawn previously and considers that the extension of use to the new species for which the application is made would not have an impact on the safety aspects already considered. However, the safety for the new target species needs to be addressed.

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6 One Unit (U) is defined as the amount of enzyme that releases 1 µmol of inorganic phosphate from phytate per minute at pH 5.5 and 37°C.
7 Technical dossier/Supplementary information August 2019/Annex II.2.1.2.7.
8 Technical dossier/Section II/Annex II.4.1.3.1 and II.4.1.3.2.
3.2.1. Safety for the target species

The current application was made for turkeys for fattening or reared for breeding and minor poultry species.

In the previous opinion (EFSA FEEDAP Panel, 2019), the FEEDAP Panel concluded, based on the results obtained in a sub-chronic oral toxicity study in rats and the supporting evidence of a tolerance study in chickens for fattening, that APSA PHYTAFEED® GR/L is safe for chickens for fattening at the recommended level of 250 U/kg feed with a wide margin of safety (approximately of 50). This conclusion was extended to chickens reared for laying. Furthermore, and considering the wide margin of safety the conclusion was extrapolated to minor poultry species for fattening purposes or reared for laying/breeding purposes.

The FEEDAP Panel considers that those data can be used to conclude on the safety of the additive to turkeys for fattening or (reared for breeding) at the same use level of 250 FTU/kg feed without the need of further data. In fact, using the no-observed-adverse-effect-level (NOAEL) from the subchronic oral toxicity study to calculate a safe level for turkeys results in a maximum safe level of 17,800 FTU/kg feed (70-fold the recommended level).

The applicant also provided a tolerance study done in turkeys which is reported below.

A total of 192 one-day-old female turkeys for fattening (BUT 10) were distributed in 48 cages of 4 birds. Six dietary treatments were allocated to the cages, representing 8 replicates per treatment. Two basal diets (starter and grower) based on maize and soya bean meal (total phosphorus 6.6 and 6.0 g/kg, total calcium 12.0 and 10.0 g/kg, respectively) were either not supplemented (control) or supplemented with APSA PHYTAFEED® 20,000 GR to provide 250 (1 × minimum recommended level), 500 (2 ×), 1,000 (4 ×) or 100,000 (400 ×) U per kg feed (confirmed by analysis). A positive control diet with higher content of phosphorus was also considered (total phosphorus 7.7 and 7.0 g/kg feed for starter and grower diets and total calcium 12.0 and 10.0 g/kg feed for starter and grower diets, respectively). Diets were offered in mash form for 42 days. Mortality and health status were checked every day and dead animals were necropsied. Animals were weighed on days 0, 28 and 42 (cage basis), feed intake was registered throughout the study per cage and feed to gain ratio was calculated. Blood samples were obtained from 1 bird per cage on day 42 for haematology10 and blood chemistry11 analyses. An analysis of variance (ANOVA) was done with the data considering the treatment as a fixed effect and block (situation of the cage) as a random effect. Group means were compared with Tukey test. Significance level was set at 0.05.

Mortality including culling was 5% (10 birds). Most of the animals that died or were removed were from the control diet due to rickets (7 birds in total, representing a 22%). The results on the feed intake, body weight and feed to gain ratio are presented in Table 1. Birds in the control diet showed a statistically significant lower feed intake and final body weight compared to the other groups. The body weight gain in the control group does not meet the performance objectives for the breed. This together with the mortality due to rickets would indicate a very low content of available P in the diet compared to the requirements. No differences in the feed intake, final body weight and feed to gain ratio of the birds were found between the groups fed the phytase and the positive control. No statistical differences were observed in any of the haematological parameters checked in blood. The biochemical parameters showed higher values of alkaline phosphatase and aspartate aminotransferase in the control diet compared to the other groups, but these modifications are considered to raise no concerns. The low performance of the birds in the control group would limit the conclusions that can be drawn from the study, however, the results would indicate that the turkeys can tolerate well the phytase at the recommended level and would support the conclusion based on the evidence from the toxicological test (as referred above).

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9 Technical dossier/Section III/Annex III.1.1.1.
10 Mean corpuscular haemoglobin concentration, mean corpuscular haemoglobin, mean corpuscular volume, haematocrit, haemoglobin, erythrocytes, leukocytes, eosinophil, basophil, lymphocytes, monocytes and heterophil.
11 Total protein, albumin, uric acid, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, gamma-glutamine transpeptidase.
3.2.1. Conclusions on the safety for the target species

The FEEDAP Panel concludes that APSA PHYTA FEED® GR/L is safe for turkeys for fattening at the recommended level of 250 U/kg feed with a wide margin of safety. This conclusion is extended to turkeys reared for breeding. In a previous opinion (EFSA FEEDAP Panel, 2019) the Panel already concluded that the additive is safe for minor poultry species at the same level.

3.3. Efficacy for the target species

In the previous opinion (EFSA FEEDAP Panel, 2017), the FEEDAP Panel assessed the efficacy of the additive in chickens for fattening. Based on improvements on the utilisation of phosphorus from three balance studies, the Panel concluded that APSA PHY TAFEED® 20,000 GR/L has the potential to be efficacious as a zootec hnical additive in chickens for fattening at the recommended level of 250 U/kg feed. This conclusion was extended to chickens reared for laying/breeding purposes. Considering that the mode of action of the phytases is well known and it is reasonably assumed to be the same among poultry species, the Panel extrapolated the conclusions on the efficacy to minor poultry species for growing or reared for laying/breeding.

The Panel considers that the efficacy data previously evaluated would support the efficacy of the additive in turkeys for fattening/reared for breeding at the same level. However, the applicant provided three balance trials which included bone measurements to support the efficacy in turkeys as reported below.

The first two short-term trials were done in the same trial site (more than two years apart). In both cases, 1-day-old birds were kept for an adaptation period of 7 days prior to the start of the study. A total of 180/360 (trial 1/trial 2) male turkeys (BUT 6) were kept in groups of 6/15 birds and allocated to 5/3 groups (representing 6/8 replicates per treatment). The birds were in pens for 25 days after which two birds per pen were selected according to their body weight (closest to the average body weight) and placed in metabolic cages for the balance study. The dietary treatments were obtained from basal diets (starter and grower) based on maize and soya bean meal and were either not supplemented (control) or supplemented with APSA PHY TAFEED® 20,000 GR to provide 250, 500 or 1,000 (only in trial 2) U/kg feed. The enzyme activities were confirmed by analysis. In trial 1, a positive control diet with higher content of phosphorus was also considered. Diets were offered in mash form for a total of 28 days (until 35 days of life), and the grower diets contained titanium dioxide as external marker. Mortality and health status were checked every day and dead animals were necropsied. Animals were weighed on weekly basis and during the balance study. Feed intake was measured throughout the study period. The balance study was conducted from day 26 to day 28 of study. At the end of the balance trials, the two birds used for the excreta collection were killed for collection of tibia bones. The bones were analysed to determine the content of ash and phosphorus. An analysis of variance was done with the data and group means were compared with Tukey test. Significance level was set at 0.05.

The third balance was done during the tolerance trial presented in Section 3.2.1. In that trial, the performance of the turkeys was measured and measurements on the utilisation of phosphorus and bone content of minerals were also done. Excreta samples were collected on days 26–28 of trial, total collection method. The diets contained titanium dioxide as an external marker and faecal samples were collected daily from the cages. Feed and excreta samples were analyzed for the marker, ash, dry matter, calcium and phosphorus to determine the utilisation. Tibia from one turkey per pen (randomly selected) was collected on day 42 and analysed for ash content.

Table 1: Effect of APSA PHYTA FEED® 20,000 on the performance of turkeys until day 42

| Groups (U/kg feed) | Daily feed intake (g) | Final body weight (g) | Feed to gain ratio |
|-------------------|-----------------------|-----------------------|-------------------|
| 0                 | 55.4<sup>a</sup>      | 1,177<sup>c</sup>     | 2.12<sup>a</sup>  |
| 250               | 64.0<sup>ab</sup>     | 1,530<sup>b</sup>     | 1.84<sup>b</sup>  |
| 500               | 63.3<sup>b</sup>      | 1,499<sup>b</sup>     | 1.87<sup>b</sup>  |
| 1,000             | 64.5<sup>ab</sup>     | 1,568<sup>ab</sup>    | 1.81<sup>b</sup>  |
| 100,000           | 69.4<sup>a</sup>      | 1,732<sup>a</sup>     | 1.75<sup>b</sup>  |
| Positive control  | 64.4<sup>ab</sup>     | 1,529<sup>b</sup>     | 1.85<sup>b</sup>  |

<sup>a,b,c</sup>: Values in the same column not sharing the same superscript are significantly different (p < 0.05).

12 Technical dossier/Section IV/Annex IV.2.1 and IV.2.2.
The results of the balance trials are presented in Table 2. In the three trials, the birds fed with the additive at 250 U/kg feed or above showed improvements on the phosphorus utilisation and bone ash/phosphorus content compared to the control. Consequently, the FEEDAP Panel considers that the additive has the potential to be efficacious as a zootechnical additive in turkeys for fattening at 250 U/kg feed.

**Table 2**: Effect of APSA PHYTAFEED® 20,000 on the phosphorus utilisation and tibia bone content of turkeys

| Trial | Phytase (Units/kg feed) | Total P – Ca (g/kg feed)(1) | Phosphorus utilisation (%) | Bone content (%) |
|-------|-------------------------|----------------------------|---------------------------|-----------------|
|       |                         |                            |                           | Ash | Phosphorus |
| 1     | 0                       | 5.0–10.0                   | 40.4<sup>a</sup>          | 27.0<sup>d</sup> | 4.0<sup>d</sup> |
|       | 250                     | 5.0–10.0                   | 50.3<sup>c</sup>          | 32.0<sup>c</sup> | 4.8<sup>c</sup> |
|       | 500                     | 5.0–10.0                   | 56.7<sup>b,c</sup>        | 32.5<sup>b,c</sup> | 5.1<sup>c</sup> |
|       | 1,000                   | 5.0–10.0                   | 60.8<sup>b,a</sup>        | 34.6<sup>b</sup> | 5.7<sup>b</sup> |
|       | Positive control        | 9.3–12.0                   | 64.3<sup>a</sup>          | 37.5<sup>a</sup> | 6.3<sup>a</sup> |
| 2     | 0                       | 5.4–10.0                   | 38.5<sup>c</sup>          | 27.1<sup>c</sup> | 4.6<sup>c</sup> |
|       | 250                     | 5.4–10.0                   | 45.6<sup>b</sup>          | 32.4<sup>b</sup> | 5.6<sup>b</sup> |
|       | 500                     | 5.4–10.0                   | 48.7<sup>a</sup>          | 33.9<sup>a</sup> | 5.8<sup>a</sup> |
| 3     | 0                       | 6.6–12.0                   | 65.3<sup>c</sup>          | 34.6<sup>e</sup> | – |
|       | 250                     | 6.6–12.0                   | 74.3<sup>b</sup>          | 41.7<sup>d</sup> | – |
|       | 500                     | 6.6–12.0                   | 79.7<sup>a</sup>          | 44.0<sup>cd</sup> | – |
|       | 1,000                   | 6.6–12.0                   | 83.2<sup>a</sup>          | 48.3<sup>ab</sup> | – |
|       | 100,000                 | 6.6–12.0                   | 84.2<sup>a</sup>          | 50.9<sup>a</sup> | – |
|       | Positive control        | 7.7–12.0                   | 70.4<sup>b</sup>          | 45.7<sup>b,c</sup> | – |

(1): Intended values for the diets administered during the collection of excreta.

<sup>a,b,c,d</sup>: Values in the same column not sharing the same superscript are significantly different (p < 0.05).

The FEEDAP Panel concludes that APSA PHYTAFEED® GR/L is efficacious for turkeys for fattening at the recommended level of 250 U/kg feed. This conclusion is extended to turkeys reared for breeding. In a previous opinion (EFSA FEEDAP Panel, 2019), the Panel already concluded that the additive is efficacious for minor poultry species at the same level.

### 3.4. 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<sup>13</sup> and Good Manufacturing Practice.

### 4. Conclusions

APSA PHYTAFEED® GR/L is safe for turkeys for fattening or reared for breeding and minor poultry species at the recommended enzyme activity of 250 U/kg feed with a wide margin of safety.

The FEEDAP Panel concludes that there are no concerns for consumer safety and no risks for the environment are expected from the use of APSA PHYTAFEED® GR/L in turkeys for fattening/reared for breeding and minor poultry species. The additive is not a skin or eye irritant, and it is not a dermal sensitiser but it should be considered a respiratory sensitiser.

APSA PHYTAFEED® GR/L is efficacious for turkeys for fattening/reared for breeding and minor poultry species at the recommended enzyme activity of 250 U/kg feed.

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<sup>13</sup> 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.
Documentation as provided to EFSA/Chronology

| Date       | Event                                                                                                                                 |
|------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 05/03/2019 | Dossier received by EFSA, APSA PHYTAFEED® for turkeys for fattening, reared for breeding and minor poultry species. Submitted by Andrés Pintaluba S.A. |
| 18/03/2019 | Reception mandate from the European Commission                                                                                         |
| 03/05/2019 | Application validated by EFSA – Start of the scientific assessment                                                                     |
| 04/07/2019 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation |
| 20/08/2019 | Reception of supplementary information from the applicant - Scientific assessment re-started                                              |
| 03/08/2019 | Comments received from Member States                                                                                                  |
| 07/10/2019 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment                                                                  |

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Abbreviations

ANOVA analysis of variance
CGMCC China General Microbiological Culture Collection Centre
CV coefficient of variation
EURL European Union Reference Laboratory
FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed
NOAEL no-observed-adverse-effect-level
QPS Qualified Presumption of Safety